
Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 15 AND 17 MARCH 2006

Chairperson: Mr. Margers Krams (Latvia)

Note by the Secretariat¹

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/2761.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENTS FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairman drew the Committee's attention to the list of Statements on Implementation and Administration of the Agreement, contained in document G/TBT/GEN/1/Rev.3, issued on 16 February 2006. He recalled that in 2005 the Former Yugoslav Republic of Macedonia, the Republic of Rwanda and Kenya had submitted their 15.2 Statements and that Colombia and the European Communities had submitted revisions to their Statements. He also noted that on 27 February 2006, Qatar had submitted its Statement (G/TBT/2/Add.87) and that, since 1995, a total of 104 Members had submitted at least one such statement. The Chairman also drew the Committee's attention to the latest list of TBT Enquiry Points (G/TBT/ENQ/27) and recalled that this information was also available (and updated regularly) on the WTO website.²

3. The Chairman drew the Committee's attention to a document on publications prepared by the Secretariat which contained a list of publications related to technical regulations, standards and conformity assessment procedures (JOB(06)/50). Where available, on-line sources of information had also been included in this document. He noted that the information had been extracted from Members' statements under Article 15.2 of the Agreement and he invited Members to submit any other information that could usefully be included in a further revision of this document.

4. The representative of Chile introduced a revision to her country's Article 15.2 Statement (G/TBT/2/Add.16/Rev.1). She highlighted that, in 2003, a Law had been enacted in Chile that established a mechanism to implement notification procedures, providing a 60 day period to formulate comments on draft technical regulations and conformity assessment procedures. The Law was enacted by the Decree n°77 of 14 June 2004, which established certain basic principles to follow in the elaboration of technical regulations and conformity assessment procedures, including, *inter alia*, the use of international standards as a basis for the measures and the avoidance of unnecessary obstacles to trade. It was noted that a national commission on TBT matters, bringing together all the relevant institutions, had been created in Chile. This commission was presided over by the Ministry of Economy, which was responsible for the implementation of the TBT obligations.

B. SPECIFIC TRADE CONCERNS

1. New Concerns

(i) *Norway - Restrictions on the Use of deca-BDE (G/TBT/N/NOR/6)*

5. The representative of Japan raised concerns regarding a measure notified by Norway (G/TBT/N/NOR/6) which prohibited the content of 0.1 per cent or more of deca-BDE by weight in all products. While Japan understood the need to protect human health and the environment, his delegation was concerned about the impact of the proposal on trade and investment. He recalled that the European Communities had decided that deca-BDE be excluded from the RoHS Directive, and was of the view that Norway needed to align its measure with this decision. He asked Norway to explain the justification of this measure, in accordance with Article 2.2 and 2.5 of the TBT Agreement.

² http://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_points_e.htm.

6. The representative of Israel shared the concerns in respect of the Norwegian proposal, and recalled that comments had been transmitted to the Enquiry Point of Norway in September 2005. His delegation was of the view that the proposed import prohibition was not based on available scientific and technical information, and that its application would constitute an unnecessary obstacle to trade within the meaning of Article 2.2 of the Agreement. He recalled that, in its notification, Norway had invoked the protection of human health and the environment as the rationale for the measure. While the representative of Israel recognized that these were legitimate objectives under the TBT Agreement, he was of the view that Norway had not demonstrated the existence of a risk and stressed that, in any case, there was no legal basis for a "precautionary principle" in the TBT Agreement.

7. The representative of Israel noted, further, that Article 2.2 of the TBT Agreement provided that in assessing risks the elements to be considered included available scientific and technical information. He recalled that the European Communities had conducted a risk assessment of deca-BDE which had not identified any risk posed by the substance. On the basis of this result, the European Communities had decided to exempt deca-BDE from the scope of the RoHS Directive. Yet Norway, instead of relying on the overwhelming scientific evidence showing the absence of any risk for human health of the environment, had chosen to base its decision on a single document, therefore not complying with Article 2.2 of the Agreement. Moreover, when examining the need for a new technical regulation, Members had, in line with the TBT Agreement, to consider whether there were alternative, less trade restrictive measures that would achieve the same objective. Israel was of the view that Norway had not considered alternative measures to fulfil its goals. As an example of alternative measure, the representative of Israel mentioned the European Union control measures, including an emission reduction programme and environmental monitoring. Norway was invited to review its proposed measure so as not to impose a ban on deca-BDE in a way that was contrary to Article 2.2.

8. The representative of Jordan shared the concerns expressed and noted that his country was a major producer of the bromine element used in the production of deca-BDE. He recalled the decision taken by the European Communities to exempt deca-BDE from the RoHS Directive; a decision that had been taken as a result of a 10 year risk assessment, which had concluded that the use of deca-BDE did not pose health or environmental risks. He pointed out that Norway had not made available the scientific or technical information that the proposed ban was based on, nor was it possible for Norway to show that a risk existed. Norway was thus urged to consider reviewing the proposed technical regulation taking into account the concerns raised by Members.

9. The representative of the United States noted that her delegation too had provided comments on the notified proposal. It was pointed out that deca-BDE was a flame retardant – manufactured in the United States as well as elsewhere – that was mainly used in electronics and textiles to increase their resistance to fire. Flame retardants such as deca-BDE were credited with the US Fire Marshals for saving lives and properties. She shared the concerns that the Norwegian proposal had failed to take into account the available scientific evidence and noted that voluntary programmes to control and reduce emissions offered Norway an alternative to product bans. She noted that detailed information on studies undertaken by the US Environmental Protection Agency had been provided to Norway.

10. The representative of Norway highlighted that her country had set a target to substantially reduce emissions on a number of environmentally hazardous chemicals; bromine flame retardants being among them. She explained that Norway had restrictions on the flame retardants penta-BDE and octa-BDE, corresponding to restrictions in the relevant EC Directives. She pointed out that recent data showed that the presence of deca-BDE in Arctic areas was of significant concern, and it was against this background that Norway had proposed to ban the use of deca-BDE with a few, limited, exceptions. She assured the Committee that Norwegian technical regulations, including those related to restrictions on environmentally hazardous chemicals were in compliance with the TBT Agreement, and that these restrictions were based on scientific evidence, respecting Article 2.2 and 2.4 of the

Agreement. It was further stressed that comments received from WTO Members, as well as comments received from other different actors in the hearing process, would be taken into account along with the developments in the European Union, before finalizing the regulation on deca-BDE. Moreover, the date of entry into force of the regulation had been postponed from the original date of the 1 July 2006 (indicated in the notification) to a date yet to be decided.

(ii) *Sweden – Restrictions on the use of deca-BDE (G/TBT/N/SWE/59)*

11. The representative of Japan raised concerns on the Swedish proposal to prohibit the use of deca-BDE in all products except automobiles and electrical appliances, in concentrations exceeding 0,1 percent by weight (notified on 23 November 2005). While he understood the need to protect human health and the environment, he was concerned about the impact of the proposal on trade and investment. He recalled the study conducted at European level which had concluded that deca-BDE did not pose a risk to human health and the environment and believed that Sweden needed to align with this scientific and technical evidence. He noted that his delegation had submitted comments on this proposal and hoped that Sweden would explain the validity of this proposed technical regulation in accordance with Article 2.2 and 2.5 of the Agreement.

12. The representative of Israel, Jordan and the United States associated themselves with the concerns raised and recalled that their delegations too had sent comments to the Swedish authorities.

13. The representative of the European Communities informed the Committee that the proposed Swedish regulation was being analyzed to verify its compatibility with internal market rules within the European Communities. The objective was to arrive to a solution that would both respect internal Community legislation as well as take into account the concerns raised by third countries. An update would be provided once the procedure at Community level was concluded.

(iii) *European Communities - Draft Commission Decision regarding the Classification of the Reaction to Fire Performance of Construction Products (G/TBT/N/EEC/92)*

14. The representative of Japan pointed out that his delegation had submitted comments on the draft Decision notified by the European Commission on 13 October 2005, amending the Decision 2000/147/EC on the classification of the reaction to fire performance of construction products. This draft Decision was intended to secure safety in the event of fire, and stipulated that an acidity test should be conducted for assessing fire performance of cables in the construction sector. The representative of Japan noted that the draft decision did not include any restriction on the amount of monoxide emissions, which, in his view, needed to be given top priority in order to reduce mortality in fire incidents. Instead, the restrictions applied only to the acidity of the emission gases in the case of fire, which was not an aspect of primary importance in international fire safety standards. It was stressed that, under proposed restrictions, the use of PVC coated cables, which had an excellent fire resistance, would become difficult. Japan was concerned that this restriction would lead to an unnecessary obstacle to trade, and requested the European Communities, in accordance with Article 2.5 of the Agreement, to explain the justification of its draft Decision in terms of Article 2.2 and to consider excluding the acidity test from the proposed restriction.

15. The representative of the United States, while supporting the objective of ensuring high standards for fire safety of construction products, was concerned about the justification of certain elements of the proposal relating to electric cables, and on their possible adverse impact on international trade. She questioned the scientific basis for the use of acidity as a proxy for toxicity, and pointed out that neither the ISO nor the IEC had validated acidity as a measure of toxicity for fire safety purposes. The representative of the United States requested the European Communities to explain the basis for using this criteria and believed that the Decision's focus on acid gas ignored the toxicity and potential effects of other gases such as carbon monoxide, the leading cause of human

fatalities in fires; in fact, she wondered how the Commission proposal addressed the threat of fatalities from carbon monoxide and other gases. It was also noted that electric cables were singled out for the acidity test, and the representative of the United States asked how the Commission had chosen these cables in particular. She believed that the proposed Decision could have the effect of banning wiring cables products, that would otherwise receive the highest fire safety ratings, and could result in the use of *less* fire safe products. The Commission was urged to revise its proposal in light of the concerns raised, and to consider removing the acidity criterion as a classification standard for wire and cable products from its proposal.

16. The representative of the Philippines was of the view that the proposed Decision had the effect of creating unnecessary obstacles to international trade, as it was more trade restrictive than necessary to achieve the European Communities' legitimate objective of fire safety. While he agreed that fire safety for construction products was a legitimate concern of high priority, it was stressed that it should not be used as a means to take trade-restrictive measures that were not required for safety, such as, in the case of electric cables, the use of the acidity criterion. He believed that such a measure would allow the European Communities to exclude polyvinyl chloride (PVC) from cable sheathing, or to effectively ban the use of PVC-coated cables in the EU market because, while PVC met safety requirements in all areas, it did not meet the acidity test. Yet, according to the scientific evidence, the failure to meet the acidity test did not mean that PVC cables were less safe than other cables. He stressed that PVC material was known to have excellent flame-retardant properties, and that the alternatives to PVC-coated cables were significantly more expensive.

17. The representative of the Philippines also pointed out that the Decision was not based on international standards, and recalled that the IEC had adopted standards on toxicity testing, which were valid for electric cables. He stressed that Article 2.4 and 5.4 of the TBT Agreement required the European Communities to use these standards if toxicity had to be addressed, and wondered why the European Communities had failed to do so. He further recalled that Article 2.4 provided for an exception where the relevant international standards would be ineffective or inappropriate, and noted that the European Communities had not provided any reason or cited any problems that would prevent the European Communities from basing its technical regulation on the relevant IEC standards. It was also pointed out that the regulation was not performance based. His understanding was that the regulation was designed for material declaration and not for the performance testing of plastic materials' potential reaction to fire. The representative of the Philippines was concerned that the regulation could adversely affect Philippine industries, and reiterated that PVC was safe, affordable and a leading material of choice for many construction materials and other indoor applications. In his view, the proposed Commission Decision did not meet the obligations under the TBT Agreement, in particular those contained in Articles 2, 5 and 12.

18. The representatives of Colombia, Brazil, Korea and Mexico associated themselves with the concerns raised. The representatives of Colombia and Brazil also noted that their written questions and comments on the proposal had been presented to the European Communities, but that no response had been provided to date.

19. The representative of the European Communities highlighted that the comments submitted had been taken into consideration in the decision-making process, which was still pending. This was the reason why written replies had not yet been provided. He explained that the Construction Product Directive's essential requirements provided that construction works had to be designed and built in such a way that, in the event of an outbreak of fire: (i) the generation and spread of smoke was limited; (ii) the occupants could leave the works or be rescued by other means; and (iii) the safety of rescue teams was also taken into consideration. Each of these essential requirements might give rise to the establishment of classes corresponding to different performance levels of the relevant construction products. It was pointed out that such classification would be established at the Community level, and that member States might then determine the performance levels to be

observed in their territory, in parts of their territory or for certain works, within the classification adopted at Community level. The European Commission had developed a classification of the reaction-to-fire performance of electric cables on the basis of several years of examination and discussion among experts. For each class, one or several test methods were defined, as well as classification criteria and parameters of "additional classification". With regard to the latter, member States would be entitled to regulate according to their needs, but were not obliged to do so.

20. The representative of the European Communities stressed that electric cables were construction products with particular risks in the case of fire and that in certain hazardous places, for instance in tunnels for passenger transport by rail, potentially high quantities of electric cables were placed. Therefore, it had been considered that the release of so-called hydrogen halides, generally referred to as "acidity" in a case of fire posed a specific risk for the safety of people. The parameter of acidity could be found in some national and international standards on the reaction to fire performance of electric cables, fire propagation and gas emission, and was used in technical regulations of some EU member States and other WTO Members, such as Japan. The parameter was also included in the technical specifications of bodies responsible for undergrounds, airports and railways.

21. In the comments received on the TBT notification, and in the concerns raised, EC trading partners appeared to assume that the possibility of classifying according to acidity should be used as a method to detect toxicity. He stressed that this was not correct, and that "acidity" as a parameter could be used as an indicator of the concentration of irritants generated in the case of fire, which were expected to produce the effect of incapacitation or lethality of human beings exposed to smoke. By referring to the proposed additional classification which would include the "acidity" parameter, member States would be allowed to require for certain works the use of electric cables belonging to a so called "low smoke/low/zero halogen" family which would prevent incapacitating effects to occupants allowing them therefore enough time to escape in case of fire and the spread of toxic gases. It was stressed that the purpose of the proposed Decision was not to ban PVC cables, and that it was not going to establish any obligation on EC member States to regulate. Instead, by means of the proposed Decision, those member States wishing to maintain or adopt national regulations could do so without conflicting with European law, and in a common, harmonized way.

(iv) Korea – Recycling of Electrical and Electronic Products and Automobiles

22. The representative of Japan raised concerns about a new Korean draft regulation, relating to recycling of electrical and electronic products, announced in the Korean Official Journal N° 16160 on 30 December 2005. His delegation was concerned that the implementation and operation of this regulation could constitute a technical barrier to trade. Considering that the regulation was expected to enter into force on 1 July 2007, Korea was requested to notify it at an early and appropriate stage, in accordance with the TBT Agreement. Moreover, the representative of Japan asked whether the Executive Order issued by the President and which was cited in the Law would be notified to WTO Members.

23. The representative of the United States supported the comments made by Japan and sought clarification from Korea regarding whether a notification would be made.

24. The representative of Korea informed the Committee that a public hearing had been held recently on the proposal and that, as a result, amendments to the original text were being made. He noted that the proposal had similarities with the EC RoHS and WEEE Directives. He assured the Committee that a notification would be made and that a 60 day comment period would be provided.³

³ Notification G/TBT/N/KOR/105 of 30 March 2006.

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

25. The representative of the European Communities referred to the above-mentioned Chinese regulation, dated 1 March 1994. She pointed out that an amendment to the Annex which listed several severely restrictive toxic chemicals had been introduced on 27 December 2005 and that, on 31 December 2005, the Chinese authorities had submitted a list of toxic chemicals banned in China. Both lists had entered into force on 1 January 2006. He noted that the two lists had not been notified to the TBT Committee and had entered into force a few days after the publication in the Chinese Official Guide, leaving trade partners without the possibility of submitting comments or adapting to the new situation. This had resulted in several shipments from the European Communities to China being blocked at the Chinese border for not complying with the new requirements.

26. The representative of the European Communities stressed that Article 2.12 of the TBT Agreement stated that, except for urgent reasons, Members should allow a reasonable interval between the publication of a technical regulation and its entry into force in order to allow trade partners to adapt to the new requirements. She sought clarification about how China had assessed the relevant risk and asked for copies of the technical and scientific information that supported the measure. She also sought information as to whether the provisions applied equally to domestic products.

27. The representative of Japan also expressed his country's concerns about the Chinese measure. He noted that the Chinese State Environment Protection Agency (SEPA) had announced through a circular⁴ that it had revised the "Highly Restricted Imported and Exported Toxic Chemicals" list and that, from 1 January 2006, it would be necessary to comply with the regulation at issue, and to obtain both a registration certificate and clearance notification in order to import toxic chemicals contained on the list. He noted that several chemicals such as dichloromethane and chloroform, which were widely used in industry, had been added to the revised list of toxic chemicals. The representative of Japan further noted that reports had been received from several Japanese exporters that the duration between announcement and enforcement had been too short, and that chemicals which had been contracted for before the announcement had also been stopped at customs in Shanghai and other ports as of 1 January 2006. This had generated confusion among the exporters, as they were unexpectedly told that they needed to obtain a registration certificate from SEPA which would cost USD 10,000 per contract, as well as a clearance notification for import, which would cost 2,000 Yuan, per shipment.

28. His delegation was concerned that the registration system at issue was an import restriction, and could damage the operation of Japanese manufacturing sites in China by blocking their supply-chains, and also interfere with Japan's chemical exports to China, depending on how the registration system would be implemented in the future. He request China to reviews the system and its methods of enforcement, in order to maintain consistency with WTO rules. In particular, with regard to industrial-used chemicals and agrichemicals, the registration system regulated the characteristics of products that did not contain chemical substances specified as toxic chemicals in the list, and imposed registration and/or other obligations on exporters when importing chemical products that contained listed toxic chemicals. This registration system could therefore be regarded as a technical regulation under the TBT Agreement. He noted that the registration system imposed requirements for the acquisition of registration certificate and clearance notification only for imported chemicals, and was concerned that this might be inconsistent with Article 2.1 of the TBT Agreement, which stipulated no less favourable treatment between imported products and products of national origin. The registration system levied fees on imports in excess of those necessary for registration certificates and clearance

⁴ Circular 65 of 2005.

notifications and Japan was concerned that this might be inconsistent with Article 2.2 of the Agreement, which stipulated the prohibition of unnecessary import restrictions.

29. Furthermore, the representative of Japan stressed that China had not provided a reasonable interval between the publication of a measure and its entry into force, and this was not consistent with Article 2.12 of the Agreement. Moreover, China had not provided Members with the possibility to submit comments, thereby not acting in conformity with Article 2.9. His country was of the opinion that the reason why this problem occurred was that although SEPA had released a draft of "Import and Export Registration Regulation of Dangerous Chemicals" for public comment in September 2002, this directive had not yet been implemented due to delayed coordination among government agencies. The directive clearly stipulated the abolition of the present "Regulation for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals" simultaneously with the date of enforcement of the new regulation. His delegation requested China to immediately implement this new regulation, which was considered to be more consistent with WTO rules. Japan also requested China to provide an adequate interval for Members to review the new regulation and submit comments on it after receiving the TBT notification.

30. The representative of the United States associated her delegation with the comments and concerns expressed by the previous speakers; she supported the request made for China to notify the measure so as to allow WTO Members an opportunity to provide comments, and to allow a reasonable period of time to comply. She appreciated the efforts that SEPA had made to delay the entry into force until the end of March 2006, but still found it not in line with WTO rules and, like Japan, had substantive concerns about the fees which had been imposed. The representative of the United States also sought clarification about the efforts under way in some Chinese Ministries to revise the regulations at issue.

31. The representative of China recalled that in February 2006, a meeting had been held between officials of the Japanese Embassy in Beijing and representatives of the Ministry of Commerce and the State Environment Protection Agency. At this meeting, the Japanese delegation expressed its concerns, and replies had been provided. First, on the newly added list of dangerous articles, the representative of China recalled that in 2002 the State Council had issued a new regulation on the control and safety of dangerous chemicals with an annex that listed more than 4,200 types of dangerous chemical products and explained that most products on the list caused severe harm to the environment. Second, on the transition period, he highlighted that a transition period was provided from 1 January to 31 March 2006, and explained that if a contract had been signed before 1 January 2006, the companies could first apply for the release declaration and then for the certificates for the importation of toxic chemicals. In this case, there was no registration fee. It was further noted that if a contract had been signed after 1 January, then the companies should apply for the release declaration and the import certificates jointly. Third, it was pointed out that the registration fee arose from the implementation of the Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals issued in 1994. The regulations were being amended by the Chinese authorities and the issue of the registration costs was being taken into consideration. The concerns raised would be transmitted to the competent authorities and further information would be provided at a later stage.

(vi) *China – Import and Export Inspections (G/TBT/N/CHN/182); Paper articles (G/TBT/N/CHN/183); Wireless Local Area Network Products with WAPI functions (G/TBT/N/CHN/187, 188 and 189)*

32. The representative of the European Communities noted that at the beginning of 2006, China had made the above-mentioned TBT notifications *after* the adoption of the corresponding technical regulations. He stressed that the transparency provisions laid down in Articles 2.9.2 and 5.6.2 of the TBT Agreement provided that a notification of a proposed technical regulation or conformity

assessment procedure should be made at an early appropriate stage, when amendments could still be introduced and comments taken into account. In particular, the notifications related to the Wireless Local Area Network (WLAN) products (G/TBT/N/CHN/187 to 189) were dated 31 January 2006 and the corresponding measures' date of entry into force was 1 February 2006, thereby preventing WTO Members from the possibility to assess the relevant documents and provide comments. It was recalled that the European Communities had continuously expressed its concerns regarding WLAN products with WAPI functions in numerous bilateral meetings with Chinese authorities. Finally, the representative of the European Communities thanked China for having provided a summary of the draft regulations in English, which had been forwarded to the experts who would be assessing it and would provide comments, if necessary.

33. The representative of the United States asked why the notifications related to the WLAN products had been made one month after the corresponding measures had been adopted. She also sought clarification from China whether these were mandatory measures applicable to all WLAN products manufactured, used and sold in China and whether an opportunity for comments was provided.

34. The representative of Japan shared the concerns expressed by the previous speakers. His delegation understood that the Chinese authorities would disclose the content of WAPI six months before to domestic manufacturers only. He was concerned that this might be inconsistent with the obligations under Article 2.1 of the TBT Agreement, as China seemed to thereby to be giving preferential treatment to products of national origin. He was also concerned that WAPI seemed to be incompatible with relevant international standards such as WPA WIFI protected access, developed by IEEE and WIFI alliance. He stressed that the Chinese regulation could therefore be inconsistent also with Article 2.2 and 2.4 of the Agreement. Clarification was sought from China on these points.

35. The representative of Mexico recalled that his delegation had, on various occasions, raised the issue that many notifications failed to give a deadline for comments and pointed out that the Chinese case was not the only one. He believed that the debate needed to be considered in a horizontal manner in the context of the Fourth Triennial Review of the TBT Agreement (see paragraph 120).

36. The representative of Canada associated her delegation with the comments made on the notifications on WLAN products and asked for a summary of the measures in English. She was particularly concerned about the need for providing a period for Members to formulate comments on the measures.

37. The representative of China fully understood the concerns raised, which would be transmitted to the competent authorities in capital; answers to the specific questions would be provided.

(vii) China – Domestic Gas Cooking Appliances

38. The representative of the European Communities raised an issue concerning a mandatory Chinese standard on domestic gas cooking appliances, in particular gas cookers, gas roasters and gas and electric double function cookers. The issue had already been raised at the bilateral level. EU manufacturers had informed the Commission that a revision of the mandatory standard regarding these appliances was underway, and that the new measure would replace the standard GB 16400.10 of 1996. Some EU manufacturers whose products did not fully comply with the proposed new standards were experiencing a significant reduction in their orders coming from China. His understanding was that a relevant international standard for the products concerned did not exist.

39. The European Communities requested China to notify the proposed amendment to the mandatory standard in accordance with Article 2.9.2 of the TBT Agreement, and reiterated the importance of fully complying with the transparency provisions. Information was also sought on the

current state of play of the adoption procedure of the standard and the objectives pursued by the amendment. His delegation understood that the proposed amendment was aimed at improving the safety level for Chinese consumers, but was concerned that some proposed technical requirements of the amended standard would constitute an unnecessary obstacle to trade. In particular, he noted that the amended standard imposed a requirements that a burner should have a 3.5 Kilowatt minimum output on each cooking appliance, and was concerned that the European experts could not see any justification for such requirement, which would lead to higher energy consumption and higher pollution in terms of CO₂ and nitrogen oxide. Instead, this requirement would effectively ban the European burners from the Chinese market.

