
Committee on Technical Barriers to Trade

REPORT OF THE SPECIAL MEETING OF THE TBT COMMITTEE DEDICATED TO CONFORMITY ASSESSMENT PROCEDURES HELD ON 29 JUNE 2004

Chairperson: Mr. Juan Antonio Dorantes Sánchez (Mexico)

Addendum to the Minutes of the Meeting of 1 July 2004

Note by the Secretariat¹

1. A Special Meeting of the TBT Committee Dedicated to Conformity Assessment Procedures (hereafter "Special Meeting") was held on 29 June 2004. The purpose of this Special Meeting was to advance the Committee's Work Program in the area of conformity assessment, bearing in mind the recommendations made at the Third Triennial Review of the TBT Committee. The agenda of the Special Meeting covered three points: (i) exchange of information on Members' experiences with Supplier's Declaration of Conformity (SDoC); (ii) information on the operation of accreditation fora; and (iii) other issues related to conformity assessment procedures.²

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

² Job(04)/91 references all documents dealing with conformity assessment circulated in the TBT Committee since 1995.

I. EXCHANGE OF INFORMATION ON MEMBERS' EXPERIENCES WITH SUPPLIER'S DECLARATION OF CONFORMITY (SDoC)

2. The Chairman recalled that the TBT Committee had previously held initial discussions on the issue of SDoC and that there had been a number of submissions from Members relevant to SDoC going back as far as 1998.³ The Third Triennial Review, recognized the benefits of the SDoC approach for the assurance of conformity when used in appropriate circumstances. The purpose of the current meeting was to start a more in-depth discussion of SDoC in the Committee ahead of the planned workshop in March 2005.

A. BRAZIL

1. Statement

3. The representative of Brazil presented his country's experience with SDoC (circulated in G/TBT/W/240). He also proposed to present, in detail, the use of SDoC in the case of disposable lighters as a case study in the workshop on SDoC to be held in March 2005.

2. Discussion

4. The representative of India asked whether Brazil, in its system of conformity assessment, utilized SDoC only in relation to mandatory technical regulations, or whether SDoC was also employed in the case of voluntary standards.

5. The representative of Brazil confirmed that CONMETRO had adopted a decision to apply SDoC only to technical regulations; it was not applied to voluntary standards.

6. The representative of Canada was interested to hear more detail on the methodology used for risk assessment (paragraph 8 of G/TBT/W/240).

7. The representative of Brazil replied that its methodology for risk assessment was based on software which had been specially developed for risk assessment and that took into account various factors, including environmental, social and economic factors concerning the particular product.

8. The representative of Canada was also interested to hear more about the "mark of conformity". Was such a mark granted through a process of third party certification, or SDoC? Was this the mark of the accreditation body, or was it a mark provided by a regulator? Moreover, with respect to non-conformance of bodies that were licensed to apply the mark, what procedures were followed to ensure that the licensee met all the requirements? Similarly the representative from Colombia asked whether under its SDoC scheme, Brazil had provided for surveillance procedures after marketing. Moreover, did the scheme contemplate any sanctions for the non-compliance with the "conformity mark".

9. The representative of Brazil confirmed that two separate product marks were required for SDoC: one granted by INMETRO, and the other mark displaying the regulation. Regarding the question from Colombia, Brazil did conduct market surveillance. If a product was found to be non-conforming it would be removed from the market.

10. The representative of the European Communities noted that the way SDoC had been applied so far in Brazil, part of the procedure included testing the product. While the European Communities shared this type of application of SDoC in some areas, in other areas the supplier's declaration was completely left in the hands of the manufacturer and no test with an accredited or authorized

³ The various submissions on SDoC are listed in JOB(04)/70 (circulated on 10 June 2004). This document also contains key points made in the TBT Committee, since 1995, specifically on SDoC.

laboratory was necessary. Did Brazil have any plans to give the responsibility entirely to the manufacturer, without any intervention of a laboratory? The representative of Egypt had a similar question (paragraph 14 of G/TBT/W/240).

11. The representative of Brazil clarified that the existing procedure did not make testing requirements for SDoC mandatory in all cases. Testing was only required in situations when and if the National Council for Metrology, Standardization and Industrial Quality (CONMETRO) considered it necessary.

12. The representatives from Mexico and China sought clarifications from Brazil on how it evaluated whether a product presented a "mild risk" (paragraph 11 of G/TBT/W/240). How were such risks evaluated?

13. The representative of Brazil said that the risk assessment methodology used was based on special software which took into account the costs and benefits, as well as the economic, social, environmental factors and the level of commercial confidence that could be achieved through implementing SDoC programs.

14. The representative of Egypt asked what proportion of the SDoC programmes adopted in Brazil applied to imported products versus domestically produced. He referred, in particular, to the case of disposable lighters (paragraph 16 of G/TBT/W/240).

15. Taking the example of disposable lighters, the representative of Brazil said that 70 per cent of the products were domestically produced and the remaining 30 per cent were imported.

16. The representative of China sought a clarification from Brazil in relation to the definition of an accredited laboratory (paragraph 9 of G/TBT/W/240). Was this for a laboratory accredited in Brazil or did Brazil accept laboratories accredited elsewhere in accordance with the ISO standard?

17. The representative of Brazil clarified that the requirement that testing laboratories be accredited was equally applicable to both Brazilian and foreign manufacturers. It was however a prerequisite that all such laboratories be accredited by the ILAC.

18. The representative from Malaysia asked whether Brazil considered SDoC a viable alternative for a wide range of products (paragraph 12 of G/TBT/W/240)? In taking the decision to use SDoC as an option, had the Brazilian authorities evaluated the costs and benefits?

19. The Brazilian representative replied that the cautious approach adopted by her country's authorities, based on risk assessment, had led to the use of SDoC on only three products. She reiterated that costs-benefits were used as a factor when taking a decision on whether SDoC was to be used or not.

B. CHINESE TAIPEI

1. Statement⁴

20. The representative of Chinese Taipei recalled that SDoC was a new conformity assessment procedure for its domestic manufactures, consumers and government officers. Batch inspection had been the only conformity assessment procedure used over the previous forty years. Recognized as the least-onerous approach to providing assurance of conformity, SDoC was introduced into the regulatory system in January 2002. Reviews of the effectiveness of the new system were carried out in August 2002 and December 2003, respectively. The experiences with SDoC faced by Chinese

⁴ Two previous papers submitted by Chinese Taipei on SDoC have been circulated in G/TBT/W/195 (12 March 2003) and G/TBT/W/195/Add.1 (16 March 2004).

