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Committee on Technical Barriers to Trade

SUMMARY REPORT OF THE WORKSHOP ON THE DIFFERENT APPROACHES TO CONFORMITY ASSESSMENT[1]

16-17 MARCH 2006

Note by the Secretariat[2]

Addendum

[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.

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 Secretariat[4] 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 LEVEL[5]

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 Toolbox[6]

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 Tamiotti, 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 Colombia[7]

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 Perspective[8]

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.

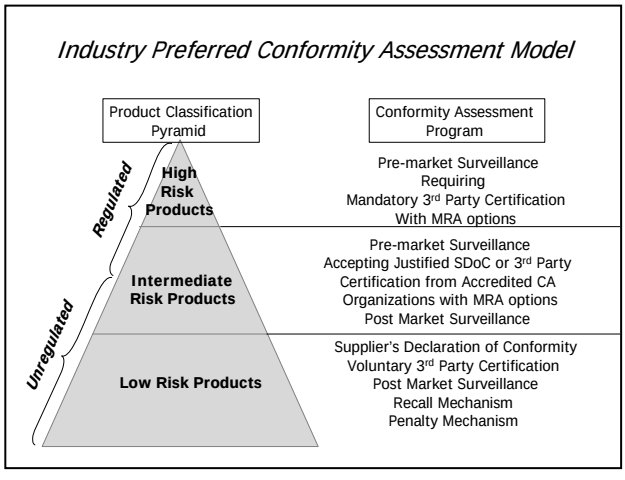
a company's survival because it ensured on-going commerce. Brand recognition only had value if brand reputation was earned by consistently meeting customers' expectations in the market place.

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 electro-magnetic 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 Mexico[9]

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 gains consumers' confidence in the products which had been assessed; and to identify improvements of 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 consumers 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 that 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 Standards[11]

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.

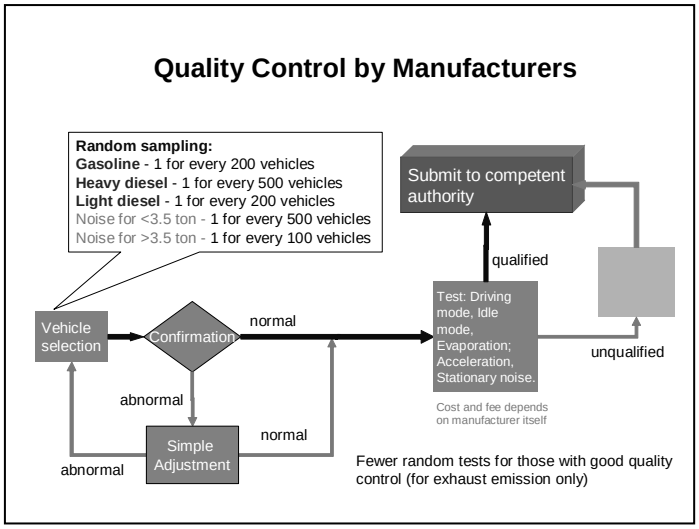
37. Before the accession of Chinese Taipei to the WTO, in 2002, imported vehicles originated mostly from the USA. US vehicle emissions management system were the most comprehensive and it was referred to as the US system in the domestic management system. After 2002, Chinese Taipei accepted foreign standards 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 Confidence[12]

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 Programs[13]

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 Certification[14]