40. The representative of the European Communities was also concerned about the requirement of a minimum temperature resistance of the burner material, which he believed to be set at 700 degrees Celsius. It was stressed that none of the existing standards in Japan, the United States, Australia and the European Communities had such a minimum temperature resistance requirement, as this was not necessary for safety reasons. Instead of setting an abstract resistance capacity of the material, the temperature resistance of the material of the burner should be related to the working temperature of the burner. He also highlighted that it seemed technically unreasonable to fix a minimum temperature resistance for the material of the burner, as this parameter varied greatly with the burners' design and the material used. As an example, he pointed out that cookers made of aluminium and with an air intake from above were suitable to pass all relevant safety standards, however, they would not be able to comply with the minimum resistance temperature of 700 degrees Celsius as laid down in the draft Chinese standard. In technical terms, only cookers made of cast iron or brass would be able to respect such minimum temperature requirement. He noted that the gas cooking appliances produced in China mostly used such cast iron or brass, while in Europe the production of such cookers had been substantially abandoned due to environmental concerns, as they contained a high concentration of lead. He invited Chinese authorities not to ban advanced technology cookers from the market which ensured high safety standards and energy efficiency. The proposed amendment should not be more trade restrictive than necessary to fulfil the legitimate objectives pursued, in accordance with Article 2.2 of the Agreement.

41. The representative of China stated that the comments received from the European Communities by the Chinese Enquiry Point would be analyzed. He stressed that the standard on gas appliances was still in the drafting phase, and that when a final draft would be available, it would be notified to WTO Members. He welcomed any further information exchange in this regard.

(viii) India – Fifth Amendment to the Central Motor Vehicles Rules (G/TBT/N/IND/11)

42. The representative of the European Communities raised concerns in respect of the above-mentioned measure, adopted on 16 September 2005, that established rules on, among other things, a new certification system for tyres. On procedure, it was pointed out that the notification had been made six weeks *after* the adoption of the measure, and that India had also failed to provide, upon request, a copy of the technical regulation in order to allow Members to assess the text and to make comments. On substance, the European Communities was concerned that the new certification scheme, which he understood would become applicable as of 1 July 2006, established that tyre manufacturers would have to emboss the logo of the Bureau of Indian Standards on the tyres (BIS logo), along with an approval number, in order to have access to the Indian market.

43. The representative of the European Communities stressed that adding this marking would have a significant financial impact on tyre manufacturers, because the moulds for all tyres would have to be adapted. Moreover, additional costs would be generated by factory inspections of Indian officials and testing procedures. Although enhancing road safety and protecting the life of passengers were legitimate objectives, the requirements as they stood were more trade restrictive than necessary to fulfil these objectives. In particular, it was stressed that tyres which were in conformity

with the relevant UNECE tyre approval procedure and marked accordingly, ensured a high level of quality and security. The European Communities requested the Indian authorities to admit such tyres as equivalent to tyres which were BIS marked pursuant to the new Central Motor Vehicles rules. It was pointed out that many problems related to the import and export of motor vehicles and parts thereof could be avoided if India and other Members would adhere to the 1958 UNECE Agreement on International Technical Harmonization in the motor vehicle sector.

44. The representative of India explained that the mandatory certification was applicable to internal as well as outside manufacturers, and that the main criteria for establishing these rules was related to meeting the environmental and road conditions of his country. He stressed that the system would ultimately benefit consumers, and that there would not be any issue of discrimination. It was recognized that some minimal costs would be associated with the system, but stressed that there were higher considerations of human safety to be taken into account. Discussions were being held domestically on the possibility for India to sign on to the 1958 UNECE Agreement WP 29. Until such time, his country would not be in a position to accept test approvals issued by authorities of other countries. However, it was noted that the Indian national standards were aligned with the corresponding EC regulations and that tyres which met the EC requirements were expected to be approved when tested in India.

(ix) India – Regulation on Medical Devices

45. The representative of the European Communities drew the Committee's attention to a proposed Indian regulation on medical devices, which would treat certain medical devices in the same way as drugs. This would imply that medical devices would have to be subject to licences by the central government in order to be manufactured, sold or distributed in India. He stressed that such a system was not in conformity with global practice and encouraged India to harmonize its medical devices regulations with the rest of the world, in particular with a system developed by the global harmonization task force for medical devices, whose funding members were Australia, Canada, the European Union, Japan and the United States. This would facilitate trade with emerging markets. He also noted that the proposed regulation should be notified to the TBT Committee.

46. The representative of the United States noted that, in the autumn of 2005, the Bombay High Court had ordered the drug Controller General of India to begin regulating medical devices and to post a notification of its regulatory plans. In March 2006, guidelines for the registration of medical devices had been issued. It was recalled that several enquiries about the regulations and the opportunity to provide comments on them had been forwarded to the Indian authorities through the US Enquiry Point, but that no reply had been received. The representative of the United States pointed out that the regulations at issue raised several questions for the US industry, and that they could have a direct impact on trade. India was requested to notify the regulations and allow a reasonable transition period for suppliers to comply be provided.

47. The representative of India agreed that every country needed to move towards harmonization in this area, and pointed out that his country was moving in that direction. He took note of the concerns raised, in particular those about the notification of the measure.

(x) Japan – Amendment to the Enforcement Order of the Law for the Promotion of Effective Utilization of Resources (G/TBT/N/JPN/156, Add.1 and Corr.1)

48. The representative of China raised concerns about the above-mentioned measure, which had been notified on 28 November 2005 and was due to enter into force on 4 July 2006. It was recalled that the Chinese delegation had sent comments to Japan. China was concerned with the fact that one of the mentioned objectives of the measure was to address the increase of imported products; this was not in accordance with the TBT Agreement, and Japan was requested to provide scientific justification

in this regard. He noted that the measure also requested that manufacturers or importers provide information on six specific chemical substances (mercury, cadmium, lead, chromium, PPB and PPD) for seven types of electrical and electronic equipment. However, no standards or other requirements for these substances had been specified. In the view of the representative from China, the measure created an unnecessary obstacle to trade and did not comply with the principle of the least trade restrictive option under the TBT Agreement. Japan was requested to provide information on the notified regulation and the relevant standards; to reconsider the date of its enforcement, and to consider providing technical assistance to developing Members.

49. The representative of the European Communities recalled that comments had been sent to Japan and that a written reply had been received. He hoped to continue the dialogue with the Japanese authorities on this matter.

50. The representative of Japan explained that, in recent years, the imports of products such as personal computers had increased. However, the eco-design measures of the Law for the Promotion of Effective Utilization of Resources only applied to domestic manufacturers. Therefore, the amendment of the Enforcement Order of the Law had proposed to require the same measures for both domestic and imported products so as to ensure equal treatment for both manufacturers and importers. He noted that Japan had allowed an adequate period of time for comments and that replies had been provided to comments received. Japan also highlighted that his authorities had provided relevant information on the provisions of the Order. In respect of the transitional period, it was stressed that the regulation of the matter was of an urgent nature to Japan, and that an adequate period for business entities to take the necessary steps to adapt had been provided. Therefore, Japan was not going to postpone the date of enforcement of the measure. Finally, it was clarified that the measure at issue did not restrict the use of certain hazardous substances, but stipulated the provision of information regarding their presence. Moreover, when products complied with the EC Directives, they were not required to be labelled.

(xi) *Brazil - Gas fueled lighters, disposable or refillable (G/TBT/N/BRA/193)*

51. The representative of Brazil informed the Committee that comments had been received by China on the measure at issue and that an answer would be provided in due time.

(xii) *Slovakia – Textiles Products and Fibers (G/TBT/N/SQV/7)*

52. The representative of Brazil noted that his delegation had provided comments on the above-mentioned measure, and thanked the European Communities for providing an answer and for taking the comments into account in terms of a possible amendment of the measure.

(xiii) *Costa Rica – Fruit Juices (G/TBT/N/CRI/14 and Add.1)*

53. The representative of Brazil noted that his delegation was examining the answer provided to comments they had made on the Costa Rican notification on fruit juices.

(xiv) *European Communities - Fireworks and other Pyrotechnic Articles (G/TBT/N/EEC/97 and Add.1)*

54. The representative of China appreciated the fact that the European Communities had extended the period to provide comments on the above notified draft directive. His delegation agreed with the objectives to ensure safety in the transportation, storage and use of pyrotechnical articles so as to improve consumers' protection. However, it was pointed out that some of the technical requirements were of a too general nature, for instance the requirement of low water and high temperature resistance, and asked the European Communities to provide specific requirements and standards. The

representative of China also sought clarification about the certification procedure, and whether certificates issued in EC member States would still be accepted. It was also noted that the proposed directive required that pyrotechnical articles be subject to a type approval testing; China considered this to be too burdensome for the manufacturers. China requested that the European Communities established a reasonable classification of pyrotechnic articles on a scientific basis. It was also of concern that the directive did not provide sufficient protection of intellectual property rights for the manufacturers and was of the view that the directive could prejudice the interests of the pyrotechnic industry of China, which was well known and established.

55. The representative of the European Communities explained that the proposed directive aimed at replacing the 25 different national legislations with one single European system for the approval of pyrotechnical articles, including fireworks. This would make it easier for exporters to place products in the European market, since they only had to meet *one* set of standards for all the EC member States. On the concerns raised about the water and temperature resistance, these would be discussed in the Council working group during the legislative process. Regarding certification, it was clarified that pyrotechnic articles of a similar nature were being grouped together, and that minor changes in the chemical composition would not result in each subtype being tested separately. Existing approvals would still be valid for a maximum of 12 years from the entry into force of the directive. Finally, he assured China that the European Communities took all necessary measures to protect intellectual property rights, which were an important field in European law. He explained that the European conformity assessment bodies had to be independent of the manufacturers of pyrotechnic articles, and that there was no need to introduce specific provisions on intellectual property rights in the proposed directive.

(xv) *United States - Energy Conservation Standards for Certain Consumer Products and Commercial and Industrial Equipment (G/TBT/N/USA/154)*

56. The representative of China raised a concern about the amendments to the energy conservation standards for 15 types of consumer products and commercial and industrial equipment, to be placed in the Code of Federal Regulations, and recalled that detailed comments had been submitted by his delegation. While he appreciated the efforts made by the United States in the energy saving and environmental protection, he was concerned about the certification and enforcement programmes. In particular, the notified standards specified that manufacturers were subject to DOE certification, and that their products needed to meet energy conservation or energy design standards set by EPCACT 2005. He sought clarification from the United States on the type of conformity assessment procedure that would be adopted. It was also pointed out that the notified standards specified that all eliminated exit signs should meet the Energy Star programme; and the United States was requested to provide detailed information about this programme. In addition, the representative of China pointed out that the energy efficiency ratio for small and large air conditioning equipment was higher than the present internal level in the United States. This would increase the costs for the design, manufacturing and consumption of raw materials, which would negatively affect energy conservation. Therefore, he requested the United States to modify the energy efficiency ratio to bring it into line with the internal level.

57. The representative of the United States noted that she would follow-up on the issue with the Chinese authorities.

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

58. The representative of the United States welcomed the delegation of Saudi Arabia to its first meeting as a Member of the TBT Committee. She noted that several enquiries had been received from US companies that were confused about the requirements of Saudi Arabia's International Conformity Certification Programme (ICCP). It was the US understanding that the previously

requested pre-market approval had been withdrawn and replaced by a conformity certificate statement. However, the United States was concerned about the lack of publicly available information on the new requirements. Moreover, the company which had been contracted to provide services to support the ICCP was falsely advertising through the Internet and claiming that its services were a mandatory requirement for access to the Saudi market. Saudi Arabia had clarified that the required statement had to be printed on the letterhead of the manufacturer or third party conformity assessment body established in the country exporting to Saudi Arabia. It was the US representative's understanding that there were still some technical difficulties associated with the publication of the relevant information in English on the Internet, but that Saudi Arabia was taking steps to address these. The United States welcomed any additional effort that Saudi Arabia might undertake to ensure transparency in its new requirements.

59. The representative of Saudi Arabia stressed that his country was abiding to the commitments in the Working Party Report. He noted that the information about the ICCP on the Internet, which was a commitment made in the Working Party, would be clarified for the benefit of all Members.

2. Concerns Previously Raised

(i) Korea – Import of Fish Heads

60. The representative of New Zealand recalled that edible hake heads which were caught in New Zealand waters and processed by New Zealand boats were prohibited from entering the Republic of Korea, while hake heads caught in New Zealand waters but processed by Korean boats were allowed entry into the Korean market. She noted that, in August 2005, Korea had proposed new requirements that would continue to prevent the import of all hake heads from New Zealand and stressed that New Zealand had demonstrated, through correspondence with Korea, how the proposed new requirements would continue to prevent trade. The representative of New Zealand urged Korea to accord hake heads caught in New Zealand waters and processed by New Zealand boats a treatment no less favourable than that accorded to those hake heads processed by Korean boats. It was stressed that her delegation had raised the issue repeatedly, both bilaterally and in the Committee; yet Korea had not been able to provide a WTO-consistent justification for its discrimination against the product caught by New Zealand boats. The representative of New Zealand expected rapid progress towards the resolution of the issue and was willing to engage in further discussion with Korea.

61. The representative of the European Communities informed the Committee that, with regard to trade in edible cod heads, good progress had been achieved in the on-going bilateral discussion with Korea. It was hoped that the two parties would be able to finalize an agreement in the near future.

62. The representative of Norway shared the concerns expressed by New Zealand and recalled that his delegation had raised the issue at previous meetings. He hoped that Korea and all concerned Members could come together to discuss all the relevant aspects of the issue in order to find a mutually satisfactory solution.

63. The representative of Korea noted that bilateral negotiations were going on and expected that the issue would be resolved in the near future.

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

64. The representative of New Zealand remained concerned that the EC Regulations 753/2002 and 316/2004, relating to wine labelling, contained provisions that were unnecessary obstacles to international trade. She recalled that her delegation had raised the issue at every meeting of the Committee since June 2002 and continued to seek written responses to the concerns raised.

65. The representative of the European Communities took note of the concerns expressed and recalled that extensive discussion had taken place on this issue. She referred to the responses that the European Communities had provided at the Committee meetings of March 2004 and November 2004.

(iii) *European Communities – Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (G/TBT/W/208 and G/TBT/N/EEC/52 and Add.1)*

66. The representative of Japan noted that his delegation had submitted a Room Document summarizing the concerns on the REACH proposal. He pointed out that some of the concerns previously expressed had been addressed, namely the "one substance, one registration" issue and the qualification of substances to be notified and incorporated in the text. However, other concerns remained. With regard to the manufacturing of polymers mentioned in Article 5.3 of the proposal, he noted that the exclusion from the registration of monomers in polymers was limited only to the registration by the upper monomer manufacturers in the supply chain. In practice, the manufacturers in the European Communities did not need to register monomers. On the other hand, even if the polymer had been produced in the European Communities, the importer of the polymer from non-EU countries had to register all composed monomers of the same polymer separately. The representative of Japan considered that this different treatment was not consistent with the WTO non-discrimination principle. He stressed that the provision in the REACH text should be improved, and that if the composed monomers in polymer had already been registered, then the exclusion of the registration on the monomers should be allowed both in the case of the polymer manufacturer and the polymer importer. He hoped that the European Communities would continue the dialogue with its trading partners and that the REACH proposal could be made consistent with WTO rules.

67. The representative of Australia was also of the view that REACH needed to be brought in fuller consistency with the TBT principles and that it was more trade restrictive than necessary to achieve the objectives enshrined in Article 2.2 of the Agreement. He was of the view that subjecting such a broad range of materials containing substances to authorization obligations captured also minerals or metals, that presented little danger of risk.

68. The representative of the United States associated herself with the comments made. She noted that a result from the internal processes in the European Communities that would show that Members' concerns had been taken into account had yet to be seen.

69. The representative of Chile shared the concerns expressed. In particular, she stressed that the final text needed to be: simpler; reduce the costs for the application of the system; contain a better approach to risk based on science; and, avoid any duplication of information. The representative of Chile was of the view that REACH should not become an unnecessary obstacle to trade by being more trade restrictive than necessary. She also recalled the concern of developing countries in terms of technical assistance that could be provided by the European Communities for the correct application of the regulation.

70. The representative of the China associated his delegation with the comments made by the previous speakers. He was of the view that REACH was trade restrictive and not in compliance with the principles of the TBT Agreement. He was also concerned about the broad scope of REACH on its impact on trade. He encouraged the European Communities to continue sharing information on REACH and to provide updates on its development. He reiterated his delegation's request that the European Communities provide technical assistance to developing country Members, as well as take special and differential treatment into consideration.

71. The representative of Cuba agreed with Chile and China that technical assistance and special and differential treatment to developing countries needed to be taken into consideration.

72. The representative of Mexico thanked the European Communities for their efforts in terms of transparency, but highlighted the importance of taking into account the comments made and to consider technical assistance at the appropriate time, as well as special and differential treatment to developing countries.

73. The representative of the European Communities informed the Committee that, in mid-November 2005, the European Parliament had given its first reading opinion on the text presented by the European Commission in 2003 and had proposed numerous amendments regarding, *inter alia*, the scope of the future regulation, the registration and authorization requirements and the future responsibilities of the Agency which REACH would establish. Following that, the European Council had come to a unanimous political agreement on the REACH proposal on 13 December 2005, which had taken into account many of the key amendments made by the European Parliament. On 8 March 2006, the Committee of Permanent Representatives had agreed on the recitals for REACH.

74. It was stressed that the European Commission had expressed its full support for the Council's political agreement, which was consistent with the EC objectives on competitiveness and innovation, while achieving an improvement in the protection of health and environment. The political agreement had to be cast into a Common Position. He explained that the drafting was expected to be finished by May 2006, and that a Common Position, which was expected to be endorsed by the Commission, could be formally adopted by 30 May 2006. Subsequently, in the summer or autumn of 2006 – and on the basis of the Common Position – the Parliament would hold its second reading. At this point the Parliament could either reject or agree to the Common Position or, more likely, propose further amendments. The further amendments would have to be agreed by the Council: if it did not agree, then a conciliation procedure between the European Parliament and the Council would have to be established. This meant that the formal adoption of REACH would ideally take place by the end of 2006, and its entry into force was planned for 1 April 2007.

75. The main changes adopted by the Council in its political agreement related to a number of issues. The first amendment, on exemptions, related to (i) the clarification that waste was exempt; (ii) exemption of certain substances from registration, in particular noble gases and cellulose pulp; (iii) exemption of minerals and ores from registration if they had not been chemically modified. The second amendment related to substances in articles, and provided that all substances intended to be released from articles had to be registered, according to the same timetable as for substances not in articles. Substances subject to authorization but not intended to be released had to be notified to the Agency. The third amendment related to reduced requirements for the registration of non-priority low volume substances and to increased requirements for prioritised low volume substances. A fourth amendment gave the Agency greater powers, particularly in evaluation procedure. Finally, all requests for authorisation had to be accompanied by an analysis of alternatives and all authorisations had to be subject to time-limited review periods.

76. The representative of the European Communities pointed out that, after the adoption of the Common Position by the Council, an Addendum to the original notification would be submitted, which would also explain how REACH would operate, while focussing on the major changes of the Common Position compared with the original proposal. He stressed that the revised REACH proposal was fully compatible with WTO rules, in particular with Article 2.1 and 2.2 of the TBT Agreement, as products were treated the same way and possible obstacles to trade were justified by the objectives to protect health and the environment. He would convey specific questions raised in the current meeting to the experts. The European Communities also recognized the EC obligations under Article 11.3 of the TBT Agreement and highlighted that extensive guidance material would be prepared and that appropriate technical assistance, and, on the Commission's request, capacity building activities to industry and authorities in developing countries were planned.

(iv) *European Communities – Restrictions on the Use of Certain Phthalates in Toys (G/TBT/N/EEC/82)*

77. The representative of China reiterated the concerns on the above-mentioned measure, raised both in previous TBT Committee meetings and bilaterally with the European Communities. His delegation considered that China's comments had not been taken into account, and further comments had been submitted in January 2006, which remained unanswered. The European Parliament had approved the proposed amendments to the directive 76/769/EEC on 6 October 2005. Therefore, his delegation believed that the European Communities had not acted in compliance with Article 2.5 of the TBT Agreement, which requested Members preparing, adopting or applying a technical regulation to explain its justification upon request. The representative of China was of the view that the notified measures lacked scientific evidence. For instance, the three phthalates DIMP, DIDP and DNOP had not yet been proved to be harmful to children's health, and there was no scientific evidence that supported the limits of 0.1 per cent of phthalates set by the EC measure. He requested the European Communities to provide scientific basis for this restriction, and to bring the measure into conformity with the TBT Agreement by adopting the ISO Standard 8124, which set the testing methods for harmful substances in toys.

78. The representative of the European Communities recalled that the directive concerned six phthalates: three of them had been identified as toxic in the risk assessment undertaken, and therefore had to be banned in toys and childcare articles. For a second group, including the DIMP, DIDP and DNOP mentioned by China, scientific information was either lacking or conflicting and, on the basis of precautionary considerations, restrictions on their use in toys and childcare articles had also been introduced. However, following the principle of proportionality, these restrictions would be less severe. He informed the Committee that a guidance paper, which would be publicly available on-line, was being prepared by the experts. A written reply to China's comments would be provided and European experts remained willing to further explain the measures, including the possible alternative substances that could be used by manufacturers.

79. The representative of the United States referred to the guidance paper that the European Communities was preparing and recalled that her delegation had asked the European Communities to prepare legally binding guidelines in the context of the RoHS Directive in order to give companies seeking to comply with this directive commercial certainty. She noted that on the Commission website there was a section on Frequently Asked Questions which also included the respective answers, but that it was not legally binding. She sought clarification on the status of the guidance paper which would be prepared on phthalates.

80. The representative of the European Communities clarified that the guidance document on the phthalates in toys would not be legally binding, because the Commission could not give legally binding guidance on a directive which had been adopted by the European Parliament and the Council. Ultimately, only the European Court of Justice could interpret and instruct specific provisions of a legal act adopted under Community rules. The guidance was instead aimed at helping manufacturers and industry to comply with the obligations contained in the directive.

(v) *China – Administration on the Control of Pollution Caused by Electronic Information Products (G/TBT/N/CHN/140)*

81. The representative of Japan reiterated his delegation's concerns about the Chinese measure on the control of pollution caused by electronic information products. His delegation appreciated the answers from China that WTO rules were being followed, but requested China to reply to the specific comments and questions posed. First, with regard to the electronic units and components and to electronic materials, he requested China to reconsider excluding them or changing their names, in line with the international practice. Second, clarification was sought on the names of electronic

information products and on the kind of products defined as household electronic products. The representative of Japan also asked whether spare parts of the products sold before the date of implementation of the law, as well as re-used products would be out of the scope of the law. Third, Japan sought clarification on compulsory product certification and imported product inspection. His delegation had received the answer that electronic information products received in the catalogue should pass the compulsory certification. The representative of Japan asked whether supplier's declaration of conformity (SDoC) would be allowed, so as to reduce unnecessary technical obstacles to trade. Finally, with regard to the sectoral standards, he wondered whether these would be notified to WTO Members.

82. The representative of the United States thanked China for the response provided to the comments made, but had similar concerns to those expressed by Japan. For instance, it was her delegation's understanding that the catalogue would provide important information on the type of assurance of conformity, and whether this could be the CCC mark or supplier's declaration of conformity (SDoC). However, she noted that this information was not yet available, and that also the related technical standards and testing methodologies were still under development. The United States asked whether China would notify Members, for instance by means of an addendum to the original notification, when these additional documents became available and whether there would be an opportunity for comments. She also sought additional information on the scope of the products covered and on the criteria, timeline and definition of the new "environmentally friendly use period" of electronic information products labelling requirements.

83. The representative of the European Communities associated herself with the comments made by the United States.

84. The representative of China recalled that, at the request of the European Communities, an extension of the comment period of one week had been provided. Comments had been received by eleven governments or enterprises from the United States, Japan, the European Communities and Singapore. The comments were being analyzed and responses to specific questions such as the ones on conformity assessment or SDoC would be provided through the Enquiry Point. He pointed out that the regulation was of a framework nature and that specific catalogues of products subject to this regulation would be developed in the future. It was stressed that China would continue to fulfil its obligations on transparency and that it was willing to continue the dialogue with its trading partners.