Taipei was discussed in four parts: (i) the planning stage; (ii) the implementation stage; (iii) the evaluation stage; and (iv) future action.

21. In respect of the planning stage, certain actions had to be taken to get SDoC included as a conformity assessment procedure in the regulatory system. This involved making revisions to applicable laws or regulations, providing adequate education to key players - including government officers, industry and consumers - as well as improving the enforcement mechanism.

22. The legislative framework was refined first in 1997 and again in 2001 to provide a legal basis for implementing SDoC. Under the new framework, provisions relating to market surveillance were strengthened and the penalties for violations were increased in order to deter manufacturers from exploiting the new procedure or attempting to market non-compliant products. The penalties that could be imposed for violations were currently twenty times higher than those allowed in the original regulation. For example, the minimum fine for violations involving false or incorrect labelling was now approximately US\$ 2,900 compared to the US\$ 140 stipulated previously.

23. Regarding the implementation stage, the SDoC system was implemented in January 2002, with 19 items of electronic products selected as the first group to be covered by the new procedure. The product list consisted mainly of parts or accessories of IT equipment and this particular group was selected because of its relatively low risk to public safety. While successful implementation of the new system could not be guaranteed, the selection was made with due consideration for the fact that the finished products remained subject to pre-market controls and that the protection of consumers would thus still be maintained.

24. The SDoC procedure, as applied to the 19 products selected required the supplier or manufacturer to be registered, the product to be tested by laboratories recognized by the regulator and a declaration to be made by the supplier or manufacturer that the product met the technical requirements. A product had to be labelled with an inspection mark, which differentiated it (by the presence of the letter "D"), from those using other conformity assessment procedures. The registration or identification number given by the regulator to the supplier or manufacturer needed also to be shown on the product, so that the person responsible for that particular product in the market surveillance programs could be identified, if necessary.

25. In respect of the evaluation stage, in order to evaluate the effectiveness of the SDoC system in the market-place, specially designed market surveillance programs were applied to the selected products. These had two parts, appearance checking and sample testing. Appearance checking was used to monitor whether the inspection mark was affixed to the products. Sample testing involved purchasing products from the open market and testing to verify whether they were consistent with the information contained in the related conformity declaration and technical report. The first review of the system was carried out in August 2002, covering the appearance checking phase only. The second was in December 2003 and covered both parts of the surveillance program.

26. The first review found a non-compliance rate of 30 per cent, the most likely reason being that the supplier or manufacturer was unfamiliar with the requirements. To correct this, specific measures were taken to increase manufacturers' awareness of the SDoC requirements and to remind them of the penalties that could be incurred through violations. Exchangeable power supply, a key component that affected the electromagnetic compatibility performance of a computer, was the product selected as the subject of the second review. This time, the rates of non-compliance were found to be 0.5 per cent in the appearance check and 48 per cent in the sample testing. The appearance checks showed satisfactory results in comparison with those conducted in 2002, where the non-compliance rate was 30 per cent, and the Chinese Taipei authorities were pleased with the apparent effectiveness of the programmes designed to raise manufacturers' awareness of the new system. The high rate of non-conformity found in sample testing, however, raised serious concerns about the effectiveness of the SDoC system to meet legitimate objectives, particularly when non-conformity could no longer be

attributed to lack of awareness, as confirmed by the appearance check results. Measures, such as the imposition of penalties and follow-up checks on the corrective action taken by the supplier or manufacturer, were being taken to correct such a high rate of non-conformity.

27. In respect of future action, and in view of the evaluation results, discussions were taking place on making changes to the procedure, to perhaps include the registration of products and the enforcement of market surveillance skills. In addition, the current year's market surveillance programme for the SDoC system was being extended in scope to include other products such as electronic calculating machines, hard disc devices, soft disc devices, main boards of computers and add-on cards. Final results were expected at the end of 2004, and Chinese Taipei would be pleased to share them with any interested Members.

28. While the experience Chinese Taipei had had from implementing SDoC might not seem very positive at the current stage, it was certainly not discouraged from using the system. Considering all the benefits that SDoC could bring to facilitating trade, Chinese Taipei was pleased to have the opportunity of sharing its detailed findings with WTO Members in the hope that this empirical case study would contribute to the discussion at the SDoC Workshop to be held in 2005. It was necessary to explore all the different aspects in order to eventually arrive at a successful and effective system that did not compromise the protection of consumers.

29. The representative of Chinese Taipei stressed that the experiences reported were based on its own particular industrial structure, which consisted mainly of small and medium-sized enterprises. She was interested in hearing from other Members that had successfully implemented SDoC and who would also be willing to share their empirical experiences, especially in terms of any regulatory action they had been taken to resolve problems along the way.

2. Discussion

30. The representative of Australia asked, in respect of Chinese Taipei's product testing mechanisms, if simple product tests administered by laboratories would be acceptable to the regulator or did such laboratories have to be accredited. In other words, was the regulator free to choose any laboratory, accredited or not? Also, had any consideration been given to the use of pre-sale testing to ensure that there would not be any failures once the product was released on the market.

31. The representative from Chinese Taipei clarified that for laboratories conducting SDoC tests to be recognized by its regulators, in addition to compliance with ISO/IEC Guide 17025, laboratories needed to comply with specific standards for the testing of electronic products. If a laboratory was interested in becoming a designated laboratory for the purposes of the SDoC scheme, they could apply to the Bureau of Standards, Metrology and Inspection for recognition. After such a request, assessment personnel would be sent. Furthermore, there was a procedure in place through which laboratories which had already received accreditation under existing international standards, could have part of this assessment waived.

32. The representative of Brazil asked how one could explain the high level of non-conformity found in the sample testing and what measures were being taken to address this problem.

33. The representative of Chinese Taipei said that her authorities were still in the process of interviewing the non-conforming manufacturers and would impose a fine if they found that a manufacturer participating in the scheme had intentionally avoided testing its products before placing them on the market. Such a fine for non-compliance could extend up to NTD 1 million.