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

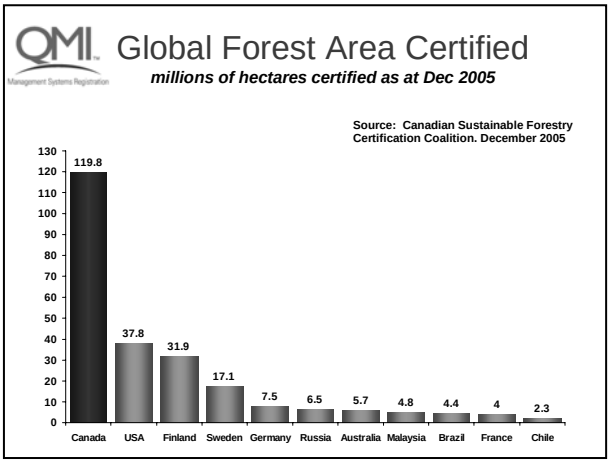
[14] Mr. Guillaume Gignac, QMI, Senior Manager, Product Management, Canada. QMI was the leading certification body in North America, part of the Canadian Standard Association group, and accredited to a number of accreditation bodies, including by the Standard Council of Canada (SCC), the ANSI-ASQ National 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 RESULTS[15]

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.

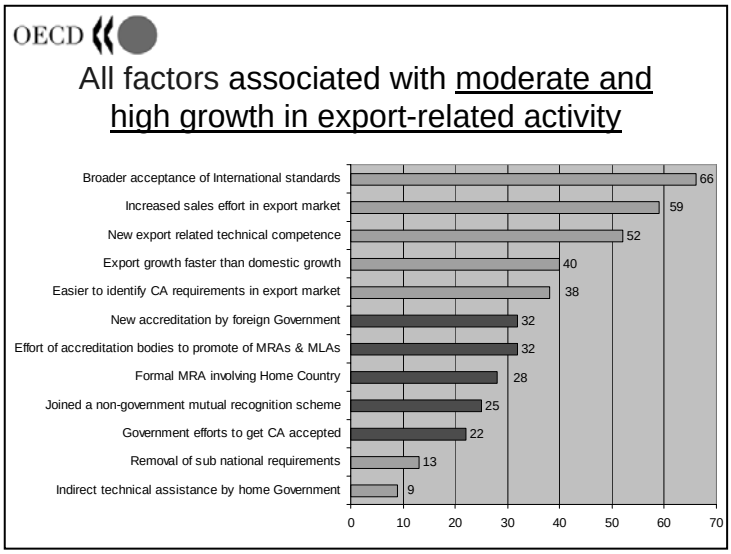
[15] This session was moderated by Mr. Juan Antonio Dorantes (Mexico).

Trends in the Mechanisms to Facilitate the Acceptance of Conformity Assessment Results[16]

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 Procedure[17]

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.

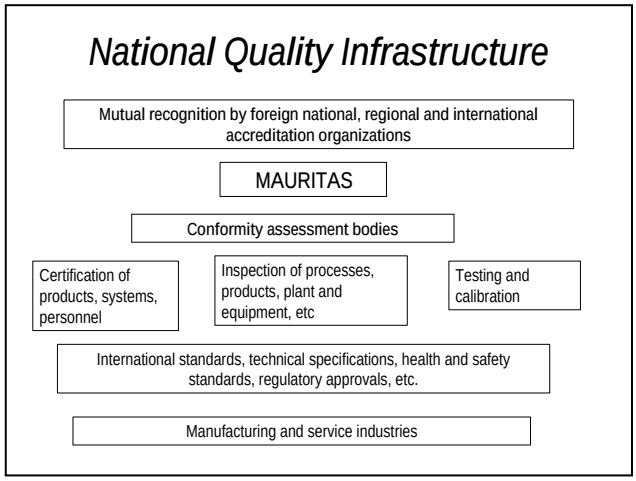
74. To conclude, over the last eight years, the awareness of accreditation and conformity assessment in Australia and New Zealand had grown. JAS-ANZ had about 48 different programmes, accredited 57 certification bodies in 12 economies, mainly in the Asia Pacific region but also in the United States and 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 Accreditation[18]

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 Accreditation[19]

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.