(vi) *United States - DTV Tuner Requirements (G/TBT/N/USA/128)*

85. The representative of the United States wished to follow up on a concern raised by China at the last meeting of the TBT Committee.⁵ She informed the Committee that, on 3 November 2005, the Federal Communication Commission had taken the decision to amend the rules taking into account the comments made by China and that this information, along with the text of the measure, had been provided to China. Information was also available for other Members on the FCC website.⁶

(vii) *European Communities - Disposable lighters (G/TBT/N/EEC/89)*

86. The representative of China noted that the above measure on child resistant lighters notified to the TBT Committee had taken into account some of the concerns raised by his delegation in previous TBT meetings.⁷ While his delegation understood the efforts to improve children's protection, concerns remained about a number of issues. First, his delegation believed that there was

⁵ G/TBT/M/37, paras. 5-10.

⁶ www.fcc.gov

⁷ G/TBT/M/36, paras.4-6.

no factual support for the exemption of child resistant requirements on certain refillable lighters. This would result in a different treatment granted to different groups of products that have the same function in an arbitrary fashion which was not consistent with the TBT Agreement.

87. Second, the representative of China was also concerned about the prohibition of placing on the market of novelty lighters. He noted that a US study on the effectiveness of child resistant requirements, which had been cited in the draft EC measure, reported a 60 per cent reduction in accidents; this proved that child-resistant devices on lighters could effectively prevent children from operating lighters. His delegation believed that the EC draft measure failed to justify why novelty lighters complying with child-resistance requirements should be prohibited from being sold in the European Communities. He further stressed that most of the novelty lighters on the European market came from China and that the prohibition would constitute a *de facto* discrimination against China. He requested the European Communities to lift this prohibition and to conduct a risk assessment of child resistant novelty lighters after one year of the enforcement of the measure.

88. Third, China was doubtful that the European Communities recognized testing bodies could conduct all the child-resistance tests within ten months as stipulated and requested that the transition period be extended to at least 20 months. He also recommended that the draft should presume that the force that needed to operate the lighter should exceed 8.5 pounds and that relevant testing centres and procedures be developed in order to avoid using several children as testing tools. Finally, the representative of China also sought clarification on the mutual recognition of test results and on the list of EC recognized testing bodies, in particular those in China. Clarification was also sought on certain definitions such as luxury and semi-luxury lighters, repairable ignition mechanism and about the requirements and procedures of the specialized service centre based in the European Communities.

89. The representative of the European Communities appreciated the recognition by China of the importance of ensuring a high level of protection for children from the risks caused by lighters and explained that the draft text, which had been notified to the TBT Committee on 5 July 2005, had been reviewed to take into account the comments received from several WTO Members, including China – both in the Committee and at a bilateral level. It was pointed out that the scope of the decision had been modified and that it was no longer based on a monetary value of 2 Euros which had been criticized by China, but on a technical definition of luxury and semi-luxury lighters. These were defined as lighters which were designed, manufactured and placed on the market so as to ensure a continued safe use over a long period of time and which were covered by a written guarantee and the benefit of after-sale replacement or repair.

90. The representative of the European Communities stressed that studies showed that the misuse of luxury and semi-luxury lighters had caused less accidents, and, given that the risk they posed when used by children was lower, they did not require child resistant mechanism. In this sense the European Communities had limited the scope of the measure to what was necessary to protect children; it was the least trade-restrictive option. The draft decision also included a provision regarding the placement on the market lighters that resembled toys or other objects which were commonly recognised as appealing or intended for use by children younger than 51 months, the so-called novelty lighters. She explained that this provision was based on the consideration that child resistant mechanisms only guaranteed an 85 per cent level of resistance which was considered sufficient for normal lighters but not for novelty lighters. Finally, it was stressed that the draft measures would apply equally to domestic producers and to those from third countries and that the ban was temporary. The European Communities acknowledged receipt of further comments from China on the amended measure, and noted that a reply would be provided.

(viii) *European Communities – Directive 2005/32 of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of ecodesign requirements for energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and of the Council*

91. The representative of the United States referred to the concerns raised by China about the above-mentioned measure at the previous meeting of the Committee⁸ and appreciated the information provided by the European Commission that the implementing measures associated with the directive would be notified. She sought information about the status of development of the directive, which she understood to be a "New Approach" directive with some unique characteristics associated with it such as the subsequent implementing measures which were not going to be standards. She asked about the products to be covered by these measures and the time frame for its development. The representative of the United States also sought information about the conformity assessment requirements and whether there would be criteria for evaluating the equivalence with other standards. It was noted that equivalence was an approach chosen by the European Communities for some of its directives, and recalled that her delegation had raised concerns in the past about the lack of transparency on its implementation. It was her delegation's understanding that there would be a consultation with stakeholders and that the European Commission was establishing a eco-design consultation forum. The United States was interested in knowing how interested parties from non-European countries could provide an input to this process at a sufficiently early stage so as to have meaningful consideration in the implementation process of the directive.

92. The representative of the European Communities confirmed that the implementing measures would be notified and pointed out that the questions posed by the United States would be transmitted to experts. He further suggested that some issues could be clarified bilaterally.

C. OTHER MATTERS

1. Scheduling of the Fifth Special Meeting on Procedures for Information Exchange

93. The Chairman recalled that the Committee's last Special Meeting on Procedures for Information Exchange had been held on 2-3 November 2004.⁹ He reminded Members that the purpose of these meetings – held on a biennial basis – was to give Members an opportunity to exchange experiences and discuss the functioning of notification procedures and enquiry points and stressed that these meetings dealt only with technical issues. The Chairman proposed that the Committee schedule the Fifth Special Meeting on Procedures for Information Exchange back-to-back with its first meeting in 2007. This would also enable the Secretariat to request funding for the participation of developing country Members in the context of the 2007 Technical Assistance and Training Plan. He invited Members of the TBT Committee to discuss this issue with the colleagues dealing with the Committee on Trade and Development so as to ensure its inclusion in the 2007 Technical Assistance and Training Plan.

94. It was so agreed.

2. Other

95. The representative of Canada drew the Committee's attention to a recent notification under Article 10.7 of the TBT Agreement, contained in G/TBT/N/10.7/48 (10 January 2006). This was a notification of a mutual recognition agreement on conformity assessment between her country and Australia, on medicines, good manufacturing practice and certification between the two governments.

⁸ G/TBT/M/37, paras. 11-13.

⁹ The report of the meeting is contained in G/TBT/M/34, Annex I.

She highlighted that this MRA would provide for mutual recognition of certification and acceptance of certificates of good manufacturing practice of medicines, issued by both Australia's department of Health and the Health Products Food Branch of Canada. The Agreement would allow each of the parties to recognize and accept each others' technical competence to certify these products for compliance with their domestic standards and regulatory requirements; it would also allow mutual recognition of certification of each batch of medicinal products.

96. The representative of Japan updated the Committee on the result of standards alignment work in APEC (G/TBT/W/262).

III. TRIENNIAL REVIEW

A. PREPARATION OF THE FOURTH TRIENNIAL REVIEW

97. The Chairman recalled that, based on its Work Programme for the Preparation of the Fourth Triennial Review¹⁰, the Committee had initiated its review work in March 2005 with the preliminary identification of possible topics for review by delegations. In June 2005, the Committee continued this exploration of topics and discussed several of them. At the Committee's preceding meeting (2 November 2005), further topics were explored and there had been general agreement in the Committee to consider the following five topics as elements of the Fourth Triennial Review: (i) Good Regulatory Practice; (ii) Conformity Assessment; (iii) Transparency; (iv) Technical Assistance; and, (v) Special and Differential Treatment. The Chairman drew the Committee's attention to a background note from the Secretariat (JOB(06)/24) summarizing the discussion held so far on each topic and aimed at assisting the Committee with its deliberations at the current meeting.

98. The representative of the United States noted the usefulness of receiving the Secretariat background note early in the triennial review process. On substance, the United States was of the view that while the first three Reviews of the TBT Committee needed to inform the Committee's discussion and Members' positions for the Fourth Review, there was a need to focus on the discussion pertaining to the Fourth Review. The distinction between the discussions and the follow-up to the Third Triennial Review and the Preparation of the Fourth Triennial Review was somewhat artificial in JOB(06)/24. The structure of the Committee's Agenda made it somewhat unclear where one Review ended and the other started. Some of the recommendations from past Reviews had not been acted on and the Committee might need to consider why no action was taken, or, whether they continued to be valid. If so, such recommendations could be noted in the context of the Fourth Triennial Review. She stressed that the review needed to be Member driven and based on consensus.

99. The representative of Mexico considered that the factual references to previous Reviews were useful as they gave perspective on past work. Moreover, the background was important when considering that many current delegations had not been involved in previous reviews.

100. The representative of Canada was of the view that the Secretariat's background document provided a useful basis and context for all Members to proceed in the Fourth Triennial Review with some understanding of what had gone on in the past. Nevertheless the content needed to reflect what was necessary to develop a common understanding which could guide the Committee forwards; it was not necessary to include all information from previous reviews. Canada also wished to have some discussion on how to address aspects of past Triennial Reviews which had not been completed by the Committee. The Committee could decide on the continued relevance (or non-relevance) of these issues.

¹⁰ G/TBT/M/37, Annex 1.

101. The representative of the European Communities, Brazil and Chile considered that the Secretariat note had successfully brought out – and given perspective to – the elements for discussion in the Fourth Triennial Review.

1. Stocktaking

(i) Good Regulatory Practice

102. The Chairman noted that during the preparation of the Fourth Triennial Review, Members had expressed a continued interest in an exchange of information on various aspects of good regulatory practice. For instance, it had been suggested that the Committee could further explore what "more trade restrictive than necessary" implied in practice in order to limit the scope for interpretation of these statements. Moreover, discussions had taken place on issues related to (i) the choice of policy instruments; (ii) efficient and effective regulation; and, (iii) regulatory cooperation between different countries.

103. The representative of Chinese Taipei introduced her delegation's submission (Part III of G/TBT/W/261) and proposed that Members continue to exchange experiences related to the implementation of good regulatory practice. In particular, it was necessary to examine how such practices could be integrated into regulatory structures, for instance in respect of specific sectors.

104. The representative of Canada introduced her delegation's submission contained in G/TBT/W/264. She proposed that the Committee advanced the discussion of Good Regulatory Practices by agreeing, in the Fourth Triennial Review, to hold at least one workshop which would include, *inter alia*, an examination of the issue of "instrument choice". It was further suggested that the year 2007 be used to continue an exchange of information, as proposed by Chinese Taipei, and that the workshop take place in the year 2008.

105. The representative of Mexico supported Canada's proposal on the workshop and noted that input from several international organizations would be useful in this respect.

106. The representative of Malaysia supported, in respect of the choice of policy instruments, the recommendation that the Committee explore how the use of performance based regulations, where appropriate, could contribute to ensuring that unnecessary obstacles to trade were avoided. It was stressed, in this regard, that the Committee needed to take into consideration the added complexities of adopting and enforcing such regulations: a high level expertise and skills was required in the assessment of compliance with performance based regulations. Hence, determination of compliance could become more demanding, especially for developing country Members where expertise and skills were in short supply.

107. In terms of the effectiveness and efficiency of regulations, the representative of Malaysia noted that several management tools were available for Members to use to improve the effectiveness and efficiency of regulations. Malaysia supported the work of the Committee to enhance the understanding and implementation of these tools. It was stressed that capacity considerations needed to be addressed: in particular, Malaysia urged Members with experience in the use of tools such as RIAs, cost/benefit analysis, to give priority in providing technical assistance to other Members who request such assistance in line with the provisions of Article 11.1 and 11.2 of the TBT Agreement.

108. In respect of equivalence, Malaysia welcomed further sharing of experiences on establishing equivalence of technical regulations as this was an area that had not had much success. The TBT Agreement, in Article 2.7, suggested that equivalency should be determined on the basis of equivalency of outcomes. This was often not easily achievable when regulations did not contain explicit statements of the desired outcomes. In other cases there could also be differences of opinion

on the actual outcomes that were being achieved. A further understanding of the issues through an exchange of experiences needed to be undertaken before the Committee considered designing a procedure to facilitate the development of equivalency. Malaysia supported the contention that regulatory cooperation could be viewed as an essential element of Good Regulatory Practice.

109. The representative of the European Communities agreed with Chinese Taipei on the need to continue an exchange of experiences in the area of Good Regulatory Practice and supported Canada's views on the importance of focussing on desired outcomes of a measure; the European Communities had positive experiences in the performance-based regulations (G/TBT/W/254). In terms of "better regulation", the European Communities wished to emphasize the need for the Committee to exchange information in the area of RIAs. It could be useful for the Committee to consider what common elements could be gleaned from different approaches to RIAs. The European Communities also wished to emphasize the need to examine the existing stock of regulations and take steps to simplify it. For instance, it was noted that the European Communities was considering steps to repeal, modify or simplify over 200 basic pieces of legislation over the next three years, starting with the most heavily regulated sectors (such as automobiles, waste and construction). In this same vein, it was important to revisit existing legislation in light of progress made in international standardization, and, wherever possible, take into account eventual changes. Last, the European Communities wished to stress the need for the Committee to consider different approaches to transparency procedures.

110. The representative of the United States shared the comments made – in particular by Malaysia – on the need for more information on equivalence, particularly as this had proved to be difficult to achieve. For some time the United States had welcomed the presentation by other Members of successful examples of the operation of equivalence. Of particular interest were the steps undertaken to arrive at a determination of equivalency in a particular case. For instance, had the decision been taken on the basis of published criteria? What other aspects of the process had facilitated the arrival at a determination? In the view of the United States, it was not always a matter of specifying regulations in terms of performance requirements because even in cases where this had been done and there existed an expressed policy of equivalence it was not always transparent; i.e. it was not always easy to determine why certain regulations had been recognised as equivalent and others not. Although equivalence had been on the agenda of the Committee from a very early stage, very little information had been provided to date on good practice regarding this concept.

111. The representative of Brazil was of the view that a more in-depth debate in this area could encourage countries to adopt simpler and more rational regulatory processes and thereby diminish the number of trade barriers imposed unnecessarily. In Brazil, the identification of difficulties in this area had entailed the creation, in 2005, of a National Council of Metrology, Normalization and Industrial Quality (CONMETRO) which, among its main tasks, set criteria and the processes of national regulation.

112. The representative of Chile supported proposals made by Chinese Taipei, Canada and the European Communities. Irrespective of the context – whether made during an exchange of information in the Committee or in presentations in the proposed workshop – elements of good regulatory practice had been raised (and would in the future) in the Committee. These needed to be taken onboard by Members. In particular, the Committee needed to continue its exchange of experiences, including on: voluntary approach versus mandatory; the evaluation of RIAs, the experiences on the use of equivalency; experiences from the use of performance-based regulations; regulatory cooperation between different countries; and, regulatory coordination at the national level.

(ii) *Conformity Assessment Procedures*

113. The Chairman presented a brief factual statement on the 16-17 March 2006 TBT Workshop on Different Approaches to Conformity Assessment (Annex 1 on page 35)¹¹ and recalled that the Committee had discussed a number of issues in respect of conformity assessment, including on the avoidance of unnecessary obstacles to trade and different approaches to facilitate the acceptance of conformity assessment results. In particular, he hoped that the Committee's work in the on-going Review would achieve greater focus and understanding than had been achieved at previous triennial reviews in respect of conformity assessment. He drew the Committee's attention to two new submissions, one from Chinese Taipei (G/TBT/W/261) and the other from Japan (G/TBT/W/263).

114. The representative of Chinese Taipei introduced Section I of G/TBT/W/261. In particular, it was proposed that the Committee's discussions focus on specific ISO/IEC Guides for third-party product certification, because third-party certification was a conformity assessment procedure widely used by Members to demonstrate compliance of a product with the relevant technical regulations. Reference was also made to ISO/IEC Guides 28, 53 and 67, which had all either been adopted or revised in the last two years. The representative of Chinese Taipei was of the view that a focused discussion on Members' experience in using these Guides would help regulators to better understand how they could be applied and, in particular, how Article 5.4 of the TBT Agreement was implemented. Moreover, as a follow-up to the discussions on SDoC, Chinese Taipei was also of the view that Members should notify when SDoC was used as a conformity assessment procedure.

115. The representative of Japan introduced his delegation's proposal (G/TBT/W/263) on conformity assessment. Regarding the section on cross-border designation, reference was made to Japan's presentation at the Workshop. On the issue of mutual recognition agreements (MRAs), some clarification on terminology was provided: in the Japanese submission the term "MRA" referred to a bilateral mutual recognition mechanism between governments for regulatory authorities to accept the result of conformity assessment issued by conformity assessment bodies in trading partners. It did not refer to the multilateral recognition mechanisms among accreditation bodies to accept the result of accreditation for conformity assessment bodies or testing laboratories and other mechanisms. The Japanese submission was proposing the possibility of cross-border designation as a trade facilitation tool. Japan was of the view that in some cases and for some specific products such cross-border designation mechanisms could be useful and more cost-effective compared to traditional MRAs. Japan's proposal also put forward some ideas on how to improve – or make more useful – international multilateral mutual recognition arrangements among accreditation bodies. Currently, such arrangements were, in Japan's view, not utilized enough by Japanese stakeholders, in particular regulatory authorities. Japan concluded from the workshop and the discussion held so far that it would be useful not only for developed country Members to provide knowledge and experiences to developing country Members, but also for developing country Members to share their knowledge and experiences among themselves.

116. The representative of the European Communities noted that the contribution from Chinese Taipei suggested that Members should notify when SDoC was used as a procedure. The European Communities was of the view that this was a good idea and suggested that the Committee could go even further: Members could be asked to provide information on the use of other types of conformity assessment procedures as well. With enough information the Committee might be able to gain some insight into how different procedures were applied in different sectors by different Members. If this was too much, the proposal suggested by Chinese Taipei could be seen as a first step. The European Communities was also positive to the proposal to share information and experiences on the use of the

¹¹ The programme (G/TBT/GEN/31) as well as presentations are available on the TBT webpage: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm#events. A summary report of the Workshop will be issued separately.

ISO/IEC Guides; in fact, the European Communities was of the view that some factual reference would need to be made in the Fourth Triennial Review report with respect to development of ISO standards in the conformity assessment area since the Third Triennial Review. Referring to the paper by Japan, the European Communities welcomed an explanation on the use of accreditation leading to the possibility of cross-boarder designation by Japan.

117. The representative of Mexico noted, with respect to Japan's document, that many of the elements were linked to accreditation; this was an activity done in Mexico in the private sector. Mexico needed to consider the proposal more carefully and reserved the right to react to all other proposals made on this topic.

118. The representative of the United States stated, in respect of the proposal by Chinese Taipei to notify the use of SDoC, it needed to be considered to what extent this would overlap with existing obligations in the TBT Agreement. While the United States welcomed more transparency and information on the use of SDoC or other approaches to conformity assurance, at the same time there was a need to avoid detracting from the existing obligation to notify the proposed conformity assessment procedures for comment.

119. The representative of Malaysia noted that the implementation of unnecessarily burdensome conformity assessment procedures created unnecessary barriers to trade and that this was a point that had been made during the course of the Workshop. Hence, it would be useful for Members to exchange views on the identification of appropriate conformity assessment procedures to use in different situations. This would assist Members in getting a better understanding on what the appropriate procedure could be in a given situation. The representative of Malaysia noted that although there were several international standards and guides defining and describing the various types of conformity assessment procedures, he was not aware of any international standard or guide that dealt with the selection of an appropriate procedures for use in specific situations.

(iii) Transparency

120. The Chairman noted that in discussions on transparency so far, the following issues had arisen: (i) publication of a notice of proposed technical regulations; (ii) notifications of proposed technical regulations and conformity assessment procedures of local governments at the level directly below that of the central government; (iii) notification of revised technical regulations and conformity assessment procedures following a recommendation of the DSB; (iv) comments on proposed technical regulations and conformity assessment procedures; (v) access to texts of notified measures; (vi) sharing of translations; and (vii) timing of the entry into force of measures.

121. The representative of Chinese Taipei introduced Section II of G/TBT/W/261. It was noted that Paragraph J of Annex 3 of the TBT Agreement allowed a standardizing body either to notify the existence of its work programme directly to the ISO/IEC Information Centre or to communicate it via the Internet. As the information made available to Members did not seem to be very clear on the specifics of how a standardizing body chose to fulfill this obligation, Chinese Taipei had proposed certain action to ensure that implementation of this obligation was as transparent as the other notification obligations in the TBT Agreement.¹² Moreover, Chinese Taipei also reiterated the importance of the notification obligation contained in Article 10.7. It was noted that in the year 2005, no notifications had been made under this Article despite recent activity in this area, both bilaterally and regionally.¹³

¹² G/TBT/W/261, para. 8.

¹³ G/TBT/W/261, para. 9.

122. The representative of Malaysia supported the initiative regarding the development of a voluntary system of sharing translations and was of the view that it would be preferable for this to be facilitated through the WTO Website rather than many Member websites. On the issue of access to final texts of notified measures, while Malaysia supported the requirement that the full text of notified measures be made easily available to other Members. It seemed burdensome, duplicative and also unnecessary that the Enquiry Point itself be required to have such texts always available; the requirement was that the Enquiry Point provide quick and easy access to the text was sufficient to fulfill the established objectives.

123. The representative of Chile stressed the importance, when submitting a notification, to include whenever possible a reference to where the full information on the technical regulation or conformity assessment procedure could be found. There was a need to include, at the very least, the Internet address where it could be obtained.

124. The representative of the European Communities supported the statement made by Chile and noted the usefulness of having the relevant draft technical regulation directly included in the notification, perhaps as an attached electronic file, or at least including a reference to a functioning Internet website where it could be downloaded. The representative of the European Communities also recalled their suggestion that Members give more precise and detailed information in the notification format under Section 6 which was entitled "Description of the content".¹⁴

125. The representative of China noted that the Secretariat's new TBT Handbook (paragraph 163) showed that progress had been made in terms of the comment period which last year had reached an average of 60.5 days. This was particularly helpful for developing country Members. In addition, the sharing of translations was important; the TBT Committee could learn from the SPS Committee's experience in this regard. The representative of China also considered that the TBT Committee could explore whether draft texts of notified measures could be provided together with the notification format so as to save time for the translation as well as time for comment.

126. The representative of Mexico stated that in respect of notifications there was sometimes no consistency between Members with respect to what was notified and under what provisions notifications were made. There was also a need to consider in more depth the time periods for public consultation. Moreover, Members appeared to have different periods of time for the receipt of notifications and Mexico considered it preferable to have one standard period of time for all. Mexico supported the suggestions made by Chinese Taipei with respect to transparency and the notification of the existence of a work programme for national standards bodies.

127. The representative of Canada considered the proposal that Members, on a voluntary basis, make available full texts of the draft regulation attached to a notification, a positive step forward. This not only reduced the time needed for receipt of the full text notification, it also improved the total period of time in which a Member could make comments and entailed, therefore, an improvement in efficiency and effectiveness. Canada also supported the comments made in respect of the sharing of translations. Regarding the time for comments, while the average time for comments had now surpassed 60 days¹⁵, the 11th Annual Review of the TBT Agreement (G/TBT/18) showed that approximately 10 per cent of the 2005 notifications had been made with a comment period of less than 45 days, and, there were also about 8 per cent of the 2005 notifications for which the time period for comments had not been specified, had lapsed or was stated as non-applicable.¹⁶ Hence, there was still room for progress. Canada continued to support its previous proposal regarding the enhancement

¹⁴ G/TBT/W/253, para. 6.

¹⁵ G/TBT/18, Figure 4.

¹⁶ G/TBT/18, Annex F.

of transparency for new or changed regulations or conformity assessment procedures which arose as a result of implementation of a recommendation of the DSB.¹⁷

128. The representative of Chile referred to a previous proposals made by other Members regarding the possibility that once a regulation was published, information could be made available on observations received on, and responses made to, those observations. There was a need to find a practical approach that would close the process of notifications, for instance, through the use of an Internet address that would archive comments made and the responses given. This would enable each Member to check how its comments had been taken into account.