34. The representative from Egypt asked how registration requirements would apply to foreign suppliers.

35. The representative of Chinese Taipei clarified that, for foreign suppliers, registration was done by a local representative within Chinese Taipei. This local representative issued a registration number that was then communicated to the foreign supplier of the product so that it could be marked upon that product.

C. THE EUROPEAN COMMUNITIES

1. Statement

36. The representative of the European Communities referred to an earlier EC submission on Suppliers Declaration of Conformity (G/TBT/W/218, 30 June 2003) in respect of the EC's own experience on SDoC. He noted that while SDoC was sometimes referred to as "manufacturer's declaration of conformity" or "self-declaration of conformity", the underlying concept of the terms was the same. The supplier was the party that supplied the product and this could be a manufacturer, a distributor or an importer of the product.

37. The EC's experience in the use of SDoC had been within the framework of New Approach Directives, which consisted of regulations covering a wide range of industrial products, such as: electrical equipment, machinery, toys, medical devices, personal protective equipment, recreational crafts, radio and telecommunication equipment and equipment for use in potentially explosive atmospheres. The Directives set down the essential public interest requirements for families of products (dealing with safety, health and environmental protection), the relevant conformity assessment procedures tailored to the specific risks inherent to the product family, and the "CE" marking to be affixed on products by the manufacturer before placing them on the market. Irrespective of which conformity assessment system was used, the product was marked with the CE mark. This mark reflected conformance with all mandatory requirements. As such, the product marking did not distinguish between SDoC and third party certification.

38. Before deciding to apply SDoC, several elements needed to be taken into consideration. In particular, issues such as the appropriateness of SDoC in view of the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of certification laboratories) and the production system. SDoC was the preferred option for product categories presenting risks that were generally considered to be low. However, the risk factor was not the only factor for deciding whether SDoC should be used for a particular category of products. Several other factors, such as: the number of existing voluntary marking schemes for a product; the types of production methods used for the manufacture of the product; the kinds of certification schemes available; and, the maturity of the standardization mechanism in a particular product sector were all taken into account. Therefore, it was possible that SDoC was used as a method of conformity assessment even in product categories which were otherwise viewed as medium or high risk, such as electrical products.

39. Regarding standards, the use of SDoC was mostly linked to the application of harmonized European standards that were elaborated by the European standardization bodies CEN, CENELEC and ETSI, following a mandate by the European Commission. These contained technical specifications for the fulfilment of the relevant essential requirements. The standardization process offered the possibility to transpose standards and base them on international standards from ISO, IEC and ITU-T as they became available. However, the use of harmonized European standards remained voluntary and manufacturers were free to choose any technical solution to comply with the relevant essential requirements.

40. Regarding the obligations on suppliers, the representative of the European Communities noted that for all products intended to be placed on the market, the supplier had to ensure that they satisfied the relevant legal requirements. Applying the declaration of conformity (DoC) imposed the obligation upon the supplier to take care of the requirements of documentation and declaration. The

supplier had to establish a technical file containing the documentation that covered design, manufacture and operational aspects of the product reflecting the results of an appropriate risk assessment and, if applicable, the test results obtained from a competent laboratory. The supplier had to also draw up and keep together with the file a copy of the DoC. The supplier had to keep it for a period ending at least 10 years after the last product had been manufactured and had to make it available to the relevant national authorities for inspection purposes. The supplier took full responsibility for placing the product on the market and had to take all measures necessary in order that the manufacturing process ensured compliance of the manufactured products with the technical documentation and with the relevant legal requirements. For some categories of higher-risk products covered by New Approach Directives, an additional step was required, which involved the intervention of a third-party certification body. This allowed for an examination of a product sample, and tests being made prior to the product being certified and being allowed to be placed on the market.

41. Regarding market surveillance and product liability laws, according to the EC experience, SDoC could facilitate market access without prejudice to the fulfilment of legitimate public policy objectives, when it was combined with well developed market surveillance systems and effective product liability laws. Market surveillance was an essential tool for the enforcement of any legislation – and in particular for goods that were placed on the market following SDoC. Market surveillance involved monitoring products to ensure they complied with legislation and taking remedial action when products did not comply. It also included penalties for false or misleading declarations. In the European Communities this was the responsibility of national authorities specially nominated or established by the Member States. To help ensure the fulfilment of legitimate public policy objectives, the lesser the involvement of a third party during the conformity assessment before the product was placed on the market, the greater the need for efficient market surveillance.

42. In conclusion, the EC representative stressed that the EC experience was that the introduction of SDoC coupled with ex-post market surveillance and effective product liability laws worked well in certain specific sectors and had not created problems with regard to the fulfilment of the legitimate public policy objectives pursued. Moreover the use of SDoC also facilitated imports from third countries and could be considered to help developing countries fully benefit from the opportunities offered by the world trading system. While the use of SDoC implied certain costs for administrations, in particular higher costs for market surveillance, it tended to imply lower costs for industry and importers, resulting in cheaper products for consumers and possibly, in the long run, higher level of competitiveness and job creation. An appropriate balance needed to be struck, taking into account the imperative objectives of protecting health, safety and the environment, and the constraints on the resources of administrations.

2. Discussion

43. The representative of Egypt sought clarification on liability related issues in the EC submission, in particular with respect to penalties being imposed upon suppliers for non-conformity. Under what conditions would a supplier be given a "second chance" in the event that it was found to be non-conforming on one given occasion?

44. The representative of the European Communities replied that the EC Directive, which dealt with product liability for non-conformance, was transposed to the laws of each Member State, so that the penalty for the faulty product would vary from State to State within the EU. In other words, the actual application of the provisions of the Directive was dependant on the Member States themselves.

45. The representative of Egypt also asked what areas had entailed the most difficulties in effectively implementing SDoC.

46. The representative of the European Communities replied that the areas of difficulty were basically in relation to two categories of products in which it was found, through market surveillance, that there was a high degree of non-conformance, namely: electronic goods and toys. The problem was particularly bad in the case of toys. In the European Communities Toys Directive, two procedures were used, one of which was SDoC. This procedure only operated if there were existing EC standards in that area. If there were no standards for the particular product category, then it went to a type approval. In this case, quite a few instances of faulty products had been discovered which was a sensitive issue given the nature of the product. As soon as a fault was detected, the "safeguard clause" was used and if the problem was detected in one Member State, then all Member States were immediately informed and steps were taken to withdraw the product from all markets and a system to investigate was set up.