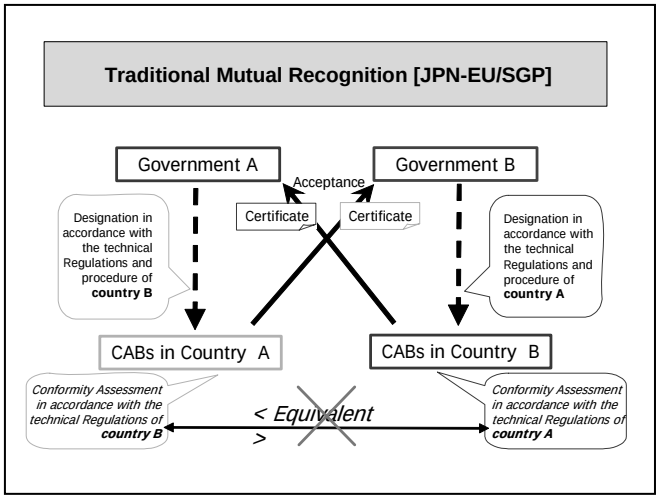
MUTUAL ACCEPTANCE OF CONFORMITY ASSESSMENT RESULTS

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 Conclusion[20]

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 Experiences[21]

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 Regulators[23]

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 Challenges[24]

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 BIS[25]

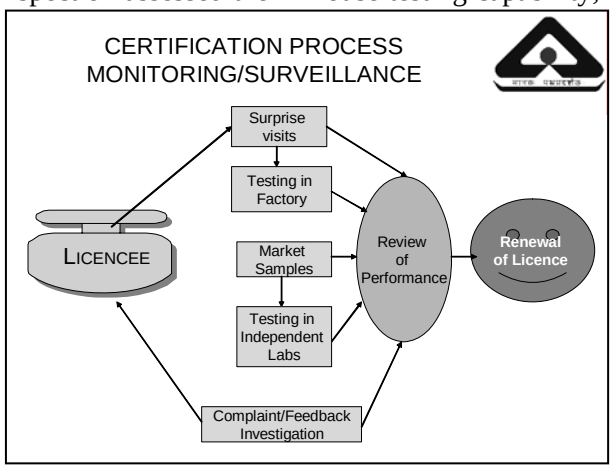
127. There was no discrimination between domestic and imported products, they were treated equally. An inspection body for exports ensured that exported products were of good quality. Concerning the conformity assessment infrastructure in India, the Bureau of Indian Standards (BIS) was a member of ISO/IEC. 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

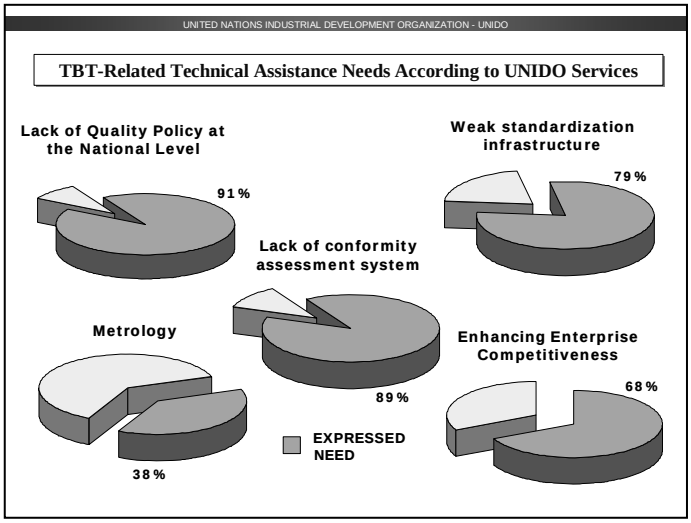
of applicant units, this was the stage of confidence building; (iii) then acceptance of results of samples tested in each other's accredited laboratories to importing country's standards (at this crucial stage, recognition of each others' standards was starting); (iv) the acceptance of inspection and 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 Questionnaire[26]

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 Patacconi, 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 IAF[28]

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 Assessment[29]

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 Assessment[30]

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 Experience[31]

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 Patacconi, 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 Zone[32]

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 a 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 UEOMA 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 Tobago[34]

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.