129. The representative of India considered that the 60 day period for comments was short, given the need to obtain full texts, translations etc. India proposed that this time limit be extended to 90 days; this would make it easier for most countries to communicate comments on notified texts. India also proposed that there be a minimum 15 days interval after the expiry of the deadline for comments and the adoption of the notified text. Moreover, India was of the view that the date of notification needed to be unified with the date of circulation of the notification by the WTO. Regarding the description of the content (Section 6 of the notification format) the varying nature of the information given made it difficult to make a preliminary assessment of the impact of the notified measure. India therefore recommended that Members give a more elaborate explanation and description of content. India also observed that certain WTO Members made notifications of measures that were voluntary in nature. This created unnecessary work in terms of distinguishing between notifications that could entail a barrier for the trade and others which did not. Member needed, in compliance with the TBT Agreement's Code of Good Practice, to make the relevant notifications to the ISO/IEC Information Centre.

130. The representative of Japan noted, with respect to suggestion to secure 15 days or more between the lapse of the comment period and adoption, that there needed to be some exceptions allowed to this rule based on the legitimate objective of the measure and according to the Ministerial Decision regarding Article 2.12 of the TBT Agreement.¹⁸ On the proposal to host comments for notifications and their responses on the WTO TBT website, although useful, Japan reiterated that some bilateral communications between Members could be of a confidential nature.

131. The representative of Canada noted in respect of the proposals made by Chinese Taipei on standardizing bodies that, provided that these proposals be considered as an encouragement, or of a voluntary nature, the provision of more information about their work programme would certainly assist all Members of the TBT Committee. In respect to the proposal that the ISO/IEC Information Centre provide the Committee with a summary statement on the status of notifications made under paragraph J of the Code of Good Practice, Canada was of the view that this would be a helpful step in providing increased level of transparency on a more timely basis to the Committee.

132. The representative of Mexico stressed the need for the Committee to be careful about creating new obligations for Members in the context of the Review work. The Committee needed to focus on how to better comply with and implement the existing provisions of the Agreement.

133. The representative of Brazil, like Mexico, was of the view that the Committee needed to concentrate on the implementation of the current obligations in the TBT Agreement and not on the creation of new obligations for Members. Brazil expressed concern about the Canadian proposal on transparency (G/TBT/W/234) which, in its view, introduced new obligations concerning the implementation of the recommendations of the DSU by subjecting members to demands which were neither set out in the TBT Agreement nor in the provisions of DSU.

¹⁷ G/TBT/W/234.

¹⁸ WT/MIN(01)/17, 20 November 2001, paragraph 5.2.

(iv) *Technical Assistance*

134. The Chairman noted that during preparation of the Fourth Triennial Review, Members had discussed issues relating to (i) transparency in demand and supply and (ii) the effective provision of technical assistance; and (iii) participation in international standard-setting bodies.

135. The representative of Egypt stressed the need to consider practical forms of technical assistance. While Egypt supported Canada's earlier proposal for a workshop on good regulatory practice, it was felt that more workshops and seminars needed to take place in developing countries; these needed to aim at achieving a more practical implementation of the Agreement. In particular, conformity assessment was a difficult issue for many developing countries, especially in terms of the acceptance of conformity results (mutual recognition agreements, accreditation, certification). Hence, there was a need for hands-on assistance in this area in particular.

136. The representative of China agreed with the need to further enhance the different aspects of technical assistance and noted that the Committee had recently adopted a voluntary notification format specifically on technical assistance needs (G/TBT/16). The representative of China encouraged all Members to make full use of this format as it could give important signals to donors on the different types of technical assistance needs. China reiterated that there was much scope for improving technical assistance, for instance through the provision of technical assistance in urgent cases.¹⁹

137. The representative of the UNIDO, referring to the statement by the representative of Egypt, noted that UNIDO did provide technical assistance in the area of conformity assessment infrastructure aimed at overcoming barriers to trade. The UNIDO was, hence, involved in building the actual capacity in the area of conformity assessment. The UNIDO would provide more detailed information on its area of expertise at the next meeting of the TBT Committee.

(v) *Special and Differential Treatment*

138. The Chairman noted that Article 12 had been a topic of consideration in the TBT Committee since 1995 and that, on various occasions, Members had exchanged information and views on the operation and implementation of this Article as well as relevant provisions of other Articles. In particular, during the preparation of the Fourth Triennial Review, China had tabled a proposal and the Committee had held some discussion on this topic (G/TBT/W/252, Section IV).

139. The representative of Mexico considered that the issue of special and differential treatment was very important and that when a country received a request for such treatment the Agreement needed to be effective. The Committee needed to have clear criteria, for instance with respect to when a country had the obligation to provide special and differential treatment.

2. Previously raised or new topics

(i) *Intellectual Property Right (IPR) Issues in Standardization*

140. The representative of China wished to give some further background to a previous submission on this subject (G/TBT/W/251). It was stressed that the incorporation of intellectual property rights into technical standards was an inevitable outcome of the development of science, technology and the economy. He recalled that the WTO's World Trade Report 2005 had explored the links between IPRs and technical standards and had cited research which had found a positive correlation between patent applications and new technical regulations, especially in innovative fields. Based on cross country

¹⁹ G/TBT/W/252, paras. 14-15 and 19.

analysis, this research had also found that sectors with a higher propensity for standardization tended to be more patent and export intensive. In the view of the Chinese delegation, there was a clear trend whereby proprietary technology entered into the standard-setting process.

141. It was noted that standards-setting organizations at international, regional and national levels, including ISO, IEC, ITU, ETSI, ANSI, etc, had neither avoided – nor could they avoid – the inclusion of patented technologies. Therefore, on the issue of incorporation of patented technologies into standards, these organizations did not object in principle to patented items. In the view of China, the combination of IPRs with standards could bring about negative impacts on standardization and international trade. With regard to the IPR declarations, patent holders could hold back patent information in the process of standard setting (a case involving Dell was used to illustrate this point). In accordance with the prevailing patent policies of standards development organizations, if the identified patent holders refused to license on Reasonable and Non Discriminatory Licensing (RAND) terms and conditions, the standards development organizations could alter the standard around the proprietary technology. However, some essential technologies were hard to avoid and, in such cases, the standard at issue might have to be withdrawn. In China's view, standard-setting work had suffered, and would continue to suffer inefficiencies due to this situation. Hence, China was of the view that inclusion of IPRs into standards could have a serious impact on international standard-setting efforts and implementation. As the TBT Agreement aimed at boosting production efficiency and facilitating international trade by encouraging the adoption of international standards, such objectives could be frustrated and, therefore, international trade held back.²⁰

142. The representative of China stressed that the international community was increasingly paying attention to IPR issues in standardization. International standards-setting bodies such as the ISO, IEC and ITU-T had recognized the impact of the above-mentioned IPR issues and had endeavoured to solve the problems. They had formulated basic principles for patent disclosure and licensing arrangements which were widely cited by other standards development organizations. In China's view, these principles also constituted a sound technical base and a roadmap for the discussion in WTO. It was noted that the ISO, IEC and ITU-T had taken into consideration the development needs in their policies and activities.

143. The representative of China noted that aside from the patent policies of international standard development organizations, the United Nations Centre for Trade Facilitation and Electronic Business (UNCEFACT) was also well aware of this issue in its standardization work and had begun to formulate its patent policy for standards on electronic commerce. In some developed countries, these issues had captured regulators' attention. For instance, in Japan, the *Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act* which had been implemented by the Japan Fair Trade Commission, stipulated that the patent holders whose patents were implicated by standards adopted by government agencies shall not use their patents to exclude or control other companies, including with respect to exclusion and/or control of commercial activities of the patent users. In the United States, the Federal Trade Commission (FTC) and Department of Justice (DOJ) had been conducting intense discussions on these issues, including the 2002 FTC/DOJ joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy. In European Union, the *EC Communication on IPRs and Standardization* recognized that IPR holders should "make best efforts to identify any IPR which they hold relevant to a standard under development and to confirm or refuse permission for its incorporation in the standard"; "Offer fair, reasonable and non-discriminatory monetary or non-monetary terms for the license to use IPR"; and "Treat their eventual agreement for incorporating an IPR in a standard as irrevocable."

²⁰ The Representative of China made reference to the Box on page 39 of the WTO World Trade Report 2005.

144. In China's view it was important to strike a balance between IPR holders and standard implementers so as to create a win-win situation. IPR issues in standardization did not mean that IPR holders would lose and the IPR users would gain: the real problem, currently, was that there were not adequate rules to respond to IPR issues in standardization in the international community, including in the WTO framework. Without well-defined rules to follow, inefficiency arose in that the resulting disputes were to the detriment of both IPR holders and IPR users of both developing and developed country Members of the WTO. While it was important to protect the rights and interests of IPR holders, it was equally significant that new international standards and advanced IPR technologies were applied as widely as possible in order to enhance efficient, high quality production and to facilitate world trade to the interests of consumers worldwide.

145. Regarding the relevance of the above-mentioned issues to the WTO TBT Committee's work, it was recalled that Article 2.4 of the TBT Agreement encouraged WTO Members to use international standards as a basis for technical regulations. However, in situations where Members were not clear about: IPRs in the relevant international standards; whether all the IPRs had been disclosed; under what terms the IPRs were to be licensed by the IPR holders – all WTO Members would face difficulties when adopting international standards. This could mean that enterprises who were subject to the implementation of the technical regulations would encounter great difficulties with relation to disclosure of IPRs in standards, as well as difficult and time-consuming negotiations with IPR holders on the terms of licensing. At both the government and company level, there existed a certain unwillingness to adopt international standards as the basis of national standards and technical regulations if there was no common rule to regulate IPRs in standardization. This situation would bring a negative impact on the implementation of TBT Agreement with relation to adoption of international standards. With a view to facilitating the setting and implementation of international standards, and therefore the smooth implementation of the TBT Agreement, IPR issues in standardization had to be addressed properly.

146. Considering the above, China proposed that the international standard setting bodies, as well as WTO Members, provide the Committee with relevant information regarding practices and experience on their IPR policies in standardization to further Members' understanding of the subject. Such an information exchange would be necessary to facilitate meaningful discussions. The subject was of great significance to the integrity of international standardization community and multilateral trade system and China was therefore of the belief that this issue needed to be carried forward within WTO.

147. The representative of Brazil noted that the Chinese proposal was under consideration by his national authorities.

148. The representative of Mexico noted that although his delegation understood the nature and importance of the problem, he still remained to be convinced that the TBT Committee was the right forum to deal with it. Mexico asked China to explain exactly what the result was that China wished to obtain by discussing this proposal in the TBT Committee. Was China looking for guidelines, or simply an exchange of information, i.e., an educational discussion on the subject. Mexico was somewhat concerned that time be spent on this in the context of the Triennial Review without being clear on the outcome that the proponent was seeking. Like Brazil, Mexican authorities on intellectual property issues were considering the proposal presented by China.

149. The representative of the United States reiterated her delegation's comments from the last meeting. In particular, it was noted that the paper made an interesting statement that there were no WTO rules to address this issue; one question the United States had posed to China in bilateral meetings was that whether China foresaw the establishment of new rules under the TBT Agreement. In such a case, the discussion would become of a different nature. Therefore, it would be helpful if China could make its intentions clear in this regard.

150. The representative of China stressed that the objective of raising the issue under the Triennial Review process was to have an information exchange so as to familiarize WTO Members with the issue.

151. The representative of the International Telecommunication Union (ITU)²¹ noted that one of the important products of his organization was standards, referred to in ITU language as "recommendations". For instance, the use of broadband or ADSL access to the Internet was based on an ITU standard. It was noted that since the liberalization of the telecoms market and the Internet, standardization had become a market in itself and that there were currently about 500 fora and consortia active in the standardization of telecoms and the Internet. The ITU was one of these, together with the ISO and the IEC. What characterized the ITU was that it had both government and private membership. Hence, IPRs in the ITU system comprised three parts: patents, software copyright and marks.

152. Regarding patents, the patent policy of the ITU was very similar to the patent policy of ISO and IEC. The three organization were currently in the process of drafting a common patent policy so that it would be the same for all three organizations. The ITU encouraged early disclosure of patent information by the holder. Such information could be disclosed by ITU members as well as non-members. Moreover, all detailed commercial licensing arrangements were left to the parties concerned. The ITU patent policy comprised three situations: (i) the company gave a free licence to everybody; (ii) payment for licence was granted on RAND terms, i.e., reasonable terms and conditions on a word-wide non discriminatory basis; and, (iii) the party was unwilling to grant the licence.

153. In addition to the patent policy, the ITU also had Patent Guidelines and a Patent Statements Database where it was possible to look up the patents or patent information that has been submitted to ITU.²² There were also Software Copyright Guidelines and Marks Guidelines. The Committee was further informed about an Ad hoc Group on IPRs²³ which consisted of both engineers and lawyers. The group met every nine months and dealt with a number of complex IPR issues.

(ii) Terms and Definitions

154. The representative of the European Communities wished to draw the Committee's attention to a previously raised topic regarding terms and definitions. In the Third Triennial Review Report Members had made reference to the fact that the ISO/IEC Guide 2: 1991 had been revised.²⁴ Since then, the ISO had provided information on these revisions. In light of this, the European Communities proposed that the Fourth Triennial Review Report, in a factual statement, make reference to these changes and state which standards were currently relevant.

155. The representative of the United States was of the view that while some information had been provided on the updating of definitions, the ISO had not fully addressed the question: the Committee needed to get a better understanding of how the revisions made related to the document currently referenced in the TBT Agreement (the 1991 version of the Guide 2).

²¹ At the outset of the meeting and on China's request, it was agreed that a representative of the ITU would make a presentation on the subject of IPRs and standards under this Agenda Item. The full presentation was distributed as a Room Document and is available from the WTO Secretariat on request.

²² <http://www.itu.int/ITU-T/patent/index.html>.

²³ <http://www.itu.int/ITU-T/othergroups/ipr-adhoc/index.html>

²⁴ G/TBT/13, para. 61 states: "On the issue of terms and definitions, the Committee agrees that the ISO/IEC could be invited to provide information to the Committee on the revised ISO/IEC Guide 2: 1991, with a view to examining whether and how far this revised document departs from ISO/IEC Guide 2: 1991."

156. The Chairman invited the ISO to provide this information in writing in advance of the next meeting of the Committee.

3. Next steps

157. The Chairman noted that according to Work Programme for the Fourth Triennial Review²⁵, the Committee would begin the drafting phase at its next meeting. In order to initiate this work, the Chairman proposed to prepare a first draft of the report of the Fourth Triennial Review. Under each element of this draft, there would be a factual summary of the issues raised by delegations, including brief information of the development of each element under previous reviews. The draft would also set out suggestions for possible recommendations drawn from these inputs. The Chairman stressed that the Triennial Review was a Committee endeavour and that the process had to be consensus-based and Member driven.

158. To allow sufficient time for discussion of the Fourth Triennial Review, the Chairman proposed an additional day for the June meetings: the dates would hence be 7-9 June. Consistent with the agreed Work Programme and past practise in the Committee, the Chairman anticipated that the drafting work would be conducted in informal mode.

IV. TECHNICAL CO-OPERATION

159. The Chairman welcomed the first two notifications from Jamaica (G/TBT/TA-1/JAM) and Armenia (G/TBT/TA-2/ARM) under the mechanism for the voluntary notification of specific technical assistance needs and responses, which the Committee had adopted at its last meeting (G/TBT/16).

160. The representative of Brazil informed the Committee that the Brazilian TBT Enquiry Point (INMETRO) had received official visits from the Enquiry Points of India, China and the United States. This mutual exchange of experiences had helped identify possibilities areas of further collaboration. In particular, INMETRO had had the opportunity to provide information on the operation of its early warning system that functioned so as to alert Brazilian exporters about the issuing by WTO Members of notifications on technical regulations or conformity assessment procedures that might have possible commercial implications for them. For the purposes of technical cooperation, INMETRO had also initiated contacts with the Enquiry Points of Venezuela, Bolivia and Paraguay.

161. The representative of Mexico noted that his government had sent experts to Jamaica and to Nicaragua for technical assistance purposes. This assistance was aimed at providing some courses on conformity assessment procedures. Moreover, Mexico had also received a visit from the Egyptian delegation for the same purposes.

162. Considering the intervention from Brazil and Mexico, the Chairman noted the importance of technical assistance being provided by developing countries themselves, who were now engaging on the donor side of technical assistance activities.

163. The representative of the Secretariat introduced a "Handbook on the TBT Agreement" which had been produced in response to a mandate from the Third Triennial Review.²⁶ It was stressed that the Handbook was a practical guide to the TBT Agreement and had been prepared to increase public understanding of the Agreement. It was not intended to provide a legal interpretation of the TBT Agreement.

²⁵ G/TBT/M/37, Annex 1, p. 25.

²⁶ G/TBT/13, para. 56 and footnote 20 .

164. The representative of the European Communities noted that at the June 2006 meeting the EC delegation intended to make a presentation on what was referred to as the "Exporters' Help Desk" which was a facility to assist developing countries to understand ways in which to access the European market.

165. The Chairman noted that the a Room Document had been provided listing the Secretariat's technical assistance activities in 2006.²⁷

V. ELEVENTH ANNUAL REVIEW

A. THE IMPLEMENTATION AND OPERATION OF THE TBT AGREEMENT (ARTICLE 15.3)

166. The representative of the United States recalled that one of the recommendations from the Third Triennial Review was to provide information on technical assistance in the annual reviews.²⁸ She asked the Secretariat to include information on content, participation and feedback from recipient members in the annual reviews.

167. The Committee adopted the Eleventh Annual Review of the Implementation and Operation of the TBT Agreement contained in document G/TBT/18.

B. THE CODE OF GOOD PRACTICE (ANNEX 3 OF THE TBT AGREEMENT)

168. The Chairman drew the Committee's attention to the Eleventh Edition of the WTO TBT Standards Code Directory prepared by the ISO/IEC Information Centre 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. He also drew the Committee's attention to two lists prepared by the Secretariat. The first list, contained in document G/TBT/CS/1/Add.10, compiled the standardizing bodies that had accepted the Code in the period under review. He noted that during the period under review, three standardizing bodies from three Members had accepted the Code of Good Practice and no standardizing body had withdrawn from the Code. The second list, contained in document G/TBT/CS/2/Rev.12, compiled all the standardizing bodies that had accepted the Code since 1 January 1995. Since 1 January 1995 – and including a recent notification of acceptance from Qatar (G/TBT/CS/N/163) – 152 standardizing bodies from 111 Members had accepted the Code of Good Practice.

169. The Committee took note of the above-mentioned documents.

170. The representative of India drew the Committee's attention to the fact that although there were more than 159 member bodies of ISO, the number of such bodies that had accepted the Code of Good Practice was inferior. In fact, there were standards bodies who claimed to follow the WTO principles of transparency in writing standards yet they had not registered themselves under the Code of Good Practice. The representative of India urged all ISO member bodies to enrol themselves under the Code of Code Practice so that all followed a uniform practice.

VI. UPDATING BY OBSERVERS

171. The Chairman drew the Committee's attention to information provided by the Codex (G/TBT/GEN/32) and the OIML (G/TBT/GEN/33).

²⁷ Updated and subsequently circulated as G/TBT/GEN/34.

²⁸ G/TBT/13, para. 55, second tiret.

172. The representative of the ITC informed the Committee that the ITC had recently prepared an information training pack on the WTO TBT Agreement from a Business perspective (available from the ITC). It was also noted that in October 2005, the ITC had held a workshop based on this training pack in Kazakhstan, and, in November, a similar workshop had been held in Uzbekistan. Moreover, in June 2005, together with the Standards and Industrial Research Institute of Malaysia, the ITC had organized a consultation to discuss with developing countries and transition economies how they tackled problems related to establishing a quality infrastructure with limited resources. The ITC had also issued a publication on this subject which was available on the ITC website.²⁹

VII. ELECTION OF CHAIRPERSON

173. Pursuant to Article 13.1 of the TBT Agreement, the Committee re-elected Mr. Margers Krams (Latvia) as the Chairperson of the TBT Committee for 2006.

VIII. DATE OF NEXT MEETING

174. The Chairman announced that the next regular meeting of the Committee would take place on 7-9 June 2006.

²⁹ <http://www.intracen.org/eqm/>.

ANNEX 1: THE TBT WORKSHOP ON THE DIFFERENT APPROACHES TO CONFORMITY ASSESSMENT

Statement made by the Chairman³⁰

1. We held, yesterday and this morning, a workshop on the different approaches to conformity assessment, including on the acceptance of conformity assessment results. To recall, the organization of the workshop was mandated in the Third Triennial Review as part of a Work Programme on conformity assessment. We heard extremely interesting presentations by 27 speakers representing a broad range of conformity assessment institutions in all parts of the world. We had identified three main focus areas for this workshop.
2. Following a presentation by the WTO Secretariat on the TBT Committee's work on conformity assessment procedures and the relevant provisions of the TBT Agreement, the first session focussed on conformity assessment procedures at the national level. In the first part of the session, speakers provided concrete examples of existing approaches at the national level and explained the mechanisms in place to make the conformity assessment procedures both effective and well-suited to the regulatory purpose at hand. ISO made a presentation on their standards on conformity assessment and their relevance to regulatory requirements; the speaker from Colombia presented the regulatory framework created to facilitate the use of the appropriate conformity assessment scheme; a representative of the US private sector provided a concrete perspective and stressed the importance of consumer confidence and brand recognition. We also heard presentations on the experience of Mexico and Brazil in working towards a more efficient and market-relevant conformity assessment system. The second part of the first session presented sector-specific approaches to conformity assessment. Speakers identified the benefits and possible problems of the different conformity assessment approaches in relation to the following sectors: Vehicle emission and noise in Chinese Taipei; electricity in Argentina; and forest certification in Canada. In addition, we heard a presentation from the US private sector on the implementation of voluntary conformity assessment market programs.
3. Session II focussed on mechanisms to facilitate the acceptance of conformity assessment results (pursuant to Article 6 of the TBT Agreement). In the first part, speakers addressed the advantages of, and possible difficulties with, various approaches in this respect. Following a report by the OECD on the results of a survey of conformity assessment bodies (CABs), two presentations were made on the work of accreditation bodies, one in New Zealand and Australia (JAS-ANZ) and the other in Mauritius (MAURITAS). The European experience of cooperation among accreditation bodies at a regional level was also discussed. The second part of Session II dealt with the negotiating of mutual recognition agreements (between governments) and the acceptance, by regulatory authorities, of results of conformity assessment bodies participating in voluntary arrangements. With respect to the former, presentations were made on experiences in Japan and Europe. On voluntary arrangements, participants heard a presentation from the electronic & IT industry's perspective and the IEC IECCE and IECEx schemes were discussed as examples in this respect.
4. Finally, this morning, the programme focused on developing countries. There were presentations on the experiences of a number of developing countries in either administering existing conformity assessment systems (e.g. India, Brazil) or working to build such infrastructure (e.g. Nigeria). We learnt of the operations of these systems and key challenges and problems faced (resource constraints, technical and infrastructural needs, etc). We were also informed of the views of some developing countries on the utility of conformity assessment systems (facilitating trade,

³⁰ The programme (G/TBT/GEN/31) as well as presentations are available on the TBT webpage: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm#events. A summary report of the Workshop will be issued separately.

disseminating information, protecting consumers) and on the developmental potential of such infrastructure. Fundamentally, significant support to developing countries is needed to support their objectives in the area of conformity assessment. A number of international agencies (UNIDO, ILAC) informed the Workshop of their role and work to assist developing countries in the identification of conformity assessment-related needs and in the provision of technical assistance. The importance of regional coordination was also well reflected during this session. The Economic Community of West African States presented its experience in building a quality system at the regional level and a representative from Trinidad and Tobago highlighted the efforts made in the Caribbean to establish a regional conformity assessment infrastructure.

Committee on Technical Barriers to Trade

**SUMMARY REPORT OF THE WORKSHOP ON
THE DIFFERENT APPROACHES TO CONFORMITY ASSESSMENT¹**

16-17 MARCH 2006

Note by the Secretariat²

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¹ All presentations are available on the WTO website at:

http://www.wto.org/english/tratop_e/tbt_e/meeting_march06_e/tbt_conformity_16march06_e.htm

² 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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INTRODUCTION

1. At the Third Triennial Review of the TBT Agreement, concluded in November 2003, a work programme on conformity assessment was agreed upon. The objective of this work programme was to improve Members' implementation of Articles 5 to 9 of the Agreement. In particular, the idea was to promote a better understanding of conformity assessment systems in general. The main elements of this work programme related to the use of international standards, suppliers' declaration of conformity (SDoC), accreditation, including the operation and participation of Members in international and regional accreditation fora, and the different approaches to conformity assessment.

2. In this context, Members agreed to organize a workshop on the different approaches to conformity assessment, including on the acceptance of conformity assessment results.³ The participation of 82 representatives from developing country Members had been sponsored by the WTO through the Global Trust Fund.