47. The representative of the United States noted that the US approach to SDoC was not guided by the risk analysis approach followed by the EC, e.g. motor vehicles in the United States used SDoC despite the high risk category of products that it falls into. It was pointed out that the infrastructure existing in the market sector was an import consideration to be kept in mind when deciding whether or not a product should be subject to SDoC.

48. The representative of India referred to the section of the EC submission dealing with the possible intervention of a third party certification body. He asked whether there was a risk threshold beyond which third party certification would be triggered?

49. The representative from the European Communities clarified that in most cases of SDoC, third party certification was not required. However, in some cases, such as in the case of telecom equipment using radio frequencies, tests would be required to be carried out to test the frequency used by such equipment. This would strictly speaking not amount to third party certification; these were simply additional tests which were required to be carried out to complement the details already contained in the "technical file".

50. The representative of Canada expressed interest in the EC's post market surveillance mechanism and the procedure used by EC Member States for tracking faulty products. She asked if the EC representative could elaborate on how these mechanisms worked and clarify whether there were any standardized procedures used by EC Member States while addressing these issues.

51. The representative of the European Communities pointed out that the peculiarity of the EC system meant that Member States were responsible for market surveillance and there was no harmonized system of conducting market surveillance. Member States approached the issue differently, for example some Member States had a more centralized system of tackling market surveillance whereas others dealt with it through local governments. Despite the differences of the approaches and the procedures used by Member States in dealing with market surveillance, the European Communities was making an effort along with its Member States through initiatives such as a "joint visit programs". These initiatives could, in the future, lead to the application of common criteria for market surveillance for all Member States to follow.

52. The representative of China sought clarification from the EC representative as to whether the "notified bodies" where manufacturers needed to have their products tested, could be located outside the European Communities if they were accredited in accordance with international standards.

53. The representative of the European Communities clarified that if pure SDoC was used, there would be no need for the involvement of any notified body, and the only requirement that needed to be fulfilled was the maintenance of the technical file. However, in some cases where certificates had to be issued by "notified bodies", the EC regulations required such "notified bodies" to be notified within the territory of the European Communities itself. However, the EC representative pointed out that it was possible for laboratories located outside the European Communities to enter into sub-

contracting arrangements with notified bodies within the European Communities, which would assist in accessing the EC market.

54. The representative of Chinese Taipei asked what had prompted the European Communities to reconsider the effectiveness of various SDoC schemes which had been employed?

55. The representative of the European Communities replied that while no formal study to measure the effectiveness of various schemes had been conducted, there was a continuing analysis of how these schemes were working in various sectors. This process of analysis involved consultations with experts and ensured a constant feedback on the effectiveness of measures taken. The EC representative gave the examples of the medical devices sector and the telecom sector in the EU, where industry and consumer views were taken into account and legislative changes made according to the feedback.

56. The representative from Malaysia wished to know whether the European Communities had conducted an evaluation of the alternatives to SDoC, and the costs to be incurred in its implementation.

57. The representative of the European Communities stated that all new proposals for legislation went through a process of rigorous impact assessment, wherein costs of implementation, benefits, available alternatives, and appropriate procedures were all assessed before introduction. The European Communities believed that impact assessment would play an important role in all its future legislation.

D. OTHER INFORMATION ON SDoC

1. New Zealand

58. The representative of New Zealand underlined her country's support for the adoption of the SDoC approach to products that did not pose a high risk to health, safety and the environment. She simultaneously recognized that this did not mean that to adopt SDoC the product needed to present absolutely no risk. New Zealand had judged it safe to apply SDoC to electrical safety equipment, for example, where there could be some intrinsic risk to health and safety. She pointed out that SDoC was appropriate for a wide range of products because it reduced the cost of compliance significantly for the exporter; it was used extensively by exporters in New Zealand. Exporters, particularly small and medium scaled enterprises (SMEs), who had not had to obtain pre-market approvals in New Zealand had found this approach less difficult to manage. There were a number of advantages to SDoC, including: the reduction in compliance costs; decrease in administrative costs for regulators which allowed them to spend greater resources on post market surveillance which they found more effective; the placing of legal liability squarely on the supplier; and, the encouragement to industry to self-regulate.

2. Australia

59. The representative from Australia pointed out that his country had had a system of accepting manufacturers' declarations of conformity since the 1950s for many products, including some products which were considered high risk. Australia's system was based on the notion of the demonstration of technical competence by the manufacturer at the pre-sale stage. This was an accreditation based system, largely based on the application of the ISO/IEC 17025 for laboratory testing. This had proven to be very effective in Australia; there had been very few serious problems in Australia as a result of inadequate quality or compliance of manufactured products – the problem was often with specification, not with compliance to the specification. Australia accepted all imported products on the same basis. This meant that a product which was tested in a system based on accreditation for testing and certification was acceptable in Australia. As had been mentioned by

Brazil, Australia also effectively recognized foreign laboratories if they were accredited to conduct the appropriate tests by a signatory of the ILAC arrangement.

3. ISO

60. The representative of the ISO noted that reference had been made to the ISO/IEC Guide 22 on the subject of SDoC. As was evident from the discussion, there were various interpretations on how to apply SDoC. This was why there had been a decision in the ISO to move from a "guide" to a "standard". He informed Members that this new standard, ISO 17050, was at its final stage of development and was scheduled to be voted upon. It would hopefully be published by the end of 2004 and used by regulators and market players to clarify the concept of SDoC.

II. INFORMATION ON THE OPERATION OF ACCREDITATION FORA

61. The Chairman recalled that the Committee had, in the Third Triennial Review highlighted the importance of accreditation as a mechanism which could promote confidence when used in accordance with international standards. The Committee, in an effort to improve Members implementation of Articles 5-9 of the TBT Agreement and to improve the understanding of Member's own conformity assessment systems, had invited individual Members and Observers to introduce their own experiences in this area of conformity assessment.

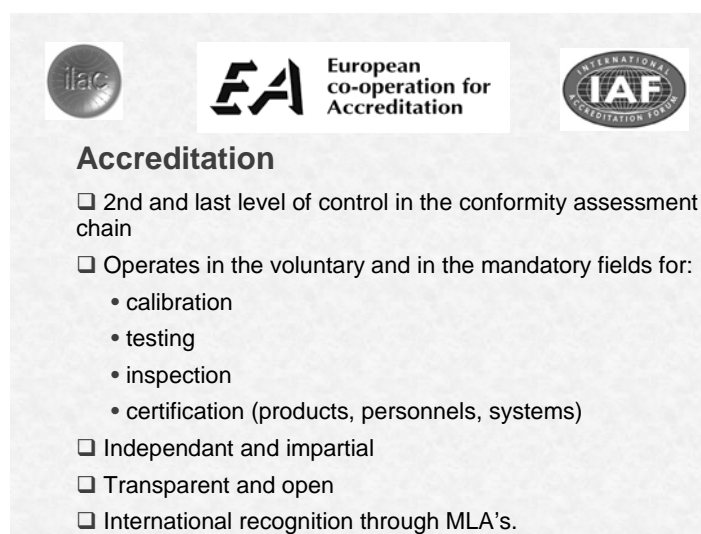
A. THE INTERNATIONAL LABORATORY ACCREDITATION CO-OPERATION (ILAC); INTERNATIONAL ACCREDITATION FORUM (IAF); AND THE EUROPEAN CO-OPERATION FOR ACCREDITATION (EA)

1. Statement

62. The representative of the ILAC, IAF and the EA⁵ began by noting that one way of describing accreditation was as third party assessment at the second level of control (in the sense that accreditation bodies controlled conformity assessment bodies). Accreditation operated in the voluntary and mandatory fields for calibration, testing, inspection and certification (Figure 1). Accreditation bodies needed to be independent, impartial, transparent and open. Accreditation facilitated international recognition based on MLAs / MRAs (Multilateral Agreements or Multilateral Arrangements). These were the ultimate products that organizations of accreditation bodies were aiming at in order to facilitate this recognition and thus avoiding multiple assessments.

⁵ Mr. Daniel Pierre, Chief Executive of the Comité Français d'Acréditation (COFRAC).

Figure 1



63. It was noted that the **ILAC** was a legal entity under the Dutch Law and a non-profit organization. The membership of ILAC was as follows:

- (a) 45 Full Members (signatories to the Arrangement) representing 36 economies;
- (b) 15 Associates representing 14 economies;
- (c) 22 Affiliates representing 18 economies;
- (d) 4 Regional Cooperation Bodies; and,
- (e) 19 Stakeholders.

64. The European Co-operation for Accreditation (EA) was one of the member regions of ILAC representing European Accreditation bodies (Figure 2). A second big region was the Asia Pacific Region, APLAC (Asia Pacific Laboratory Accreditation Cooperation). Other regions included the IAAC (Inter-America Accreditation Co operation) and SADCA (the Cooperation Body for South Africa).

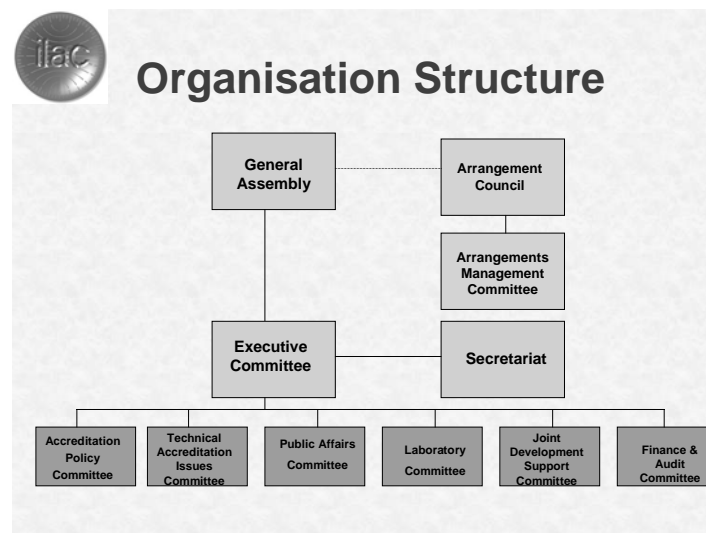
Figure 2

Full Members (MRA Signatories)

EA	APLAC	IAAC	SADCA	Unaffiliated
Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom.	Australia, Canada, Hong-Kong China, Peopole's Republic of China, Indonesia, India, Japan, Republic of Korea, Malaysia, New Zealand, Singapore, Chinese Tapei, Thailand, USA, Vietnam.	Brazil	South-Africa	Israël

65. In respect of the organizational structure of ILAC (Figure 3), it was noted that the Joint Development Support Committee was dedicated to help accreditation bodies in developing countries in order to enable them to join the status of ILAC MRA Signatories.

Figure 3




66. The IAF could be described as a sister organization to the ILAC; it was a legal entity under the US law and had similar membership and organizational structure as the ILAC (Figures 4 and 5). With respect to Members, there were:

- (a) 41 Accreditation Body Members (of which 32 MLA signatories);
- (b) 15 Associates (stakeholders);
- (c) 4 Regional Groups; and,
- (d) 2 Special Recognition Interest Liaison Groups (ISO, QUEST).

67. The Asia Pacific region was represented in the IAF through the PAC (Pacific Asia Cooperation). For the time being, the IAF had established its Multilateral Recognition Agreement only in the field of quality systems certification. The intention of the IAF was to extend the scope of this MLA to product certification and environmental management system certification in the near future. With respect to inspection, the two organizations (ILAC and IAF) had decided to cooperate in order to establish equivalent multilateral agreements in the field of inspection. This had, however, not yet been established.