3. The WTO Secretariat⁴ presented an overview of the TBT Committee's work on conformity assessment procedures and of the relevant provisions of the TBT Agreement based on a background note contained in JOB(05)/261.

SESSION I – CONFORMITY ASSESSMENT PROCEDURES AT THE NATIONAL LEVEL⁵

4. The intention of this session was to give participants an opportunity to share experiences of conformity assessment approaches and procedures at the national level and to address considerations that were to be taken into account for the use of conformity assessment procedures.

NATIONAL CONSIDERATIONS FOR THE PREPARATION AND APPLICATION OF CONFORMITY ASSESSMENT PROCEDURES

5. The first part of this session dealt in particular with the national considerations for the preparation and application of conformity assessment procedures. Presenters were invited to identify their various considerations that were relevant when deciding on the need for a conformity assessment procedure and on the type of procedure including costs and benefits of alternatives, level of risk, incentives for users to comply, technical and physical infrastructure, and existing monitoring and enforcement mechanisms.

Conformity Assessment and Regulations: The ISO/CASCO Toolbox⁶

6. One of the imperatives of ISO/CASCO was to ensure that conformity assessment standards were implemented and applied the same way everywhere. The ultimate goal of conformity assessment was one standard, one test accepted everywhere. The basic conformity assessment process entailed three levels of work: the identification of the object of conformity assessment; the evaluation of the object against requirements; an attestation to the validity of those tests, through a first party in the context of Supplier's declaration of conformity (SDoC), through a second party doing an audit on the suppliers premises, or through third party certification. A level upon would be accreditation or peer assessment in the context of certification bodies.

7. The CASCO toolbox consisted of 24 ISO/IEC documents covering: vocabulary, principles and common elements of conformity assessment, code of good practice, product certification, system certification, certification of persons, marks of conformity, testing, calibration, inspection, SDoC, accreditation, peer assessment, and mutual recognition arrangements. 100 countries were involved

³ The final programme for this workshop is available in document G/TBT/GEN/31.

⁴ Mrs. Ludivine Tamietti, Trade and Environment Division, WTO Secretariat.

⁵ This session was moderated by Mr. Margers Krams, Chairman of the TBT Committee.

⁶ Mr Peter Dennehy, Secretary of ISO/CASCO.

through ISO member bodies in CASCO: 63 were participating members and 37 observers. CASCO also benefited from the experience of nine international organizations who were liaison members.

8. CASCO's structure reflected its various roles of policy development, writing of technical documents, promotion of documents, and monitoring market feedback on the use of documents. A continual improvement cycle ensured that CASCO provided globally relevant documents that reflected modern conformity assessment practice. The Policy and Coordination Group had to ensure that CASCO's work matched member bodies' needs. The working groups themselves were composed of experts from the 100 countries and the nine liaison bodies. Guides and standards developed in working groups were then sent to member bodies who debated the content and use of the documents, commented on them, changed the documents remotely and voted. That was the double level of consensus that ensured that documents were acceptable for the industry at any given time. Once published, those documents were promoted and supported by two different bodies: the Regulations Interface Group; and the Promotion and Support Group. Finally, the Market Feed-Back Panel had to ensure that standards were still useful or to identify standards that needed to be modified or improved.

9. There were also a number of basic documents developed by CASCO concerning conformity assessment procedures, for instance: ISO/IEC 17000:2004 on vocabulary and general principles, which contained the terms, definitions and theoretical basis for conformity assessment; and ISO/IEC Guide 60:2004, which was a Code of Good Practice to facilitate trade. Moreover, CASCO was developing common elements for conformity assessment that would be used in all CASCO documents. These common elements included: impartiality, confidentiality, complaints and appeals, disclosure of information, and use of management systems in conformity assessment.

10. There was a number of documents in the CASCO Tool Box: on accreditation and peer assessment, which addressed the relationship between conformity assessment bodies (CABs); mutual recognition arrangements; marks of conformity; and sector specific applications of conformity assessment procedures. In the technical area, there was a number of other standards: on SDoC; testing and calibration laboratories (17025 which was a set of technical and management system requirements for the laboratories and Guide 43 about proficiency testing); inspection (17020); for product certification, there was a whole range of documents that addressed different aspects of product certification; and for system certification, 17021 on certification bodies and 17024 on person certification, which was a relatively new approach in conformity assessment.

11. For developing countries, DEVCO was running a five-stage programme that enabled all conformity assessment standards and all other ISO standards to be developed and implemented by developing member bodies: (i) improve awareness; (ii) develop capacity; (iii) increase national and regional cooperation; (iv) develop electronic communication and expertise in IT tools; and (v) increase participation in governance and technical work of ISO.

12. To conclude, technical barriers to trade in relation to tests, certificates and similar requirements could be addressed using international standards and conformity assessment. However, to achieve this goal, there was a need to ensure that the regulatory requirements, which relied on them, were performance-based. ISO was also trying to develop its standards using performance-based requirements. Relying on ISO/IEC international standards on conformity assessment to demonstrate compliance with technical regulations would reconcile public objectives, such as safety and security, and compliance with commitments of the TBT Agreement.

13. During the *Questions and Answers Session*, it was further indicated that the Regulations Interface Group had already carried out three comprehensive surveys on the use of ISO and IEC standards on conformity assessment. The extent to which the surveys could be used depended on the accuracy of the information provided by member bodies. The convener of the group was restructuring one of those surveys to be more focused on particular aspects of the use of the guides. However, there was already evidence that in different parts of the world there were different uses by

regulators of the same standards. For instance, in one country regulators would allow for the use SDoC for a particular requirement and for the same requirement, in another country, regulators would require third party certification.

Existing Good Regulatory Practice in the Area of Conformity Assessment in Colombia⁷

14. Conformity assessment and good regulatory practices were closely linked as it was very difficult for a conformity assessment procedure to be carried out without good regulatory practices in other related sectors. In Colombia, there were open discussions on what was the best conformity assessment procedure for a particular technical regulation. These discussions involved the participation of all stakeholders, i.e. consumers, industry, certifiers, accreditors, etc. Moreover, Colombia had national legal instruments dealing with conformity assessment procedures and as part of the ANDEAN community of nations, regional standards.

15. Colombia's conformity assessment system had a few weaknesses. First, Colombia lacked accredited laboratories. Many private laboratories were not accredited. The level of activities was not enough to justify going through the whole procedure of accreditation, which was time consuming and costly. Therefore, the fact that a number of unaccredited laboratories existed weakened the whole process of accreditation at the national level. Second, Colombia lacked skilled professionals to really carry out the procedures required in the accreditation process. Moreover, some entities at the government level developed what they called "accreditation procedures", which were in fact mere recognition or designation; sometimes, national producers needed a double certification for the same product from two different authorities. Finally, there was a problem of link between the accreditation of conformity assessment bodies and the risk that needed to be addressed.

16. Colombia was working towards international recognition of its accreditation body. There was an infrastructure that could be developed further providing support to neighbouring countries and to the region as a whole. Colombia had a very positive experience in conformity assessment of third parties and a very good implementation of the CASCO Tool Box. The conformity assessment system in Colombia also faced a number of challenges: the adjustment to modifications of international standards on conformity assessment procedures; the important rotation of human resources trained for conformity assessment; the very high costs involved in conformity assessment for producers and importers; and the question of the sustainability of laboratories over time.

17. To conclude, it was noted that the whole regulatory process was crucial. There had to be transparency and participation of all stakeholders in the entire conformity assessment process. That was indispensable in developing standards and in determining what was the best conformity assessment procedure for each regulation. Conformity assessment procedures needed to be closely linked to risk management. Regional cooperation and international cooperation for conformity assessment were indispensable for developing countries to establish good regulatory practices, in particular with regard to conformity assessment.

Trade Impact of Conformity Assessment Procedures: A Manufacturer's Perspective⁸

18. From a company's perspective, trade was all about meeting consumers' needs first. Conformity assessment provided a way for consumers and regulators to gain confidence in products and services offered by suppliers and to differentiate between them. A company's objective were: to differentiate between those who produced high quality service and those who did not; and for legitimate suppliers to build confidence in their products and services. Brand building was critical to

⁷ Mr. Ramón Madriñán, Chief Regulatory Officer, Ministry of Trade, Industry and Tourism, Colombia.

⁸ Mr. Robert W. Noth, Manager, Engineering Standards, Deere and Company, United States. Deere and Company was a 169 year-old company, which had a long experience of international trade in agricultural and industrial equipments.

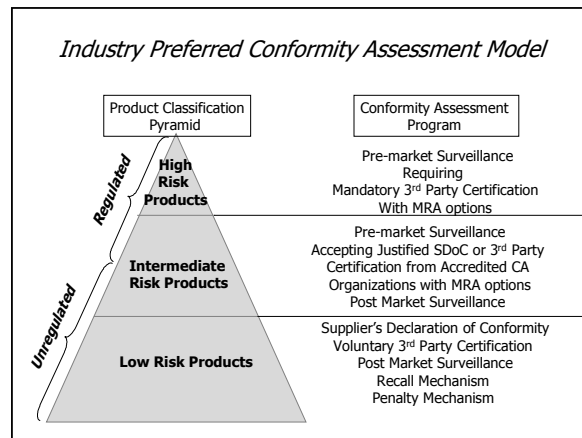
a company's survival because it ensured on-going commerce. Brand recognition only had value if brand reputation was earned by consistently meeting customers' expectations in the market place.

19. Conformity assessment consisted of four things. First of all, a consistent set of standards and regulations that provided the baseline for an assessment. The second and third elements were inspection and testing. Assessment systems were classified according to which party performed the inspection and testing. SDoC was usually done by the manufacturer. It was stressed that, especially for complex products, manufacturers knew their products best and nobody had invested more in the delivery of these products than the manufacturer. Therefore, SDoC had a strong basis in competence and delivery. Second party referred to the customers' assessment. And third party was an independent assessment used voluntarily for brand-building and risk assessment by many companies in areas where risk was a concern.

20. The fourth element of conformity assessment was time. Products were expected to continuously meet requirements. Pre-market surveillance ensured initial compliance but was not sufficient: post-market surveillance was essential to ensure continued compliance. Legitimate manufacturers supported principles contained in the TBT Agreement, such as the avoidance of unnecessary obstacles. Unfortunately, this was not always the case in the market place. Requirements were often out of proportion to the risk involved, for instance in the case of electromagnetic interference (EMI) regulations for IT products. There, the likelihood of non-conformance and harm was almost non-existent and historically there was plenty of evidence of the adequacy of SDoC. SDoC was acceptable for earthmoving equipment in the United States and Europe countries with minimal negative experience but not acceptable in many other WTO Members.

21. Another problem was unique and non-value added testing. The redundancy of having to test the same product for different markets only added to the cost burden, which was ultimately passed on to the consumer. For instance, in the area of agricultural lighting equipment, the existence of different regulations made it difficult to produce tractors, which were often for markets in small volumes. Likewise unique earthmoving equipment requirements in a few countries required local third party testing beyond globally acceptable norms. The impact was ultimately on manufacturers: the time to market was affected because of the time necessary to get the testing and the certification done; there was also the issue of the cost of third party assessment. Two ratios were important to consider: the cost to risk ratio, i.e. the comparison between the cost and the possible risk of the product; and the cost to margin ratio, i.e. the question of whether the manufacturer would be able to cover the cost. By far, the most important cost in this area was the redundancy of third party assessment especially where SDoC was accepted in some markets, and third party required in others.

22. In a model of industry's preferred conformity assessment system, there was a particular place given to high risk products, recognizing that pre-market surveillance and mandatory third party assessment were necessary, for instance for medical devices and food products. For the group of intermediate risk products, there should be a combination of different types of assessment. And for the vast majority of products, SDoC should not be a problem provided that post-market surveillance, recall and penalty mechanisms were in place. One other consideration in relation to market surveillance was the importance of recognizing and rewarding sustained performance in the market place.



23. The primary challenges for the TBT Committee were: the elimination of redundant and unnecessary inspection and testing requirements around the world; the harmonization of what was considered high risk, intermediate risk and low risk; and the development of guidelines on how to set up effective and non-discriminatory conformity assessment programmes. The benefits of meeting these challenges would be: greater product's availability; more choice for consumers; more confidence in the goods manufactured; lower costs; more trade, faster growth and hopefully more capital investment in developing country markets; and, for all manufacturers, faster time to market, lower cost, more effective competition and more investment opportunity.

24. During the *Questions and Answers Session*, further information was provided on the relationship between brand recognition and conformity assessment procedures. If consumers had a good and consistent experience with certain products, there was less risk involved. In this context, SDoC through brand-building was a less expensive and more efficient way to perform conformity assessment. If consumers had less experience with a particular brand, manufacturers would need to provide a little more assurances in terms of conformity assessment. It was also noted that the cost of redundant conformity assessment was very much depending on the size of the market. For example, in Europe, there were specific requirements for tractors, e.g. on how far the headlights could be from the ground. Those kind of design requirements also had to be added to the cost. Therefore, the impact of the cost of different conformity assessment procedures and requirements could be significant and as high as 30 or 40 per cent of the cost. In response to a questions on how to evaluate the risk encountered by the product so as to define the best applicable conformity assessment procedure that should be used, it was noted that industry tended to build its products according to standards and specifications that were established and globally accepted. If products met those requirements, the risk for individual consumers was reduced.

Conformity Assessment Procedures in Mexico⁹

25. The legal basis for conformity assessment in Mexico was a Federal Law introduced in 1992 and revised in 1997. This Federal Law covered: metrology; voluntary standards; technical regulations; calibration laboratories; test laboratories; inspection bodies; standards development organizations; product, quality and environment certifiers; who could accredit; and when and how to perform conformity assessment. In Mexico, most standards were effectively voluntary and the rules of civil responsibility in the country were weak.

26. Mexico had free trade agreements with 43 countries and the import taxes were zero or near zero for these countries. Mexico applied the procedures for conformity assessment based on international practices. Mexico, the United States and Canada worked, even before entering in the free trade agreement, to harmonize electro-technical standards. There were also some other working groups in steel and the automotive industry, which helped to increase the flow of products and services within the three countries.

27. Mexico had also been working internationally with other Latin American countries through several free trade agreements such as: G-3 with Colombia and Venezuela; the north triangle with Guatemala, Honduras and Salvador, plus Nicaragua, Costa Rica, Chile and Bolivia. Nowadays, some negotiations were under study: with Panama, Ecuador and Peru to integrate the G-3; MERCOSUR; and Korea. In all these agreements, there was a "chapter" regarding standards and technical regulations, local value content and rules of origin.

28. As regards accreditation, there were numerous procedures in America which all followed ISO/IEC standards. A common accreditation system like the Inter-American Accreditation Cooperation Organization (IAAC) could help gain confidence in conformity assessment bodies. Moreover, this year, Mexico would enter into the mechanisms of IEC. A regional approach facilitated

⁹ Mr. Rafael Nava, President, Commission of Standardization and Conformity Assessment, Mexico.

the knowledge of needs because of natural similarities. However, international standards were essential to have better results and global relevance, while it was also necessary to consider some essential differences based on local meteorological conditions, infrastructure or energy situation. Since 1997, when the Mexican Law was modified for the last time, 10 products certifiers and more than 30 systems certifiers (ISO 9000, 14000 and the like) had been accredited.

29. In 2005, Mexico bought 222 billion dollars of products and services with a minimum amount of trouble for suppliers. There were 800 technical regulations, but only 6 per cent of them were mandatory before products entered the country, covering less than 25 per cent of the imports, mainly in relation to product safety; health and environmental protection, and energy efficiency; in other words 75 per cent of products, or over 165 billion dollars, entered Mexico without any conformity assessment requirement.

Handling Complaints in Brazil (Pursuant to Article 5.2.8 of the TBT Agreement)¹⁰

30. In the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), there were three main channels to receive complaints related to activities under its responsibility: a call centre, a programme on product analysis and the Brazilian TBT Enquiry Point. Through these channels, complaints were received from different sectors on products subjected to conformity assessment procedures. The objectives were: to ensure credibility in the Brazilian system of conformity assessment as well as INMETRO activities; to gain consumers' confidence in the products which had been assessed; and to identify improvements or opportunities in conformity assessment procedures. However, it was not enough just to establish those channels and hope for the consumers to present their complaints. It was necessary to publicise those channels so as to guarantee that more complaints be presented. The call centre offered a few communication modalities: a toll-free line, a telephone, fax, internet, and personal consultations by appointment.

31. It was interesting to point out that most complaints did not come from consumers but from the private sector. INMETRO received a vast diversity of requests, most of them being in relation to information. The complaints represented a small part of the requests. When there was a complaint, the request was forwarded to the person in the department of INMETRO in charge of the particular area and each department had its own person responsible for handling complaints. This information flow was managed by a system, specifically developed for the call service. As soon as the complaint was taken care of, the system was updated with the information gathered.

32. INMETRO carried out a product analysis programme since 1996 according to Guide 46/1985 on "Comparative testing of consumer products and related services". This programme aimed at supporting the Brazilian industry on quality improvement and raising consumer awareness. The programme methodology consisted of identifying a set of products to be analysed based on complaints received from different sources. The following actors were involved: the consumer protection and defence department under the Ministry of Justice, other officials and civil entities related to consumer protection, national media, private sectors and the INMETRO call centre. A first research was carried out to identify standards and technical regulations that needed to be complied with. Then, a laboratory accredited by INMETRO was selected to test compliance. The relevant official responsible for the product regulation was invited to participate and manufacturers' associations and federations were informed. The product was analysed and the laboratory sent the results to INMETRO, which forwarded them to each manufacturer with a deadline for the response.

33. After a clarification process on manufacturers' possible queries, the test results were released on a national television network in a Sunday evening show. Other media linked to consumer's protection released these test results on a voluntary basis. After this phase, meetings gathering manufacturers and consumer protection entities in the government were carried out to define

¹⁰ Ms. Anna Camboim, Manager, International Affairs, INMETRO, Brazil.

measures to improve the quality of the specific sector. 50 per cent of the manufacturers decided to adopt the immediate correct reaction, 18 per cent considered the programme a decisive quality improvement factor for national products. In the last 10 years, the product analysis programme analysed more than 200 products involving more than 2200 brands.

34. In addition to raising society awareness on low quality or illegal products, the programme was an opportunity to develop specific conformity assessment programmes for specific sectors. INMETRO provided the possibility to receive complaints through the internet concerning problems identified on domestic products. Some complaints related to difficulties in complying with foreign technical requirements. In such cases, there were two possibilities: either there was a technological gap and the manufacturer was really unable to comply with the requirements requested, or there was a technical barrier to trade for this product. If the analysis of the complaint demonstrated a technical gap or a non-conformity aspect, the issue was forwarded to a specific government programme, which was able to help the producer to meet the relevant technical requirements. On the other hand, in case of doubt about the legitimacy of the technical requirements, INMETRO would get in touch with the relevant TBT enquiry point of the WTO Member.

SECTOR-SPECIFIC APPROACHES TO CONFORMITY ASSESSMENT

35. In this session, speakers had been invited to identify the benefits and possible problems, including respective costs, of the different conformity assessment approaches and to focus their presentations on specific products or sectors.

Vehicle Emission and Noise Standards¹¹

36. Chinese Taipei had the highest vehicle density in the world. As a result, mobile-source emissions had become the major cause of air pollution in urban areas. This had caused a continual rise in respiratory illnesses associated with air. The vehicle industry in Chinese Taipei relied heavily on imported technology. Most of the major motor vehicle technology providers were Japanese manufacturers. In addition, the average age of a vehicle in Chinese Taipei was high which needed to be considered in the emissions controls. Considering economic, trade and environmental factors, Chinese Taipei had adopted conformity assessment procedures to reduce barriers to trade, while implementing increasingly stringent standards. These procedures were harmonized with international conformity assessment standards.

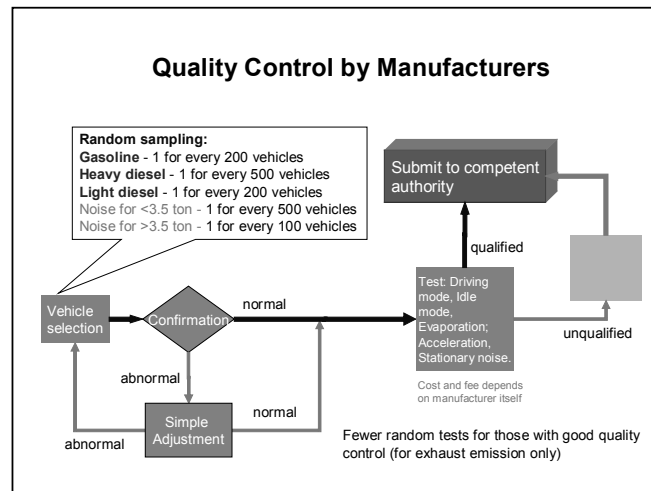
37. Before the accession of Chinese Taipei to the WTO, in 2002, imported vehicles originated mostly from the USA. US vehicle emissions management system were the most comprehensive and it was referred to as the US system in the domestic management system. After 2002, Chinese Taipei accepted foreign standards and certifications in line with UNECE WP.29. In relation to acceleration and stationary noise, Chinese Taipei referred to Japan's standards in the early stages and further harmonized with UNECE and EC standards. Chinese Taipei adopted a type approval conformity assessment procedure to ensure that new vehicles meet such standards. In the design phase, vehicles were required to meet mandatory standards and apply for type approval certification. After the production process, authorities randomly selected vehicles for compliance checks and the manufacturer was required to do on-line checks and random tests for quality assurance.

38. The type approval procedure was working as followed. For new vehicles, the applicant needed to select the vehicle to be certified and sent to the lab for testing. If the test report qualified, a certificate would be issued for imported vehicle already holding EC and US certification. Applicants should use the foreign certification to apply for domestic certification. Document review included durability, manufacturer's specification and quality control plan. In order to ensure that all produced vehicles meet Chinese Taipei's standard, a new vehicle inspection would be carried out and vehicles

¹¹ Ms. Hui Chen Chien, Senior Specialist, Department of Air Quality Protection and Noise Control, EPA, Chinese Taipei.

would be randomly selected from the new vehicle lot and then delivered to the testing laboratory for emission and noise compliance test. If the vehicles were not in compliance, then retest would be performed or if necessary, the certification withdrawn.

39. The manufacturer was also required by law to carry out tests for quality control. The selected vehicle first needed to do a confirmation check; if it was normal, it would perform a conformity test; if the test result complied with relevant standards, it was submitted to the authority; if the vehicle did not comply, then the vehicle maker had to provide an explanation and propose the correction for follow-up review. Some improvements had been made in the conformity assessment system: the differences between laboratories had been minimised; communication had been enhanced to



increase the understanding of compliance certification documents; for vehicle with a new technology, such as hybrid vehicles, a new test procedure was accepted to reduce the risk for import vehicle recall cost and promote vehicle industry technology; and in accordance with the objectives and requirements of the TBT Agreement for acceptance of conformity assessment results, Chinese Taipei accepted European emission and noise certification as well as vehicles imported from other countries and holding EC or US certification.

40. To conclude, after Chinese Taipei's accession to the WTO, the imported value of vehicles and components continued to rise at a rate even higher than the GDP growth. Second, given the high vehicle density, the need to protect the environment, public health and to remove non-tariff trade barriers, Chinese Taipei was harmonizing its vehicle control standards and would place more emphasis on assessing cost effectiveness in the future. Third, with the harmonization of regulations and standards, Chinese Taipei's conformity assessment of vehicle emissions and noise was consistent with international practice. Finally, as a Member of the WTO, Chinese Taipei would continue to meet its obligation to reduce non-tariff barriers to trade and its commitments under the WTO.

41. During the *Questions and Answers Session*, it was indicated that new vehicles without an EC or US certification needed to be tested again. Also, if a car met the national level standard in Chinese Taipei and it could be proven, it was possible to import this car.

The Electricity Sector: Trade and Confidence¹²

42. Trade and conformity assessment needed trust and confidence of consumers. Consumers had to be sure that products were harmless, safe and long lasting. Concepts of trade and trust would consolidate further conformity assessment if one managed to gain the trust of consumers and ensure a better flow of goods and services in the country and with other countries. Authorities establishing conformity assessment procedures needed to make sure that technical regulations were followed and abided by. Authorities had to take into account what the best mechanism was to ensure that the domestic market was well covered and that consumers' interests were protected.

43. In Argentina, certain mechanisms had been put in place in order to ensure the security and the safety of products. The government had developed a series of regulations for the protection of

¹² Ms. María Juana Rivera, Technical Barriers to Trade, Ministry of Economy and Production, Argentina.

citizens. Special care had been given in establishing instruments that would guarantee technological improvements taking place in national enterprises. Several systems had been established for a wide variety of products: electrical products, personal protection equipment, lifts or elevators, toys, bicycles and lighters. The common features in all these systems included the following: a regional rule or standard accepted by the parliament, or an international standard; a system of conformity assessment through certification by third parties on the basis of ISO models and a system of marketing monitoring.

44. In the electricity sector, there was a regulation to guarantee the security and safety of electrical products that covered: all electrical equipments; the type of materials that needed to be used in making any electrical appliance; electronical goods; and household electrical goods. The regulation applied to local producers, importers, distributors, wholesalers and retailers and the system was therefore not discriminatory because all products marketed in the country were covered whether national or imported. On the product, reference had to be made to the basic features of the equipment, the country of origin, legal domicile and the type of product.

45. In Argentina, the certification procedure was done by a third party. This system had to ensure the participation of all the different parties concerned, it had to be accredited by the Argentinean office of accreditation which was a full member of IEC, and it had to be acknowledged by the competent authority in the country. There were different kinds of certification: type certification or certification through the conformity label system or through the batch certification system. There was also a system of monitoring of the market of these products with certain verification procedures: certifications were checked and regularly reviewed.

46. If governments based conformity assessment procedures on international standards, if certification and accreditation bodies subscribed and endorsed multilateral arrangements, if laboratories, certification and verification bodies were accredited, certified and recognised according to international rules and instruments, there would be every possibility of successfully and mutually recognising products; this would ensure that trade was based on one product, one test. From Argentina's point of view, there was not a single system for conformity assessment. Each one of the systems had advantages and disadvantages and each country should take very much into account the particular conditions at its own stage of development so as to choose the best system for conformity assessment. Such system should not be inconvenient for trade development and the variables that should be taken into account were the level of risk of the product, the development of its fiscal system, the legal framework of company responsibility and the legal structure. With these elements, considered jointly, each country could choose the best system for conformity assessment.

47. During the *Questions and Answers Session*, it was pointed that the cost of testing and certification of electrical equipment fell upon producers.

Implementation of Voluntary Conformity Assessment Market Programs¹³

48. There were many entities that could play a role in ensuring the market obtained what it needed. The market could choose to purchase or not to purchase the product as a brand or as an individual product. The government could set requirements for high risk issues and manufacturers themselves could help preserve the market for their own future. There was a need for regulation in certain product categories. These regulations had to be based on a full risk assessment, which would provide the consumer and the government with confidence and fair commerce.

¹³ Mr. Wayne Morris, Vice President, Division Services, Association of Home Appliance Manufacturers, United States. The Association of Home Appliance Manufacturers represented 200 companies scattered throughout the world doing business in the United States.

49. In the area of confidence building, testing, inspection, SDoC, certification and registration could play a part. The key was to find what level of confidence was necessary to satisfy the risk. In some cases, SDoC could meet that need, in others it might require product certification or even government regulation; this depended on the type of activity and its risk. In deciding upon conformity assessment, the government had to consider the actual level of risk. An overuse of conformity assessment could restrict trade, slow down the introduction of products, create barriers to small emerging companies, reduce the technological advancements of many products, and reduce harmonization regionally or internationally. One of the questions facing new markets and new goods was whether they should use voluntary or mandatory conformity assessment. This decision should be based on the level of risk and consider the public, consider confidence levels of the market forces, the time to move the product from one market to another and the overall cost/value ratio.

50. There were many examples of mandatory programs of conformity assessment: the CCC mark in China, nutritional labelling in the United States, energy efficiency labels in North America or Europe. Cooperation of industry and certifiers, the market value of the products, their relatively lower risk, the value of the manufacturer's name on the product, the checks and balances that were already present on the market could meet the need without mandatory programs. These could operate within or outside third party systems and still be voluntary in nature. If a product was low risk and subject to rapid market turnaround, a program of voluntary conformity assessment could work very effectively.

51. Voluntary programs had the market place as their basis, as the key driver. The name of the company was on the product and the true incentive was to have a market that continued year after year. Developing markets in nations should consider each product sector separately: sectors of textiles or information technology, appliances, earth moving equipment or building materials had to be thought of as independent sectors. Emerging nations and developing countries needed to consider recognising existing conformity assessment systems, recognising international standards and not just international standards that had the word "international" in their title.

52. Developing countries should notify WTO Members of significant changes in their systems of conformity assessment and seek comments. Lastly, any changes in conformity assessment should be notified with significant time for manufacturers and industries to make the necessary modifications. Manufacturers needed a minimum of 18 to 24 months in order to make changes in design, manufacture and distribution. Conformity assessment could be very effective in meeting the market needs but it had to be based on risks, needs and effects. For many sectors, voluntary systems could meet these needs. At the end of the day, the consumer would see the name of the brand on the product, not the certifying mark at the back of the product.

53. During the *Questions and Answers Session*, it was noted that the responsibility to educate consumers on voluntary conformity assessment was on manufacturers and their associations but also on the government, the media, the legal system to help punish severe offenders. The retail sector also had a great responsibility and this was the case in the United States. For instance, while there was a voluntary system in the electrical sector for conformity assessment of appliances, it was largely the retail sector which enforced it.

Canada's Experience in Forest Certification¹⁴

54. Canada had about 10 per cent of the world's forest representing 402 million hectares and 93 per cent of the forest land was publicly owned. There was a high level of private forest land in the eastern part of Canada. The forest management was the responsibility of the ten provinces and three

¹⁴ Mr. Guillaume Gignac, QMI, Senior Manager, Product Management, Canada. QMI was the leading certification body in North America, part of the Canadian Standard Association group, and accredited to a number of accreditation bodies, including by the Standard Council of Canada (SCC), the ANSI-ASQ National Accreditation Board (ANAB) in the United States, the Mexican Accreditation entity, and the National Standard Institute in Chile. QMI had extensive experience in forest certification: it certified over 54 million hectares of forest through two standards.

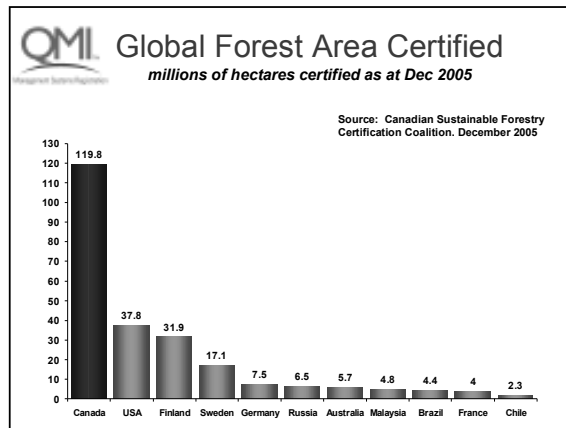
territories. Canada exported 80 per cent of its forest products. Three forest certification schemes were available in Canada: (i) the CSA Z809 Sustainable Forest Management (SFM) standard, which was the Canadian national standard and was accredited by the SCC; (ii) the Forest Stewardship Council (FSC); and (iii) the Sustainable Forestry Initiative standard (SFIS), which was accredited by the ANSI-ASQ National Accreditation Board (U.S.).

55. CSA Z809-SFM, which was only used in Canada, had three broad sections: (i) public participation, (ii) system requirements, and (iii) performance requirements. The public participation process involved putting in place a group of stakeholders to determine objectives and targets and a timeframe to meet these objectives. These stakeholders were representatives from industry, academia, conservation and environmental groups, first nations (i.e. the aboriginals) and a number of other stakeholders. The Standard Council of Canada was the overseeing body which accredited the standards development organizations, the certification bodies and also the products certification bodies. The Canadian Standards Association was the organization that had the responsibility to develop national standards. The Standard Council Sustainable Forest Management accreditation program and currently the Standard Council of Canada had accredited four certification bodies to be able to conduct CSA Z809-SFM.

56. The Forest Stewardship Council (FSC) was an international system covering forest management practices and the tracking and labelling of certified products and paper products with recycle content. It had developed a set of 10 principles and 57 criteria for forest management this addressed legal aspects, indigenous rights, labour rights, multiple benefits and environmental impacts surrounding forest management. However, countries had to develop their own national, or even in some aspects regional, standards using these global principles and criteria.

57. The Sustainable Forestry Initiative Standard (SFIS), which was originally developed in the United States, was based on 9 principles that addressed economic environment, cultural, and legal issues, in addition to a commitment to continuously improve sustainable forest management. That standard was both applicable in Canada and the United States. The standard contained 13 objectives covering sustainable forest management, procurement of wood and fibre, public reporting, continuous improvement and mitigating illegal logging.

58. There was a fourth organization which originally started in Europe: the Programme for the Endorsement of Forest Certification (PEFC). It was a membership based global umbrella organisation that provided mutual recognition framework for national forest certification systems developed in the multi-stakeholder process. Canada's Sustainable Forest Management Program, including the CSA Z809 – SFM and SFIS, had been endorsed by PEFC. As of December 2005, Canada had about 120 million hectares of forest land that were certified to one of the three standards. This slide showed where Canada was in relation to forest certification worldwide.



59. There were three driving forces which encouraged forest companies in Canada to go towards forest certification: (i) the market place, (ii) the industry itself, (iii) and the governments. In the market place, there was a number of business and government buyers particularly in Europe and North America that had been significant drivers for demand of certified wood and paper; as a consequence, Canada being an exporting nation was tremendously affected by that. Some companies also committed to have certified forest products when buying wood for their product lines. Other companies explicitly had certified products according to their own established policies. They had

their own environmental policies and requested that their suppliers provide them with products coming from well managed forests. The second driver was the forest industry itself. The Forest Product Association of Canada (FPAC) represented the large majority of forest companies in Canada which were responsible for 75 per cent of the working forest in Canada. In 2002, FPAC committed its members to be third party certified to one of the three main forest certification schemes (i.e. CSA, SFI and FSC) by the end of 2006. It was the only trade association in the world with this type of commitment. Forest certification increased 7 times in 4 years since then. The last driving force was the governments. In Canada, some provincial governments had enacted in laws (or were considering) on forest certification of public land.

60. The forest industry faced a number of challenges in getting certified. When forest certification first emerged as a tool, some businesses thought that demand for certified products would be driven by the willingness of the consumer to pay a price premium for forest products labelled as certified. However, since it did not happen, companies wondered about the utility of certification. Some companies tried to implement forestry standards without a management system in place and found out early that it did not really work. Then, these companies realised that instituting a strong environmental management system standard, like ISO 14001, would provide the proper foundation to move on to some of the forestry-specific certification standards. In fact, there was 169 million hectares that were certified in Canada under ISO 14001. Other challenges included: some environmental NGOs and purchasers lobbied for one forestry standard to be recognised in the market place only; and the lack of information and education of decision makers on the differences and benefits of the different schemes.

61. To conclude, Canada had learnt a number of lessons with this process. First lesson, it was important to be third party certified by an accredited certification body as it provided credibility and market access. Second, it was important to have four certification schemes in order to take into account national and regional differences. Third, it was essential that decision makers be properly informed on the different forest certification schemes. Finally, it was important to ensure that not only one forest certification scheme be imposed by stakeholders.

62. During the *Questions and Answers Session*, it was further stressed that globally the forest industry was well committed to forest certification. For instance, in Chile, in Brazil, in Europe, all forest industry companies were certified to one scheme or another. Replying to a question on the education of consumers on voluntary conformity assessment, it was noted that it was a challenge for the industry to educate consumers on the differences between schemes. For instance, the Forest Products Association of Canada had an office in Europe to inform consumers on forest certification.

SESSION II – FACILITATING THE ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS¹⁵

63. The intention of this session was to focus on the implementation of the obligations contained in Article 6 of the TBT Agreement on the "Recognition of Conformity Assessment by Central Government Bodies" and discuss the effectiveness of the different mechanisms to facilitate the acceptance of conformity assessment results.

APPROACHES TO FACILITATE THE ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS

64. Speakers were asked to address the advantages of, and possible difficulties with, various approaches to facilitate the acceptance of conformity assessment results and in particular the use of accreditation.

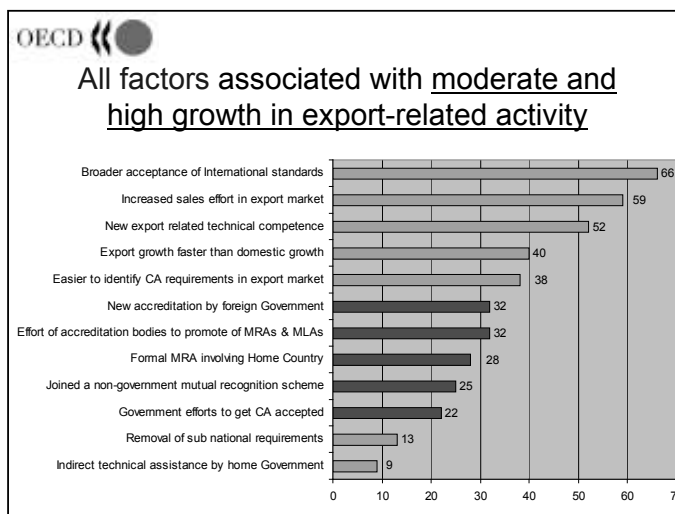
¹⁵ This session was moderated by Mr. Juan Antonio Dorantes (Mexico).

Trends in the Mechanisms to Facilitate the Acceptance of Conformity Assessment Results¹⁶

65. The OECD carried out a survey of CABs and exporters in 2004 and 2005. The purpose was to obtain evidence from key players in the field on perceptions of conformity assessment barriers to trade in manufactured goods, what they were, where and how important. The survey identified trends in the practices of conformity assessment procedures including concerning mechanisms to facilitate the acceptance of conformity assessment results. Several mechanisms were covered by the survey and the following general conclusions could be drawn: (i) for government-to-government mutual recognition agreements (MRAs), CABs reported benefits from MRAs, while exporters remained concerned; (ii) for voluntary arrangements of recognition between domestic and foreign bodies, the survey noted that there was an important activity; (iii) on SDoC, the survey found that there was some activity but so far only limited signs that it was actually replacing third party certification; and (iv) on accreditation and designation by governments, the survey found that multiple accreditation was still a practice and that government designation was often used.

66. 430 CABs responded to the survey: 272 bodies from Europe, covering 21 countries; 60 from America, covering 10 countries in that region; 78 from the South Pacific region including Australia and New Zealand; and 40 from the Middle East and North Africa. To reply to the survey, these bodies had to be involved in trade and certify traded goods. There were less responses from exporters: 110 responses came from exporting companies of all sizes, most were small and medium sized enterprises. Some common characteristics included that: they sold products mostly identical at home and abroad; they operated in sectors such as machinery, scientific instruments, medical devices and a lot in the area of electrical equipment, including electronics and IT products; and their export markets were typically North America, China and individual members of the European Communities.

67. In the CABs survey, as part of the factors associated with moderate and high growth in CABs' export-related activity, an important number of CABs identified new accreditation by foreign governments as being a factor which helped them in their export trade activity. The majority of these CABs were based in Europe. Factors identified as being important for the good performance in the export activity included: the efforts of accreditation bodies to promote their mutual recognition agreements and arrangements; the existence of formal MRAs involving the home country of the CAB; efforts by the government to push for conformity assessment to be accepted in foreign markets; efforts of CABs to join non-governmental mutual recognition schemes; and a broader acceptance of international standards for conformity assessment and product regulation.



68. Concerning accreditation, 23 per cent of CABs which were accredited for product testing and certification reported multiple accreditation. Some CABs reported that they had to refuse potential export-related CA orders and many of them mentioned as a reason the lack of accreditation in destination markets. Concerning government designation, there was a positive correlation between conformity assessment performance and being designated by a foreign government. Therefore, the designation by a foreign government helped CAB activities and international trade.

¹⁶ Ms. Barbara Fliess, Principal Administrator, Trade Directorate, OECD.

69. Turning to the exporter survey, one question was "In your effort to export, offer a general judgement of the seriousness of problems caused by the need to apply conformity assessment procedures for exports different from or additional to your practice in your home market". For 50 per cent of the respondents, these problems were critical or major and for 27 per cent it was not a problem. Critical or major problems included that conformity assessment procedures increased costs of exporting and delayed the marketing of new products. On the issue of duplication and non-recognition, exporters expressed some concerns about the refusal of governments and export markets to accept home country test reports or certificates. Almost half of the exporters expressed a concern about the imposition by governments in export markets of different tests.

70. In the *Questions and Answers Session*, it was further noted that there seemed to be a real discrepancy between the findings of the CAB and the exporter surveys with respect to the role that information played. It appeared that CABs had information at hand while exporters did not or at least, did not get it as easily or as timely. It was very important for exporters to have information on the requirements in export markets in a timely, accurate and comprehensive fashion.

Accreditation as an Approach to Facilitate the Acceptance of Conformity Assessment Results and the Benchmarking Procedure¹⁷

71. The Joint Accreditation System of Australia-New Zealand (JAS-ANZ) was set up to support a trans-Tasman TBT arrangement for management systems, products, personnel and inspection bodies. Accreditation underpinned international trade through providing confidence in the integrity of conformity assessment activities through the accreditation of CABs against international norms. JAS-ANZ had developed a number of programs with regulators and industry groups to assist in the establishment of conformity assessment schemes which facilitated trade. In cooperation with industry groups, JAS-ANZ developed a number of programs, generally codes of conducts, sustainability and demonstration to regulators and consumers that products were in compliance.

72. JAS-ANZ now provided 18 different programmes for the regulatory sector and 14 programmes for the industry. This was in addition to the 15 programmes based on certification and inspection to national and international standards. JAS-ANZ developed programmes for regulators, such as the Aust Quarantine and Inspection Service (AQIS) and the New Zealand Food Safety Authority (NZFSA) to underpin the issuance of export certification. Accredited certification programmes had also been developed to facilitate government funding of service providers in the area of medical general practice and disability employment services. Industry used accredited certification to ensure that suppliers were meeting basic customer standards and regulatory requirements, to provide evidence of due diligence, and reduce costs in maintaining expensive supplier monitoring activities.

73. JAS-ANZ participated in the EUREPGAP benchmarking programme. This programme used the international infrastructure to facilitate recognition of schemes that provided an equivalent outcome to the EUREPGAP schemes. The objective was to reduce the need for farmers to meet the requirements of multiple standards, thereby reducing audit impost for food producers. JAS-ANZ was the first organization to start this kind of programme and now there was one or two other accreditation bodies who performed that function. The benchmarking process required the comparison of an applicant scheme standard and scheme rules against those of the appropriate EUREPGAP scheme.

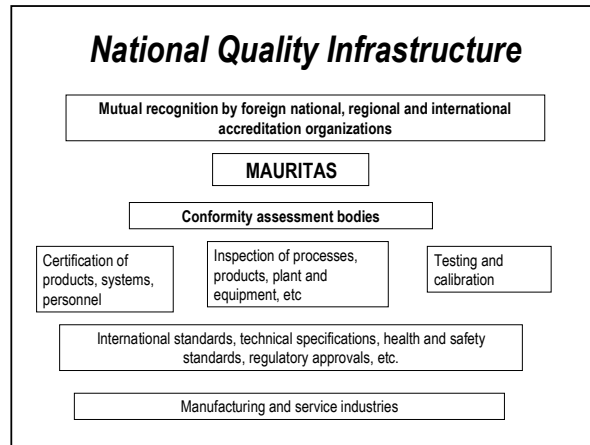
74. To conclude, over the last eight years, the awareness of accreditation and conformity assessment in Australia and New Zealand had grown. JAS-ANZ had about 48 different programmes, accredited 57 certification bodies in 12 economies, mainly in the Asia Pacific region but also in the United States and in the United Kingdom.

¹⁷ Mr. Tony Craven, Chief Executive, Joint Accreditation System of Australia-New Zealand.

75. During the *Question and Answers Session*, it was indicated that three staff members of JAS-ANZ provided technical assistance. For instance, Singapore, Malaysia and Thailand received such assistance. There was also a project for Cambodia, Laos, Vietnam and Myanmar to provide them with some advice on setting up an accreditation infrastructure and another one with the Gulf states to provide technical services to help them set up an accreditation system for both laboratories and management systems.

The Experience of Mauritius in the Use of Accreditation¹⁸

76. In 1994-1999, the World Bank carried out a technical assistance project in Mauritius and recommended the establishment of a national accreditation body. Following that recommendation, a National Laboratory Accreditation Council was set up in 1997 and the Mauritius Accreditation Service Act was adopted in December 1998 by the National Assembly. The main functions of the Mauritius Accreditation Service (MAURITAS) were: to provide a national unified service for the accreditation of conformity assessment bodies, i.e laboratory certification bodies and inspection bodies for the whole country and also for the region; and to establish mutual recognition arrangements with other national, regional and international accreditation bodies. The first step to establish an accreditation body was to set up a national quality infrastructure. To support the industry, Mauritius needed testing and calibration laboratories, inspection bodies and certification bodies for certification of products, personnel and management systems. MAURITAS consisted of a director, one person in charge of the laboratory's accreditation section and another person of the certification bodies section.



77. Accreditation was important for trade facilitation but also for the protection of health, safety and the environment. The first pillar of the strategy used in Mauritius to implement accreditation was to create awareness of training laboratories, all technical assessors, and the staff of the accreditation body. The second pillar of Mauritius strategy on accreditation was based on twin agreements with two foreign recognised accreditation bodies which could help with the technical expertise and the first assessments. MAURITAS signed these twin agreements with the South African National Accreditation System (SANAS) and the Norwegian accreditation body. MAURITAS had already started assessing conformity assessment bodies with the help of experts from these accreditation bodies.

78. MAURITAS was also sponsoring and building capacity at the local level. There were already 13 laboratories who had applied for accreditation, four of them had undergone a document review and pre-assessment and would probably be undergoing the real assessment in a few months and be awarded the certification of accreditation. In Mauritius, the level of awareness had raised on accreditation and laboratories were seeing the importance of having accreditation in the country.

79. Two examples of the use of accreditation could be mentioned. First, following the death of two children who swallowed gadgets sold together with snacks and other food stuff, it was decided that all food stuff accompanied by gadgets and toys had to have an accredited test certificate. The second example was in relation to a number of second hand imported cars. Following the import of

¹⁸ Mr. Robin Neeren Gopee, Acting Director, Mauritius Accreditation Service (Mauritas).

stolen cars, it was decided to impose an accredited pre-inspection shipment certificate to accompany all second hand imported vehicles.

80. Following these incidents, the government had taken the decision to have a reference to accredited conformity assessment bodies in the text of technical regulations. The government was also considering the promulgation of technical regulations on a number of items to ensure consumer safety, for instance for electrical appliances. Developing countries needed also to adopt good regulatory practice while introducing technical regulations. Once a country had a national quality infrastructure, standards bodies, a metrology institution, the government had to make sure it had a good framework for developing technical regulations that would take into account impact assessments and issues of accreditation of CABs.

81. International recognition was the ultimate aim of MAURITAS as a national accreditation body. MAURITAS wanted to obtain the signatory status, with both ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum). It was therefore necessary to use international standards, promote proficiency testing among laboratories, and, very important for developing countries, have traceability of measurements, i.e. metrology facilities.

82. During the *Questions and Answers Session*, it was further noted that the accreditation activities of MAURITAS had only started in mid-2005. MAURITAS had established a strategic partnership with SANAS because the accreditation provided in Mauritius would then be recognised by IAF and ILAC as the assessment would be done jointly by MAURITAS and SANAS. As to the difficulties which the laboratories had to cope with, those were mainly financial and human resource problems, as this was a very technical and specialised sector.

Approaches to Facilitate the Recognition of Results: The Experience of the European Co-operation for Accreditation¹⁹

83. The development of the European accreditation infrastructure started with the establishment of the Western European Calibration Cooperation in 1976, and the Western European Laboratory Accreditation Cooperation in 1987, and progressed with the merging of these two organizations into the Laboratory Accreditation (EAL) in 1994. Meanwhile, in 1991, the Accreditation of Certification and Inspection Bodies (EAC) was also established. The European Cooperation for Accreditation (EA) was formed through the merging of EAL and EAC and became a legal entity, in form of a non-for-profit association registered in the Netherlands in June 2000.