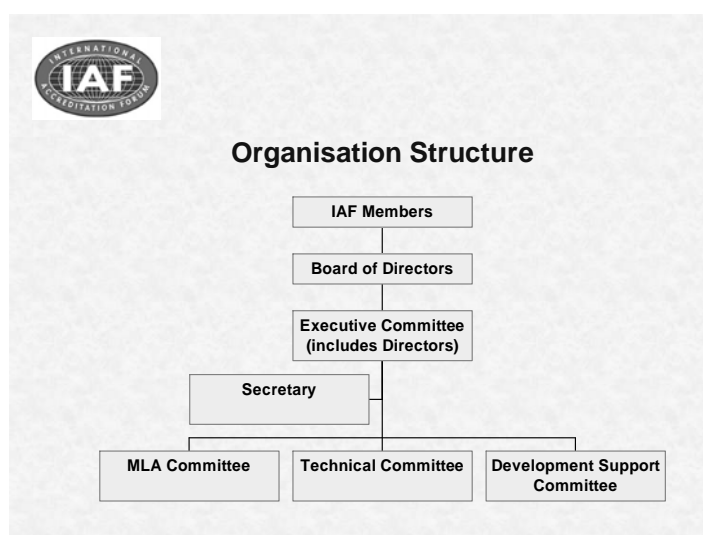
Figure 4



MLA Signatories

EA	PAC	IAAC	SADCA	Unaffiliated
Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom.	Canada, China, India, Indonesia, Japan, Korea, Malaysia, New Zealand, Philippines, Singapore, Thailand.	Brazil Mexico	South Africa	USA

Figure 5

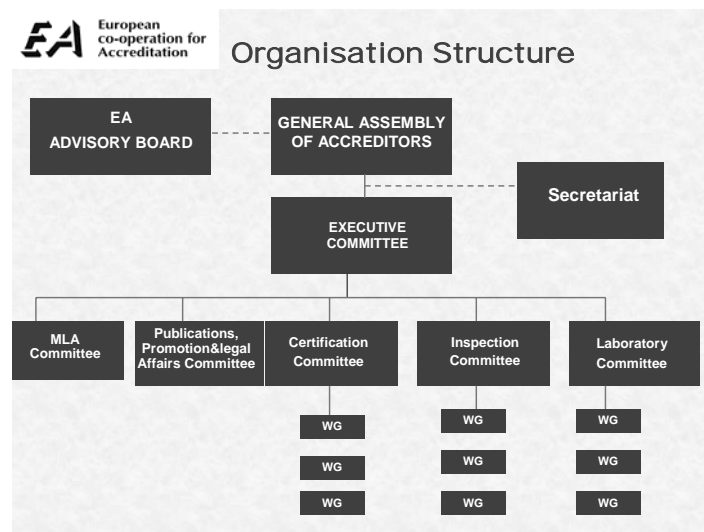


68. The **European Co-operation for Accreditation (the "EA")**, was a legal entity under Dutch Law. It was noted that the difference between the EA membership structure compared to the ILAC and IAF, was that the stakeholders were not Members of EA, but constituted the EA Advisory Board. There were:

- (a) 39 Full Members (of which 31 signatories to the MLA);
- (b) 3 Associate members; and,
- (c) 12 Contracts of cooperation.

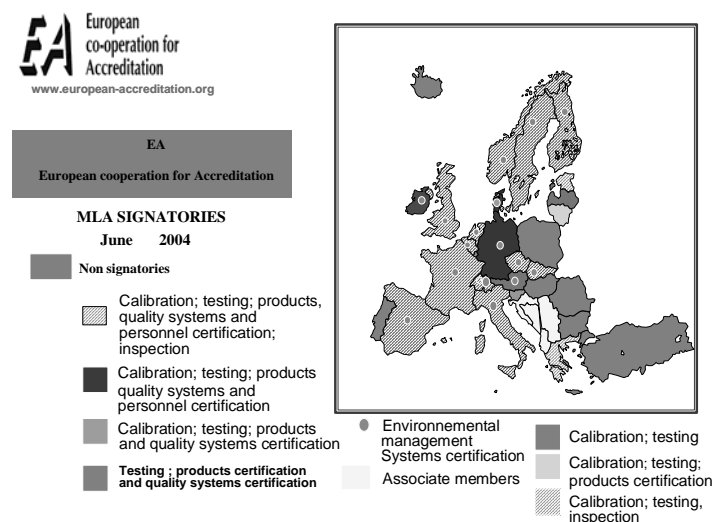
69. All the categories of stakeholders were on the Advisory Board. This Advisory Board, which had been established five years ago, permitted the stakeholders at the European level to give accreditation bodies (Members of EA) their views. The MLA Committee of the EA was in charge of managing the MLA. There existed also a number of Technical Committees (Figure 6).

Figure 6



70. Regarding the EA MLA Signatories, it was explained that the EA MLA covered all the fields of accreditation (testing, calibration, inspection, product certification, quality system certification, environmental management system certification, product certification, personnel certification). However, the establishment of the Multilateral Recognition Agreement was done as a step-by-step process, which meant that while some of the EA Members had been recognized as competent and impartial to deliver accreditation in *all* fields, others had not yet reached that level of recognition. Figure 7 showed the various levels of recognition achieved by the EA MLA signatories.

Figure 7



71. The representative of ILAC, IAF and EC noted that the ILAC (laboratories) and IAF (certification bodies) operated world-wide and that the EA was an example of a regional co-operation accreditation body, operating only in Europe. It was important to underline that none of these organizations provided themselves any accreditation. Only their Members provided accreditation, and therefore, it was important to stress the role of these organizations as *organizations of* accreditation bodies. Their main tasks were:

- (a) harmonization of accreditation practices between members (establishing guidance);
- (b) establishing a multilateral recognition agreement / arrangement (peer evaluations);
- (c) promoting accreditation as a tool for facilitating trade; and,
- (d) helping developing countries to set up their own accreditation schemes.

72. Regarding the work of *accreditation bodies* themselves, it was explained that these worked more or less in the same way as conformity assessment bodies. The first step was the receipt of a request for accreditation. Second, an assessment of the applicant was undertaken. This assessment was, in essence, an audit with an assessment team composed of a quality assessor and technical experts. The third step was the decision made on the basis of the assessment report. After the decision was taken the applicant bodies were granted accreditation, and this accreditation was monitored. This meant that there would be surveillance visits and accreditation was renewed after a certain period. He noted that the future ISO Standard 17011 would give more guidance on how to harmonize the surveillance and reassessment periods.

73. It was stressed that there was a need to harmonize accreditation practices even when these relied on international standards established by ISO (ISO established international standards used by accredited bodies, but also by the accreditation bodies themselves). All actors relied on the use of the international standards. However, these standards needed to be clarified or needed some precision in their application so as to ensure that one accreditation was equivalent to another. This was the first main role of *organizations of accreditation bodies*.

74. The second one was to establish the Multilateral Recognition Agreements. These were based on peer evaluations. All accreditation bodies that were accepted as signatories to an MRA (or MLA) had been evaluated by their peers. An example of this was the assessment of COFRAC (*Comité Français d'Acréditation*) by an EA team. In this case, COFRAC was audited for one full week by six peer evaluators from several countries of Europe. This worked in the same way at the international level. ILAC and IAF relied on their regional cooperation bodies (for example, EA in Europe, APLAC or PAC in the Asia Pacific) in this respect. Only those accreditation bodies that had been peer evaluated could be signatories to the MLAs. These peer evaluations were conducted every four years.

Figure 8



75. The third main task of ILAC, IAF and EA was to promote accreditation as a tool for facilitating trade (Figure 8). Trade facilitation was meant both from a national and international

perspective. The role of accreditation was to reduce the need for multiple assessments, this was sometimes referred to as "one-stop testing, one-stop certification". If there was confidence in a test or in a certificate because it had been covered by an accreditation body, then there should be no need to repeat that test, or check the certificate. Moreover, accreditation in the field of laboratories also provided confidence in the traceability of measurements to SI units.

76. Industry, as the main stakeholder in accreditation bodies, was involved in accreditation bodies' work, and, therefore, recognized accreditation as important to establish confidence. The issues were the same with respect to regulators. It was important that regulators had confidence in the work done by accredited bodies (MoUs between the EA and the European Commission existed, for example). Accreditation in itself was not so important. What was important was the conformity assessment activities done under the control of accreditation and the confidence in these activities.

77. ILAC and IAF also cooperated with standard-setting bodies and there existed an MoU between ILAC, IAF and ISO which was signed in March 2004. This MoU was designed to facilitate cooperation in technical work and to exchange views on the complaints received. The purpose of this was to avoid, for example, deficient ISO 9000 certification or accreditation, which could happen despite surveillance.

Figure 9



78. In respect of assistance given to developing countries to set up their own accreditation schemes (Figure 9), there existed a joint ILAC/IAF Committee which addressed this goal and identified the needs of new and developing accreditation bodies. This work dealt mainly with the training of assessors and translations of documents. The joint ILAC/IAF Committee organized seminars in order to provide information to newly established bodies. ILAC and IAF had allocated some money from their budgets which was drawn from the fees which came from each Member (Figure 9). It was also noted that there was an important cooperation between ILAC, IAF and UNIDO (for the time being through separate MoUs between UNIDO and ILAC and IAF). The objective of this co-operation was to develop accreditation bodies. At the European level, the EA coordinated projects financed by the European Union, such as the PHARE project for Central and Eastern European countries, and MEDA which was for the Mediterranean area.

79. The representative of ILAC, IAF and the EA stated that a global approach to conformity assessment based on accreditation, carried out by IAF and ILAC MLA or MRA signatories offered

the best means to reduce and eliminate conformity assessment-related trade barriers and, therefore, facilitated trade.

2. Discussion

80. The representative of the United States wished to know more about the ILAC requirement regarding the need for accreditation bodies to be "independent". What did it mean for an accreditation body to be independent? Second, the United States also asked for some details on the issue of ILAC Membership. She understood that there were 45 Full Members which were signatories to the arrangement. But there were also "19 stakeholders" and "4 Regional Co-operation bodies" (paragraph 63, above). What were the differences? Also, was it possible for several countries to join together, so as to pool resources, and establish one accreditation programme that would service a combined market? And if so, could such an organization be a signatory under the ILAC procedures?

81. Regarding the independence of accreditation bodies, the representative of ILAC, IAF and EA replied that international standards required accreditation bodies to be independent and impartial. The forthcoming publication of the ISO/IEC Guide 17011 would clarify exactly what was meant by the independence and impartiality of an accreditation body. For the time being there was the ISO Guide 58 for the accreditation of laboratories; Guide 61 for accreditation of certification; and Guide 17010 for accreditation of inspection. All of these dealt with what constituted "independence". But, he noted, nobody was ever fully independent; some accreditation bodies, for example, were linked to their governments, or to their National Measurement Institutes (NMIs). What was important was the independence and impartiality of the *decision* of accreditation itself. Finally, it was confirmed that an accreditation body established commonly between several countries could become a signatory to the ILAC or the IAF MLAs.

82. In respect of how ILAC/IAF were dealing with specific programmes, the representative of ILAC, IAF and EA noted that it happened sometimes that a sector of the economy wished to establish its own scheme for standardization, accreditation and certification (examples existed for organic food producing or sustainable forest operating). The difficulty in those cases came from the structure of the schemes which were not independent and/or impartial and could be competing with nationally recognized accreditation bodies. For the time being, there were still discussions on this issue in both ILAC and IAF, but they could not be offered membership as their goal was not to enter in to a multilateral recognition arrangement. Another goal was to avoid double accreditation for some conformity assessment bodies in certain countries.

83. Regarding the status of the stakeholders in ILAC and IAF, the representative of ILAC, IAF and EA presented the different categories: direct stakeholders (organizations of laboratories or certification bodies), indirect stakeholders such as industry associations (such as ISCA), end-consumers associations and regulators. With respect to getting the participation of regulators, this was easier at the national level and not so difficult at the regional level (the EA had, for example, close links with the European Commission). However, it was difficult at the global level. It was perhaps a good sign that the ILAC and IAF could speak at the WTO; this kind of co-operation was necessary.

84. The representative from Chinese Taipei asked, first, if there were any studies that had been undertaken by ILAC or IAF with respect to how their test results or certification results (coming from accreditation schemes recognized by ILAC and IAF) had been recognized by regulators? Second, she sought some clarification and elaboration on the content of the MoUs between the European Commission and EA. Moreover, regarding the MLA or MRA between various accreditation bodies within ILAC and IAF, how did this agreement work? Did this mean that the results of accredited laboratories, or certification bodies, were accepted by other accreditation bodies? How did the recognition work in terms of the acceptance of test results, or certification results? Third, were there

studies showing how the MRA in ILAC (or MLA for IAF) affected the use by regulators of the results of the accreditation?