84. EA was the association of the national European accreditation bodies providing accreditation of all conformity assessment activities (calibration, testing, inspection, management system certification, product certification, personnel certification, EMAS declarations). It operated under a Memorandum of Understanding (MoU) with the European Commission and the European Free Trade Association (EFTA) and its main purposes were: to develop accreditation criteria and guidelines which would ensure effective and harmonized performance of national accreditation bodies in Europe; and to contribute to the pursuance of similar achievements worldwide, through its active membership in ILAC and IAF. This mission was pursued by a number of activities and, chiefly, by the management of the EA Multilateral Arrangement (EA MLA).

85. Currently, EA gathered 32 full members – among which 24 EA MLA signatories – and 2 associate members, representing 34 European countries; 16 contracts of cooperation had been signed with accreditation bodies representing 14 countries outside Europe. The EA organizational structure consisted of an advisory board, a general assembly, an executive committee, a number of technical committees (among which the EA MAC Committee ruling the EA MLA) and a permanent secretariat with three full time staff. At the level of single national economies, accreditation created

¹⁹ Mr. Lorenzo Thione, Chairman, European Co-operation for Accreditation.

confidence in the accredited conformity assessment services and the corresponding results. At the European level, the EA MLA confirmed and enhanced such confidence and eliminated (or limited) multiple assessments. To ensure the effectiveness of the EA MLA, each signatory was subject to rigorous routine evaluations by peer assessment teams, in order to verify continuous conformity to the provisions of international standards and guides, as well as to ad-hoc EA application documents.

86. The development of EA was linked to expected developments, in respect of conformity assessment, at the European level. The European Commission was going to present a proposal for a new horizontal legislative approach to technical harmonization in Europe with the aim of providing a legal basis for a number of activities, such as accreditation and market surveillance. This new legislation should represent the basis for the juridical recognition of accreditation in Europe, by legally formalizing its function of service of general public interest.

87. It was expected that EA would be formally recognized by European institutions through agreements with the European Commission and EFTA. In order to properly perform such tasks, EA was called to: (i) strengthen its corporate infrastructure and its administrative and technical organization, including a more effective and wider involvement of European stakeholders; (ii) improve its peer evaluation system; (iii) invigorate its contribution to the consistent and coherent interpretation and application of the standards for accreditation, by providing optimized supplementary guidance; (iv) strengthen the cooperation with European and international standardization bodies; (v) reinforce its cultural role, both in terms of contribution to the continuous improvement of the competence of its members and of support to the building up of conformity assessment infrastructures in developing European and non-European countries; (vi) strengthen its capability of supplying technical expertise to the European Commission; and (vii) reinforce its capacity of influencing the activities of international organizations like IAF and ILAC in order to promote the diffusion of the "European way of accreditation".

88. European accreditation was looking towards a future of growing success and greater achievements, provided it would be capable to properly manage the outstanding challenges. One of the major threats currently at EA was to safeguard the value and credibility of management certification but in particular of ISO 9000 accredited certification. There was worldwide about one million of ISO 9000 accredited certification; about half of this certification was in Europe. The goal was that this certification be a real indicator of the capability of the certified organisation to consistently provide products and services able to fulfil the applicable requirement. EA was going to enhance the activities of its accreditation system, to introduce new criteria in order to safeguard the value and the credibility of this management system certification. To achieve this, EA needed feedback from the market, cooperation with the industry, users and consumers and stakeholders.

89. During the *Questions and Answers Session*, it was noted that the issue of multiple accreditation was not so critical in Europe. Accredited conformity assessment attestation in Europe could freely circulate without the need to have different accreditation. EA was doing its best at the European level to harmonize the operation of the different accreditation bodies so as to ensure full confidence in the accredited attestation of conformity. Following a question on whether the activities in Europe should be accredited by EA or if being accredited by European accreditation bodies was enough, it was noted that the general trend was that conformity assessment attestations in Europe were being issued by CABs accredited by EA members or by ILAC or IAF members. EA was trying to extend its multilateral agreement in order to have all European accreditation bodies inside the multilateral agreement. The EA was also establishing a contract of cooperation with a number of non-European accreditation bodies. Following a question on the assessment of ISO 9001 certified companies, it was clarified that EA was looking not only at the operation of the certification body, its organisation, its procedure but also at the real conditions of the management system being certified. This was important as if EA did not enhance its control on the ISO 9000 certification, there would be a serious risk of disqualifying the value and credibility of such certification on the world market.

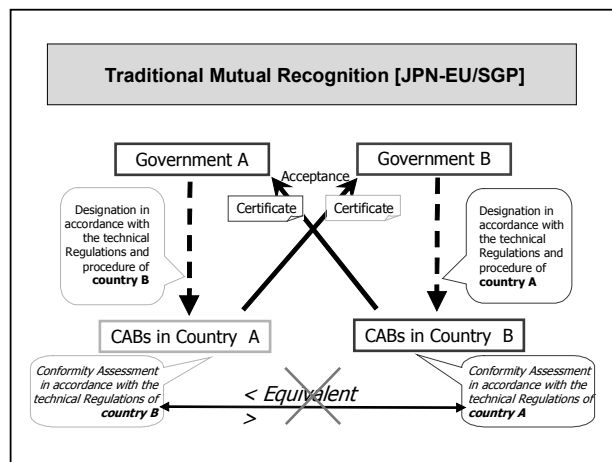
MUTUAL ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS

90. Speakers were asked to address the merits and possible difficulties in negotiating government-to-government mutual recognition *agreements*, and to discuss ways to promote acceptance by regulatory authorities of results by conformity assessment bodies participating in voluntary *arrangements*.

Experiences in Formal Mutual Recognition Agreements: Sectors Covered, Possible Difficulties Faced in the Negotiations and Key Elements for a Successful Conclusion²⁰

91. To recall, Article 6.1 stipulated that Members shall ensure that results of conformity assessment procedures in other Members were accepted even when those procedures differed from their own on the condition that they were satisfied that those procedures offered an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures. From the viewpoint of MRA negotiators and regulatory authorities, this article was very restrictive. Article 6.3 was proposing concrete actions, i.e. to enter into negotiations for the conclusion of a MRA but with a very restrictive precondition, i.e. that such agreements fulfil the criteria of Article 6.1 and give mutual satisfaction regarding their potential for facilitating trade. Based on Article 6.3, Japan had concluded MRAs with the European Union and with Singapore.

92. This graph showed the MRA mechanism. In the case of the MRA with the European Communities, the Japanese government designated its own domestic CABs located in the territory of Japan. In such a process, the government of Japan had to completely understand and manage the rules, regulations and procedures of the European Communities. However, in this case, the government of Japan had not visited directly European CABs since it only had to communicate with Japanese CABs. Therefore, there was less cost involved and Japanese CABs were designated by the Japanese government in accordance with the EU Directives. These Japanese CABs conducted the conformity assessment activities in accordance with European rules and the Japanese industries were only in contact with Japanese CABs.



93. Four areas were covered by this MRA: electrical products, telecommunication products, GLP for chemicals, and GMP for medicinal products. In the field of electrical products, Japanese designated CAB issued less than 40 certifications. In the field of telecom equipments, no CABs were designated in Japan. On the European Communities side, in the field of electrical products, no CABs were designated by European authorities on behalf of Japan. In the field of telecom equipments, two CABs were designated and about 600 certifications issued in the last 3-4 years. To summarize, in the field of telecom equipments, the MRA had contributed to the export from the European Communities but no contribution to the export from Japan. On the other hand, in the electrical products, this MRA mechanism had not contributed to exports for both sides.

94. Regarding the MRA with Singapore, two areas were covered: electrical products, and telecommunications terminal equipment and radio equipment. However, for this MRA, there was no concrete results and no contribution to the trade between Japan and Singapore so far.

²⁰ Mr. Shinji Fujino, Director, International Affairs Office of Technical Regulations, Standards and Conformity Assessment Policy Unit, Ministry of Economy, Trade and Industry, Japan.

95. Another trade promotion mechanism was referred to in Article 6.4, which stipulated that Members were encouraged to permit participation of CABs located in the territories of other Members in their conformity assessment procedures and under conditions no less favourable than those accorded to bodies located within their territories. This basically encouraged Members to treat CABs in other Members as equally as possible to domestic CABs. In the field of electrical products, under the Electrical Appliance and Material Safety Law, a Japanese designating authority could also designate foreign CABs as equally as Japanese CABs. From the viewpoint of trade facilitating functions, this contributed to promote exports from foreign countries to Japan. If another country also conducted such cross-border designations, it would be a kind of mutual cross-border designation mechanism. The main difference with the traditional mutual recognition mechanism was who designated the CABs in each country.

96. For the industry, there were no differences between these two types of mechanisms because companies only had to directly contact its own domestic CABs. For the government, traditional MRAs were more costly, in particular their negotiation. Implementation costs depended on who designated CABs, domestic authority or trade partner authorities. There were two types of mechanisms available between Japan and the European Communities: the traditional MRA and direct designation under their cross-border designations. From the viewpoint of the European Communities, under the traditional mutual recognition, there were no concrete results, there were no CABs under this MRA. On the other hand, under the cross-border designations, there were two CABs, which were designated by Japanese authorities directly and about 120-140 certifications had already been issued. The conclusion was that European CABs preferred cross-border designations even though they were well aware that there existed a traditional MRA between Japan and the European Communities. Such a cross-border designation worked well. However, this was just an example in the field of electrical products and it was not sure that the comparison would have the same result in other field.

97. To conclude, cross-border designation worked well for electrical products, compared to traditional MRAs,; also private network mechanisms worked better, including commercial networks and mutual recognition mechanism like IECEE-CB scheme. Therefore, from the point of view of policy planners, before negotiating MRAs, it would be better to promote the awareness of private mechanism networks. Even though, it was needed to negotiate for some mechanisms, the possibility of cross-border designation mechanism would be a promising, concrete and practical choice. Japan was now negotiating with some Asian countries based on this cross-border designation mechanism.

Mutual Recognition Agreements and Regulatory Cooperation: Some EU Experiences²¹

98. MRA involved the recognition of results of compulsory certification required by a party where the certificates were issued by CABs in the territory of another party. Such an MRA did not itself imply harmonisation of technical regulations or standards. Currently, the European Communities had MRAs in place with Australia, Canada, Israel, Japan, New Zealand, Switzerland and two with the United States.

What MRAs are in place?

Country	Entry into force
Australia	1 January 1999
Canada	1 November 1998
Israel	1 May 2000
Japan	1 January 2002
New Zealand	1 January 1999
Switzerland	1 June 2002
United States	1 December 1998
United States (marine equipment)	1 July 2004

Note: PECAs or ACAAs with accession countries were withdrawn on their accession to the EU.

99. There were different types of MRAs. First, traditional MRAs were without alignment of rules or standards. Such traditional MRAs were in place with the United States, Canada, Australia, New Zealand and Japan, and part of the MRA with Switzerland was also based on that principle. Second, some agreements were based on the *acquis* of the European Community, pre-

²¹ Mr. Paul De Lusignan, DG Trade and Mr. Brian Jenkinson, DG Enterprise, European Communities.

accession, i.e. the set of European legislation. That was the case with protocols to European agreements (PECAs). Countries that were candidate for entry into the European Union had the right to negotiate agreements that brought their legislation in line with the European Community ahead of their accession in order to get free movement of goods. Third, based on the *acquis*, but without foreseeing accession, were the agreements on conformity assessment and acceptance of industrial products (ACAAs): they worked the same way but for countries in the European neighbourhood wishing to align their legislation and standardization with that of the European Union and gain access to the European market on the same terms as member States. Finally, there were agreements based on international rules or standards, for instance the agreement on marine equipment with the United States. This implied that the US coast guards were in effect recognized as one of EC notified bodies, so the European Communities had in effect adopted some of the Japanese approach of cross-border designation. Equally, European Union CABs could mark their products approved by the US coast guard. A traditional MRA enabled certification to the other party's rules by a local CAB rather than by a CAB located in the other party. An MRA based on common rules and standards eliminated duplicate testing and improved market access for both sides. PECAs and ACAAs recognised in addition progress towards adoption of European legislation.

100. Concerning the results of MRAs, the example of the MRA with Japan showed some substantial activity in the area of telecommunications certification. Also, in the area of marine equipment, the MRA had a lot of activity and a certain amount of certification from both sides. It was working well and the EFTA recently made a parallel MRA so as to improve trade in the marine equipment area. On the other hand, the EMC agreement with Canada was in a way a success as it would soon be obsolete because both sides were moving to SDoC. On electrical safety, there were no compulsory third party certification requirements so this was purely one-sided and the MRA had no effect on trade to Europe. To conclude on these experiences, PECAs and ACAAs were of interest for potential partner countries in the European neighbourhood. A positive consequence of MRAs was the development of a dialogue between MRA partners' regulatory authorities. Little or no trade had been observed under some MRA sectors. A last finding was that MRAs were ineffective if they did not cover *all* requirements for a product.

101. In relation to conformity assessment, the European Communities had a four-fold strategy: (i) support the TBT Agreement; (ii) bilateral agreements at government level; (iii) regulatory cooperation activities; and (iv) technical assistance. In an ideal world, the best way to eliminate trade barriers was harmonization. However, harmonization might be fairly difficult for several countries to achieve together.

102. Regulatory cooperation could be viewed as a part of good regulatory practice. It was a long term process but it contributed to avoiding unnecessary obstacles to trade. It could help to achieve better understanding between regulators, especially concerning the objectives and scope of a legislation. Typically regulatory cooperation was voluntary and informal. Regulators in different countries consulted each other, on a bilateral or multilateral basis, and this could result in more formal agreements. There were three elements of regulatory cooperation: (i) good governance, which was tied up to the concept of good regulatory practice; (ii) trade policy in order to reduce trade barriers; and (iii) competitiveness of industry by reducing, or if possible eliminating, duplicative requirements.

103. Some examples of bilateral cooperation included cooperation with the United States, China, Canada and Japan. With the United States, a trans-Atlantic economic policy was in place and produced some regulatory cooperation guidelines, which had been applied in a number of sectors. There was a regulatory policy dialogue with China on 12 different areas. There were working groups for example on conformity assessment, on standards and on several industrial sectors. With Canada, the regulatory cooperation was just starting. With Japan, a Standard and Conformity Assessment Working Party was meeting annually for about 10 years and it had been a very productive forum to exchange information and to learn from each other. Some examples of multilateral cooperation included: cooperation in the area of medical devices; UNECE was active in regulatory policy and in

the automobile sector; OECD on good laboratory practice for chemicals; the EuroMed cooperation; and the European/Asian meeting.

104. Regulatory cooperation actions were often productive as they could help to converge regulations and procedures. For instance, the telecommunication sector had deregulated over years both in the United States and in Europe. However, it was time consuming and not possible to have dialogues with all potential partners. Prioritisation was necessary as it might be a problem to apply this in a general sense in developing countries with limited resources.

105. In the *Questions and Answers Session*, it was further noted that EC's experience demonstrated that about five conditions needed to be considered for a traditional MRA to work: (i) the possibility of a substantial trade between parties; (ii) a general commitment to the use of the MRA by regulators concerned; (iii) a compulsory third party certification being a substantial obstacle to trade in the goods concerned; (iv) regulatory convergence needed to be possible; and (v) the MRA had to cover all the mandatory requirements for placing the product on the market in both parties. In the case where an MRA did not cover all requirements, there was an assessment to be made to see whether complying with additional requirements was too trade restrictive to justify an MRA on certain requirements only. It was also stressed that implementation issues were important because some sectors required a lot of confidence-building, particularly sectors that related to health, such as medical device, and pharmaceuticals. These were probably the type of sectors where it was most difficult to negotiate an MRA because it took a very long time for regulators on both sides to have the confidence to trust the second party in the MRA to designate conformity assessment bodies.

Sector-Specific Examples of Arrangements Between Conformity Assessment Bodies ("Peer Assessments")²²

106. The electronics and IT industry sector was one of the biggest users of conformity assessment. Concerning safety requirement for TV broadcasting receivers, there were 74 countries and regions stipulating regulatory requirements. All these countries and regions had transposed, or made reference to, the IEC safety standard for their conformity assessment. 32 countries/regions implemented mandatory certifications prior to product marketing (for instance CIS, Middle-East & Far-East Asia, etc). 42 countries/regions implemented SDoC (for instance Australia, New Zealand, the European Communities, Eastern Europe, etc.). Product design conformity to IEC standard was an essential tool for worldwide one-stop testing.

107. There were three essential elements in conformity assessment activities: assessment quality, cost effectiveness, and global acceptance. Various tools were used for conformity assessment: product standards; the TBT Agreement; the IECEE-CB scheme; conformity assessment standards; mutual recognition agreements and arrangements; laboratory accreditation; and SDoC.

108. Concerning Japan's contribution to the IECEE-CB scheme, 60 per cent of the total number of CB certificates issued worldwide were for electronics and IT products and 22 per cent of them were from Japan. Another tool was the use of laboratory accreditation. For product safety the MLA integration scheme was a much finer tool. On the other hand, in the EMC areas, the laboratory accreditation scheme was based on ISO/IEC 17025. The big advantage of promoting MLA was that it was a cost effective conformity assessment and it meant a shorter time to market with credible data and also a maximum use of resources for the assessment of new safety technology.

109. Some of the main findings from the conformity assessment experience in the company in relation to the TBT Agreement, included: (i) conformity assessment was a lengthy procedure but drastic regulatory reform was possible, like the Chinese CCC scheme; (ii) it was expected that Russia

²² Mr. Toshiyuki Kajiya, Senior manager, Engineering Administration Group, Corporate R&D Strategy Office, Matsushita Electric Industrial Co., Ltd, Panasonic, Japan.

became a Member of the WTO; (iii) reference to international standards/guides as a basis for CA procedures should be more binding. Findings on mutual recognition agreement and arrangements included: (i) Lengthy procedure and limited to selected countries appropriate for FTA/MRA; and (ii) in some cases, MRAs were limited to products domestically manufactured in both countries and did not cover the ones manufactured in third-countries.

110. Concerning the use of IECEE-CB scheme: (i) the scheme enabled one-step testing among National Certification Bodies (NCBs), but a full certification scheme including factory inspection was still not in full operation; (ii) EMC as a new tool box of CB Scheme was welcome, but countries implementing mandatory certification did not participate; (iii) the new NCBs and the CB test laboratories from developing countries were welcome but this should not hinder the sound operation of the scheme. On laboratory accreditation: (i) some accreditation bodies did not accept MTL due to reasons of neutrality and independency; (ii) specification of ISO/IEC 17025 was management system oriented and not appropriate for specific technology sectors such as EMC; (iii) accreditation forum such as ILAC should approach closely the national regulators to influence their legislation.

111. To conclude, possible improvements to achieve one standard, one test accepted everywhere included for regulators: the promotion of good regulatory practice with a minimum intervention of conformity assessment procedure prior to product marketing; the transposition of international schemes into national legislation; and the designation or accreditation of CABs under the national legislation to be based on technical competence only, not dependent on physical location. For standard developers, the following achievements could be made: speed up the standardization to catch up technology development; and standardization activities should be more appropriate for proper conformity assessment. Finally to CA providers, improvements could include: further promotion of homogeneous implementation among CABs; the establishment of equal partnership with CA users by offering value-added CA services as a means of supplementing SDoC.

IEC Experience in Arrangements Between Conformity Assessment Bodies Used by Regulators²³

112. The IEC was celebrating its 100th anniversary this year. There was one national committee per country. IEC national committees had a certain number of rules to follow but no organizational requirements. Therefore, there was a large variety of organizations in the national committees. IEC was both developing standards and providing conformity assessment services. However, IEC itself did not actually test any product but organized conformity assessment bodies worldwide in the area of electronics, electricity and related technologies, so that mutual recognition could occur.

113. IEC clearly encouraged everybody to adopt IEC standards because they were industry-driven and drafted by experts in the field. IEC standards were designed to be useful in all kinds of conformity assessment, including SDoC. The conformity assessment board was in charge of three conformity assessment schemes, each of which was a third party scheme. The three schemes were respectively in the area of electrical equipment, explosive atmospheres and quality assessment system for electronic components. The last one was almost entirely on a voluntary basis and had very little connection with regulations.

114. The acceptance of certification bodies and testing laboratories into IEC schemes was done by peer assessment. Certification bodies typically assessed each other. Neither IEC nor the schemes carried out testing or issued certificates. The testing was carried out by laboratories and certificates were issued by certification body members of the schemes. Openness was a basic principle in the IEC. Schemes were open to any manufacturer anywhere in the world: a country did not have to be in an IEC member country to enjoy the benefits of the schemes. IEC schemes were product-based, not system-based, although IECQ had a system component. That was almost exclusively product certifications that were mutually recognized: once issued in one country, recognized in all countries.

²³ Mr. Gabriel Barta, Secretary of the IEC Conformity Assessment Board and Head of Technical Coordination.

115. Industry used IEC schemes even though comparatively few regulators today rely directly on IEC schemes. IEC schemes gave them a lot of confidence in the quality of the products supplied to them by their suppliers. This was not IEC business to know whether regulators relied on its schemes or not. The IECEE-CB scheme was a big seller: 41 000 certificates were issued in 2005. There were many categories in which the CB scheme was active.

116. The process was as followed. A manufacturer made an electrical product and sent it for testing so it could be certified. A laboratory tested the product for conformity to IEC standards and issued a test certificate. If the manufacturer wished to sell the product in another country, it sent the certificate to a test lab in the second country. The second laboratory issued its certification mark without having to test the equipment because it recognized the testing and assessment that had already been done. The manufacturer was then able to affix the national mark of conformity of the second country to the product and export the product to that country. Therefore, it was the certificate that made the trip and not a person. This was obviously important to industry for cost reasons.

117. The IEC Scheme for Certification to Standards for Electrical Equipment for Explosive atmospheres (IECEx), was a much smaller scheme. IECEx was a Type 5 ("full") CA system because explosive atmospheres were very dangerous. It included systems, competence, and surveillance. There were already several regulators relying on IECEx test certificates as satisfying the regulations.

SESSION III – BUILDING A CONFORMITY ASSESSMENT INFRASTRUCTURE IN DEVELOPING COUNTRY MEMBERS

THE CONFORMITY ASSESSMENT INFRASTRUCTURE OF DEVELOPING COUNTRY MEMBERS

118. This session examined ways to put in place an effective conformity assessment infrastructure in developing country Members, taking into consideration the resources available to them and their technical and infrastructural concerns.

Nigeria's Example of a Conformity Assessment System in a Developing Country Member: Concerns and Challenges²⁴

119. The Standards Organization of Nigeria (SON) was in charge of inspection of products and factories. About 97 per cent of domestic consumption in Nigeria was imported. These products had to be tested in order to protect the safety of consumers, and the protection of the environment. SON concluded a partnership with UNIDO and established an infrastructure for testing, calibration and certification. It started with the certification of policy management systems and the training of personnel in ISO 9000 and ISO 14000, and then the establishment of testing laboratories.

120. For all products that were manufactured locally in Nigeria, conformity was expected with the Nigerian industry standard (NIS) or any other acceptable international standard. By so doing, SON facilitated international trade, prevented the sale of substandard products to the country, protected health and property, and prevented pollution of the environment. This had inspired consumers' confidence in purchased goods and created a level playing ground where products were competitive in the market and able to stand the dumping of substandard products especially from the eastern market. This had been one of the biggest challenges in Nigeria. The government was putting an emphasis on diversification to agricultural products rather than oil.

121. Facilities and means to check for compliance included: standards elaborated by a national standards body and used for evaluating products; and since there were no accredited laboratories, a process was put in place to establish a national accreditation system through technical assistance from UNIDO. There were similar programmes with other countries such as Uganda. Under the UNIDO

²⁴ Mr. John Ndanusa Akanya, Director-General, Standards Organization of Nigeria.

agreement on technical cooperation, a big laboratory was commissioned in April 2006, a textile and leather laboratory was established and an engineering lab in the eastern part of the country for testing materials and other technical products.

122. Imports of products from the eastern market had become an economic threat in recent times. A conformity assessment programme (SONCAP) was set up to use special agencies that had the competence to certify products offshore before they came in the country. In line with this, there was a mandatory conformity assessment program (MANCAP) for all the manufactured products. Although standards were not mandatory but voluntary, once implemented, they became de facto mandatory as it was necessary to ensure the conformity with those standards.

123. Metrology was very crucial to sustainable economic development. Therefore, with the collaboration of UNIDO, calibration laboratories for mass, length, volume and force were established in the country. Staff were currently undergoing training in different parts of the world in order to gain experience and come back to the country to run these laboratories. MANCAP was checking and ensuring that products manufactured in Nigeria met both domestic and international standards. Products that did not conform were not allowed to be shipped out of Nigeria and even to neighbouring West African countries.

124. In order to face the challenges of the establishment of the accreditation system, SON partnered with the South African Accreditation System (SANAS) to benefit from its experience. PTB in Germany also organized some training with the aim of establishing an accreditation system for the ECOWAS sub-region. It was very expensive to establish laboratories and there were no laboratories downstream that were competent enough to go for accreditation. However, things were changing and about 29 laboratories would be accredited for different types of tests.

125. The non-existence of standards for certain products had led to the adoption of all international standards so that once laboratories would be accredited, they would be acceptable internationally. The goal was to establish an ECOWAS region accreditation system which would be responsible for the accreditation of the whole West African sub-region.

126. During the *Questions and Answers Session*, it was further indicated that in case imported products did not meet the requirements of Nigerian standards or any comparable international standards, there was a process to return these products back to their destination. Nigeria was undergoing an MRA with Niger for products which were transhipped especially from eastern markets. With the MRA, it would be possible to identify Nigerian products and almost all the products would carry the NIS mark, which was already on most of the products that were manufactured in Nigeria. In order to gain experience, SON was working very closely with regional bodies like SANAS in South Africa, UNIDO and countries from the Pacific Ocean region.

Overview of the Conformity Assessment Procedures in India: Role of the BIS²⁵

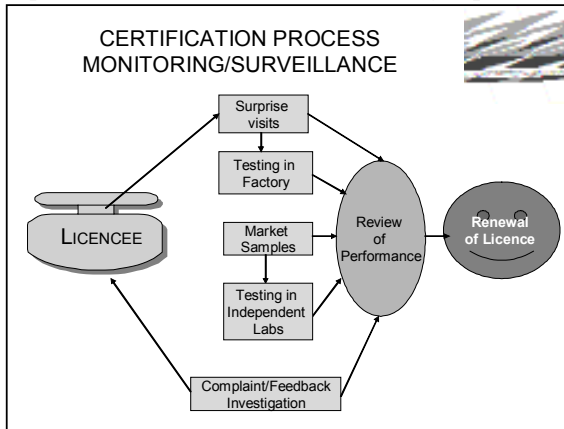
127. There was no discrimination between domestic and imported products, they were treated equally. An inspection body for exports ensured that exported products were of good quality. Concerning the conformity assessment infrastructure in India, the Bureau of Indian Standards (BIS) was a member of ISO/IEC. India had an independent accreditation system. The objectives of BIS included: the harmonious development of activities of standardization; marking and quality certification; providing new thrust to standardization and quality control; and developing the national strategy for according recognition to standards and integrating them with growth and development of industrial production and exports.

²⁵ Mr. Rakesh Verma, Additional Director General, Bureau of Indian Standards, India.

128. The main activities of BIS, apart from standard formulation, were the following: certification for products hallmarking of gold jewellery, quality management system, environmental management systems, occupational health and safety management systems, international activities training services and other services.

129. In the BIS certification schemes, there were at present about 20000 licences issued, out of which 18900 belonged to products, 860 to foreign products, 200 to hallmarking, 1400 to quality management system and the remaining ones to EMS. Certification activities were voluntary in nature, except 109 products which needed mandatory certification due to reasons of human health and safety, and were operated through 38 offices of BIS located throughout the country. There were around 19000 licences in operation, 2000 products and 8000 industrial units covered by it. For product certification, ISO type 5 scheme was followed which was basically modelled on ISO Guide 28 and conformed to ISO Guide 65. It was voluntary and almost 1200 products were covered. This system was satisfying not only for consumers but also for the industry.

130. In the certification process, a preliminary inspection assessed the in-house testing capability, then some samples were tested. Once the samples conformed to BIS requirements, the company was asked for acceptance of Scheme 4 testing and inspection and of course the marking fee. Only then, the licence was granted. In addition, there was also a continuous monitoring and surveillance system. The system included surprise visits and testing in the factory itself, just to ensure that the laboratory in the factory was functioning well. If a complaint was received from any consumer throughout the country, there was a real and in-depth checking of the complaint and a review of the performance before renewing the licence. A very good laboratory infrastructure was available in the country: eight captive laboratories which were under BIS; and 100 accredited laboratories recognized by BIS. Therefore, 108 laboratories in the country were carrying out tests for almost all categories of products.



131. Two BIS certification schemes existed for products manufactured overseas: one for foreign manufacturers and one for Indian importers. Any manufacturer had to apply to BIS, which would inspect the office, the factory and test or accept the testing. If products were fulfilling BIS requirements, the licence was granted. Therefore, the prime objective of this scheme was to increase good quality imports. This certification scheme for foreign manufacturers already had a lot of success. BIS had already given 60 licences to countries such as France, South Korea, Nepal, Switzerland, Thailand, Bhutan, China and products certified included packaged drinking water, cement, wood products, steel products, milk products, clinical thermometers and other products.

132. Critical issues in relation to conformity assessment included: the reduction of technical barriers to trade, acceptance of inspection and test reports, acceptance of certification of other countries, and acceptance of accreditation of other countries. Several steps were being taken with other countries for that matter. First, there was a continuous interaction with industrial units in India and outside, and an interaction with other standard bodies located outside India and especially in the south region. Second, before entering into a MRA, the first step to build interest and confidence in each other was to enter into a MoU. Then, BIS had developed a five-stage model designed on gradual confidence building amongst two or more MRA partners.

133. The five-stage model for MRAs was: (i) carry out surveillance inspections of samples for independent testing on request; (ii) authorize each other for carrying out pre-certification evaluation

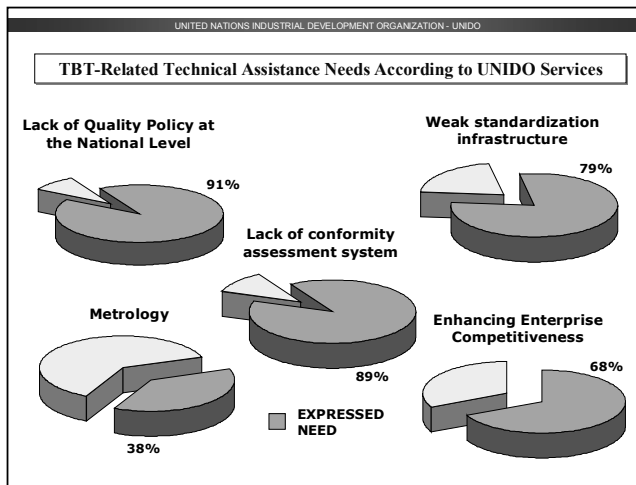
of applicant units, this was the stage of confidence building; (iii) then acceptance of results of samples tested in each other's accredited laboratories to importing country's standards (at this crucial stage, recognition of each others' standards was starting); (iv) the acceptance of inspection and test reports of each other (after harmonization of standards and practices) for taking certification decisions; and (v) granting the licence based on a similar licence granted by a MRA partner.

134. This model was presently under negotiation with Sri Lanka and would be proposed to other South countries for mutual acceptance of product certification results both in mandatory as well as voluntary sectors. India had already entered into MoUs and MRAs with Cuba, Israel, Mauritius, Turkey, Armenia, Bhutan, Nepal, Ukraine and Singapore and the process was already on with Germany, Sri Lanka, Pakistan, Afghanistan, Thailand and Bangladesh.

135. During the *Questions and Answers Session*, it was further explained that the 5-stage model for MRAs concerned government-to-government MRAs. The Phase 4 or 5 meant that India accepted tests and inspections of each other after harmonization of standards and practices. This model had now been in force for quite some time and there were many countries which had already entered into MoUs. Replying to a question on whether any MRAs had reached Phase 5 yet, the example of Sri Lanka was provided which was at Phase 4 for 85 products. In the context of the foreign manufacturers certification scheme, it was possible for manufacturers to request that BIS visit their factory to assess the management system, the laboratory system and examine whether that particular system had been duly accredited or not. Once BIS was satisfied, the licence would be granted and these manufacturers would be able to export its goods to India with the BIS mark.

Specific Needs and Technical Considerations Identified in Relation to the Conformity Assessment Infrastructure of Developing Country Members Through the Analysis of the Responses to the WTO Questionnaire²⁶

136. UNIDO analysed the WTO questionnaire on developing country Members' needs in the TBT field.²⁷ There were five main needs expressed: the lack of quality policy at the national level, the lack of conformity assessment system, a weak standardization infrastructure, the need to enhance enterprise competitiveness, and metrology. It came out from this survey that the private sector needed to know the TBT and SPS Agreements and their implications. Therefore, UNIDO was working for business association, data association to spread that knowledge. UNIDO tried to focus on those sectors that had a potential for export. UNIDO carried out a number of enterprise level surveys and tried to understand what were the key problems enterprises faced in terms of infrastructure and other related problems. Clearly, the most common problems related to customs, conformity, their productivity and their ability to really produce goods that could be exported.



Another important element was that for enterprises, producers and exporters, conformity assessment costs were not easy to understand and usually conformity assessment related costs were treated as overheads. The costs of complying with differing technical regulations in Europe, USA and Japan were estimated to add up to 5-10 per cent to product cost.

²⁶ Mr. Gerardo Pataconi, Industrial Development Officer, UNIDO.

²⁷ The questionnaire is contained in G/TBT/W/178; responses are compiled and summarised in G/TBT/W/186 and Add.1. An analysis by the WTO Secretariat is contained in G/TBT/W/193.

137. One survey carried out in Lebanon with 100 food manufacturers showed that the top problems were price competition, test certificates, and accreditation. In fact, many of the respondents said they lost an opportunity in the market because tests and certificates were not recognized. To conclude, it was clear that there was an important need for technical assistance and capacity-building activities and that harmonized solutions were required. It was important to prioritize the needs and that answers responded to actual needs.

138. During the *Questions and Answers Session*, it was further noted, concerning the lack of national quality policy, no model probably existed. A number of countries needed to harmonize activities related to quality. That did not mean that it was necessarily a regulatory practice but rather an overall objective to move the country towards a higher quality. For example, UNIDO had been working with Mozambique recently on a national policy. Different actors dealing with quality related issues were brought together in relation to certification, inspection, and enterprise work.

Accreditation: Role of ILAC and IAF²⁸

139. ILAC and IAF were two international sister organizations: ILAC in the area of laboratories, IAF for certifying bodies. The main tasks of ILAC and IAF included: (i) harmonize accreditation practices and methods between members of the two bodies; (ii) set up mutual recognition agreements based on peer evaluation; (iii) promote accreditation as a tool for facilitating trade, as accreditation was not very well known, even in developed countries; and (iv) help developing countries to establish their own accreditation system.

140. The harmonization of accreditation practices was a vast area. For instance, for the ISO/IEC 17011 standard on general requirements for accreditation bodies, ILAC and IEC were working together. Standards of the series ISO/IEC 17011 were the very basis of the work of ILAC and IAF but it was necessary to train assessors, i.e. the peer evaluators, and some training courses were organized for the evaluators. There was a joint committee of ISO, ILAC and IAF to enable good mutual understanding among accreditors on the way to apply standards.

141. The principle of mutual recognition agreements was that country A recognized country B's certificates as equivalent. The point there was that a test or a certificate done in country A should be recognized in country B as if it had been done under country B's system. The advantage of mutual recognition agreements among different CABs was that it made them more standard, more universal to cover conformity assessment areas, not just on food or electrical appliances. The core job of ILAC and IAF was to reach mutual recognition agreements. ILAC had 52 signatories and IAF, 35. These two organizations worked together for the management of their MLAs because many members belonging to ILAC also belonged to IAF so that there was one and the same peer evaluation for both.

142. On the third task of promoting accreditation as a tool to facilitate trade, a new joint working group had been set up recently between ISO, ILAC and IAF. It met twice a year and addressed the problem of laboratories' understanding of the objectives and functions of accreditation based on ISO/IEC 17025 (General requirements for competence of testing and calibration laboratories) and certification of laboratories based on ISO 9001. The goal was to avoid the accreditors being the certifiers. ILAC, IAF, ISO, UNIDO and IEC cooperated together, and ILAC also cooperated with the International Bureau of Weights and Measures (BIPM) and the International Organization of Legal Metrology (OIML).

143. Developing countries truly needed to have access to a recognized accreditation system, either by setting it up themselves in their country or by using the one of a neighbouring country or a regional one. Today, it was essential to be able to get tests and certificates recognized through accreditation.

²⁸ Mr. Daniel Pierre, ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum), ILAC Chair.

To set up an accreditation system, developing countries needed to have competent and trained evaluators. At the basis of such a system, it was necessary: to have basic metrology so as to ensure the traceability to a basic measurement unit; and to have access to reference materials to be able to calibrate the machines. Another problem was the access to proficiency testing schemes, because in developing countries there was no organizer of these schemes and they had to call on organizers from far away with the problems this implied for trade. Together with UNIDO, IAF and ILAC organized pre-peer evaluation so that organizations be ready for the real evaluation. IAF and ILAC also organized training of assessors, produced publications, translations, and organized seminars.

144. To conclude, there was a lot still to be done as this was a long-term activity and in the short-term, the focus would be on pre-peer evaluations because results were already good. A number of organizations considered that this was a very good way of helping them to have access to ILAC/IAF recognition.

145. During the *Questions and Answers Session*, it was further noted that the Joint ILAC/IAF Inspection Committee addressed the activity of accreditation inspection bodies and its task was to harmonize the way to accredit inspection bodies.

ESTABLISHMENT OF A CONFORMITY ASSESSMENT INFRASTRUCTURE

146. Presenters were invited to share ideas on ways to put in place an effective conformity assessment infrastructure in developing country Members.

The Experience of Brazil in Establishing a Conformity Assessment System and Existing Educational Programmes on Conformity Assessment²⁹

147. In Brazil, the conformity assessment system consisted of a council that established the policies and INMETRO, the national institute of metrology and industrial quality, which was the central executive of the system in relation to the activity of conformity assessment. INMETRO was the accreditation body and coordinated the establishment of the conformity assessment procedures. Mechanisms of conformity assessment were traditional ones and included certification, labelling, inspection and a software to analyse risk and consider technical, social, economical and legal factors in order to choose the best option for conformity assessment. There were 68 families of products with conformity assessed compulsory, 198 in the voluntary field, and more than 18000 ISO 9000 certificates issued and more than 1700 ISO 14000.

148. Several programmes followed certified products in the market. One was inspection, which was carried out by police officers. They looked for the mark of conformity assessment on the product and had the power to prohibit the sale of the product if the mark could not be identified. Another important programme was market surveillance. In this case, somebody collected samples of the product, sent them to the labs, which analysed them. Another programme was the follow-up by competition. In 2005, almost 70 million of units were inspected and 1.46 per cent of irregularities found. In the market surveillance programmes, 14 families of products were penalized and in six cases an opportunity to improve the conformity assessment procedures was identified.

149. In Brazil, a programme was in place to provide education on conformity assessment to consumers. The last survey showed that 84 per cent of Brazilians accepted conformity assessment. The focus of the education programme was on regulatory authorities, manufacturers and consumers. The first action in terms of education was to provide information to consumers, including on the objectives of conformity assessment, such as the protection of health, security, environment, etc. There were many publications about conformity assessment, educative campaigns on TV, a Sunday programme providing information about quality programme and quality of products. Conformity

²⁹ Mr. Alfred Lobo, Director, Department of Quality, INMETRO, Brazil.

assessment concepts had been introduced in the Brazilian educational system. Today, there were more than 1000 professional trainers in the country constituting a large network to spread information about conformity assessment.

150. During the *Questions and Answers Session*, it was further noted that INMETRO had established procedures for inspection and organized the training of inspectors to be prepared to inspect all kinds of certified products. In relation to education, there was also a website for consumers to find information about conformity assessment and products.

The Example of Technical Assistance Provided to Costa Rica on Conformity Assessment³⁰

151. Set up in 1995, the quality control system in Costa Rica was both voluntary and mandatory in nature. From 1996 to 2001, a draft legislation was elaborated and its objective was to set up a legal system that would provide support to the Costa Rican accreditation system. In May 2002, this legislation on national quality control was approved. This legislation was elaborated together with the private and public sectors and with academic circles.

152. The Costa Rican accreditation body, known as ECA in Costa Rica, had representatives from all stakeholders in the area of conformity assessment, i.e. the government, the private sector as well as consumers, users and academic circles. Between 2003 and 2004, ECA worked on developing regulations and approved fees for accreditation. In 2005, fees were established, this was a change as consumers were used to having these government services free of charge. ECA was actually bearing 70 per cent of the costs for accreditation.

153. One of the objectives of ECA was to become a full and active member of the IAAC. ECA had been chair of the Information Committee and the Training Committee. This had meant a lot of work but ECA also gained a lot of experience. ECA put an emphasis on sharing experiences with regional organizations. An important element of ECA cooperation activities was that those who received training should pass it on and put it in a written document for ECA. There were a number of cooperation projects: with the Organization of American States; with an accreditation organization; with China and Taiwan; and some multilateral projects. Capacity-building projects were in place with a German organization, the PTB and with AGACE, which was the quality infrastructure development project.

154. The secretariat of ECA had grown to seven people in 2006 at a very high professional level. A pre-assessment had been carried out in 2006 by IAAC. In April 2006, a final assessment was prepared aiming at signing a MLA in August 2006. The goal of ECA was to be a full member of IAAC.

Establishment of Conformity Assessment Schemes in Developing Countries: UNIDO's Experience³¹

155. There were methods and systems to analyze the needs but the key was to identify real problems of developing countries and LDCs, in particular. UNIDO was a key service supplier in this field. Two main issues had to be considered: what was actually needed in terms of conformity assessment infrastructure; and what were the minimum requirements for a country in certain conditions at a certain economic development. For a laboratory, an accreditation body, for improving standardization, it was far more difficult to decide what was the best option. The regional dimension was also essential to consider. UNIDO was trying to define a model under which it was possible to decide what was the best option for conformity assessment in a given country. UNIDO also worked together with other partners. There was, for instance, a joint exercise of UNIDO and ITC.

³⁰ Ms. Maritza Madriz, Manager, Ente Costarricense de Acreditación, Costa Rica.

³¹ Mr. Gerardo Pataconi, Industrial Development Officer, UNIDO.

156. Coordinated and harmonized action was essential to respond to developing countries' needs. Needs had to be identified for the different parts of the society, of the economy, both for export and consumer protection. Countries needed specific solutions within the international context. The sequence of actions was also important. The establishment of an accreditation body required a gradual and moderate approach: what was the demand, the investment, the cost required, what was the impact on the economy and on the society. UNIDO funding had increased from \$7.6 million in 2002 to \$70 million in 2006. It was essential to make sure that these resources were properly channelled and that they really produced the expected results. UNIDO carried out a number of regional projects. They were difficult to manage but they could be effective. It was important to really balance what should be done at a national level *vis-à-vis* the international level.

Building a Quality System at the Regional Level in the UEMOA Zone³²

157. The West African Economic and Monetary Union (UEMOA) zone included the following countries: Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Mali, Niger, Senegal and Togo. This region had a common currency and a common economic policy. Within this economic policy, a trade policy was in place concerning relations between these countries and third countries. Because there was a common market for all products, it was necessary to have a common strategy for conformity assessment. This had led UEMOA members to work towards conformity, not just to ensure quality for products manufactured within the Union, but also to allow for access to the international market.

158. With regard to promoting quality, countries realized that companies did not yet have a system in place and that there was no accreditation body. Therefore, there was a need to undertake a regional initiative in this area. UNIDO carried out regional initiatives to draw up a quality control programme. This was financed by the European Union and this programme dealt with three specific areas: (i) accreditation; (ii) standardization; and (iii) quality promotion. There was also a metrology project financed by the government which was carried out by the German metrology organization. The objective of these initiatives was to facilitate trade within the region and at the international level and allow for quality promotion and metrology programmes and standardization.

159. On accreditation, it was decided to set up one structure in the Union as it would not make sense for each individual country to have its own accreditation service. With regard to standardization, the Union undertook to harmonize national regulations and standards, to enhance countries' participation in standardization activities, and help the creation of national standardization bodies or support the activities of existing national standardization bodies. Concerning quality promotion, companies and consumers were involved in awareness-raising campaigns. The Union was also promoting the use of metrology services in the economy in general and in SMEs in particular.

160. Concerning achievements, a number of activities had been undertaken in terms of regional coordination of standardization bodies. For countries that did not have national structures, national standardization bodies had been set up. All national bodies were linked up on line so that the information was readily accessible. There were national documentation centres and in these centres, information was exchanged about all member countries of UEMOA. There was now a regional database on standardization which could be found on the UEMOA website.³³ Some legal texts and regulations had been harmonized and this was done in the context of the common market and with major stakeholders in order to foster trade relations between countries. Common UEMOA standards were prepared for a number of products, in accordance with international standards, for instance: oils, food salt, cashew nuts and shea butter.

161. With regard to achievements in the promotion of quality, the UEMOA had trained experts in various countries and carried out pilot projects in companies. There were a number of training

³² Mr. Abdou Seyni, Director of Industry, West African Economic and Monetary Union.

³³ www.uemoa.int

seminars organized for companies in order to get the necessary expertise at a local level. Experts had been trained from 2001 to 2005. In order to strengthen this promotion of quality, centres were set up to ensure that quality be developed at the regional level so that no country be left behind and that all countries could move forward together. With regard to metrology, achievements included the provision of equipments to legal metrology services. The metrology project extended beyond the Union with countries such as Ghana and Guinea.

162. With regard to accreditation, since there was no accreditation system, the UEOMA had to work together with laboratories and test centres. There was a database of laboratories, also available on the internet. All member states committed to work towards a joint infrastructure at a regional level for accreditation. The idea behind the establishment of the West African accreditation system was to speed up accreditation. An agreement was signed with the French accreditation organization so as to benefit from its expertise. The West African accreditation system also started a process to become affiliated members of both ILAC and IAF.

163. During the *Questions and Answers Session*, it was further stressed that member states of UEMOA were fully behind a strategy to develop a high quality infrastructure and had undertaken this through an additional instrument signed by heads of states. It would be extended to the whole of West Africa, i.e. 16 countries. The European Communities financed this project and UNIDO was the executing agency.

Building a Conformity Assessment Infrastructure at the Regional Level in the Caribbean Region: the Experience of Trinidad and Tobago³⁴

164. At the Trinidad and Tobago Bureau of Standards (TTBS), conformity assessment practices were traditional. TTBS provided both product certifications and batch certifications services. TTBS had developed its own quality management system and did not use the ISO 9001:2000 system because since companies were quite small Guide 53 was used. Trinidad and Tobago was moving from voluntary certification to compulsory certification through regulations. For management systems, TTBS followed ISO 9001:2000 and 14000 and developed an integrated system with certification for small and medium sized enterprises. TTBS also offered tourism certification. TTBS was contracted by the tourism development company as a certification body for tour guides, tour operators and car rentals. TTBS had entered into the Green Globe System, which was an accredited service for environmental and social responsibility. In the future, TTBS would engage in personnel certification (ISO/IEC 17024: 2003) and enter into MRAs.

165. With regards to inspection, Trinidad and Tobago had to face a significant import of illegal tyres and electrical appliances, and because of that Trinidad and Tobago had become very active in the ISO's Committee on consumer policy (COPOLCO). Trinidad and Tobago played an influential role in developing standards for second hand goods and developed its own national standards for second hand and used goods, in particular tyres. For new items, marks or certificates of conformity from accredited institutions or acceptable institutions were accepted as equivalent. Inspections were conducted at ports of entry, wholesalers and import premises.

166. With regards to testing, domestic testing and calibration laboratories used internationally accepted methods and procedures. The laboratories were accredited by the United Kingdom Accreditation Service. There was a fairly good traceability for metrology and TTBS as the custodian of national weights and measures; in fact TTBS was the national measurement institute. TTBS offered testing services in the chemical area, metrology, fibre, electrical and materials.

167. Lastly, TTBS was a national standards body, a certification body within the national standards body, a testing body but also an accreditation body, and this raised some challenges. thirty steps were

³⁴ Mr. Terrence Awai, Head, Certification Division, Trinidad and Tobago Bureau of Standards.

required for international recognition as a National Accreditation Body (NAB). These included: national policy on quality, management structure, equipment, quality documentation, independency, lead assessors, technical assessors, metrology support in country, and MLA/MRA. Almost half of the steps had been completed or nearly finished. TTBS expected to sign the MRA with ILAC and IAF at the end of 2006.