85. The representative of ILAC, IAF and EA confirmed, in respect of first question, that studies had been undertaken for ILAC two years ago and that another survey was under way. He stated that the situation in each country was different depending on the relation – or links – between national accreditation bodies and their governments. In some cases there was a good recognition by regulators of accreditation. Regarding the MoU between the European Commission and EA, it was noted that it had resulted in the provision of technical help through the EA to some EC Member States to set up accreditation bodies. Moreover the European Commission was represented in the EA Advisory Board (Figure 9). More specifically on the content of the ILAC or IAF or EA MRAs, it was noted that each signatory to an MRA recognized, at the same level of confidence, *any* accreditation granted by another signatory. This meant that a test report covered by an accreditation granted by an MRA signatory was considered at the same level of confidence as in another country where there was another MRA signatory. To get the recognition of the results themselves the two laboratories needed to be using the same test standard.

86. The representative of Egypt sought a clarification from ILAC/IAF relating to the procedures through which a member was granted accreditation. It was his understandings that the first procedural step for the granting of accreditation was the receipt of a request. What was the type of request made, its content, and what was the time frame involved for assessing such a request? This was of importance to African countries.

87. The representative of ILAC, IAF and EA noted that the procedure was rather simple: the applicant needed to contact its accreditation body requesting accreditation for the scope of conformity assessment. The first step in the process was to define the scope: was it testing, or calibration, or both? And what kind of testing or calibration did it constitute? This was done jointly between the applicant and the accreditation body. The second step was the assessment. The assessment team was constituted depending on the scope which determined the choice of technical expert, and the size of the team. Finally the assessment report was studied and the decision taken on its basis. The full process needed at least several months, depending also on the responsiveness of the applicant.

B. ISO/IEC STANDARDS FOR ACCREDITATION

1. Statement

88. The representative of the ISO⁶ began by stressing that ISO was not an accreditor. The ISO's role was to set the framework, the overall rules, procedures, requirements for all types of conformity assessment, one of which was accreditation. The so called ISO/CASCO "toolbox" covered all these various aspects of conformity assessment (Figure 10). With one exception (out of 23) all the documents were ISO/IEC International Standards or Guides.⁷ The "CASCO" (the conformity assessment committee) developed these documents that subsequently were voted on by the Members of ISO. These were also voted on and approved separately by the IEC National Committees. In other words, CASCO was run under the ISO Central Secretariat, but produced documents that were approved by both ISO and IEC Members.

⁶ Mr. Graeme Drake, Head of Conformity Assessment at the ISO Central Secretariat.

⁷ The only exception is ISO Guide 27:1983, Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.

Figure 10

ISO/IEC tool box for conformity assessment

- A tool box covering all aspects of definition, implementation, evaluation, recognition and use of conformity assessment (calibration, testing, certification, inspection, accreditation)
- Through the *ISO Committee on conformity assessment* (CASCO), ISO and the IEC provide a neutral platform for the establishment of internationally recognised CA procedures, covering 1st, 2nd and 3rd party assessments
- These International Standards and Guides fall into the 'international standards' referred to in the WTO TBT agreement

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Figure 11

Accreditation : Determining and monitoring competence

- Once requirements for products, systems or personnel are established, there is often a demand, whether from public authorities or from the market, for some form of attestation of conformity
- The purpose of accreditation bodies is to provide a process to determine and monitor the competence of conformity assessment operators (laboratories, certification bodies/registrars, inspection bodies). It facilitates acceptance of results, i.e. through Multilateral Agreements (MLAs) between accreditation bodies based on peer assessment
- The ISO/IEC toolbox provides the International Standards and Guides that set out fundamental requirements for the accreditation process, accreditation bodies, accredited activities, as well as guidance on peer assessment and mutual recognition.

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89. Accreditation was *one means* of establishing the competence of people and organizations that in the market place held themselves out to be good conformity assessment operators. Accreditation established that the product certifiers, the testers, the laboratories, etc., were competent, and that they had the right skills in order to provide the services they claimed to be able to provide.

Figure 12

ISO's partnership with the international accreditation community

- ♦ ISO does not undertake accreditation or other conformity assessment activities
- ♦ IAF-ILAC-ISO Memorandum of Understanding (MoU) signed in March 2004:
 - ♦ reaffirms ISO/IEC Standards and Guides as the prime vehicle for setting international requirements for accreditation and accredited conformity assessment activities;
 - ♦ IAF and ILAC may establish guidance statements to ensure consistent application by accreditors, without adding requirements; and
 - ♦ Organizes the collaboration on the development and updating of standards, as well as for the handling of complaints

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90. Regarding the relationship between ISO, IAF and ILAC, and EA (Figure 12). It was noted that with the exception of ISO, these bodies were either international or regional associations of accreditors. ISO set the rules for *how* accreditation could be done, but did not *involve* itself in actually doing accreditation. The MoU with IAF and ILAC separated out the functions of each organization. Basically it reaffirmed a number of understandings that had evolved over the past 20 years. That ISO/IEC standards and guides were the prime source of rules, procedures, and requirements for how things must be done in a generic way. The IAF and ILAC, on the other hand, developed guidance documents on how accreditors should apply, in a consistent manner (and without adding additional requirements), the more generic texts of the ISO.

91. The other main component of the MoU with IAF and ILAC was a commitment to share complaints about how the system was working. However, while the IAF, ILAC and ISO had agreed to share complaints of a generic or structural nature to examine whether there was anything wrong with the system or the standard, or the guidance provided, they would not address other more business-oriented complaints that were not of a generic, structural nature or motivated by commercial self-interest.

Figure 13

ISO/IEC 17011

- ♦ ISO/IEC 17011, *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*
- ♦ Will replace:
 - ♦ ISO/IEC Guide 58:1993, *Calibration and testing laboratory accreditation systems -- General requirements for operation and recognition*
 - ♦ ISO/IEC Guide 61:1996, *General requirements for assessment and accreditation of certification/registration bodies*
 - ♦ ISO/IEC TR 17010:1998, *General requirements for bodies providing accreditation of inspection bodies*

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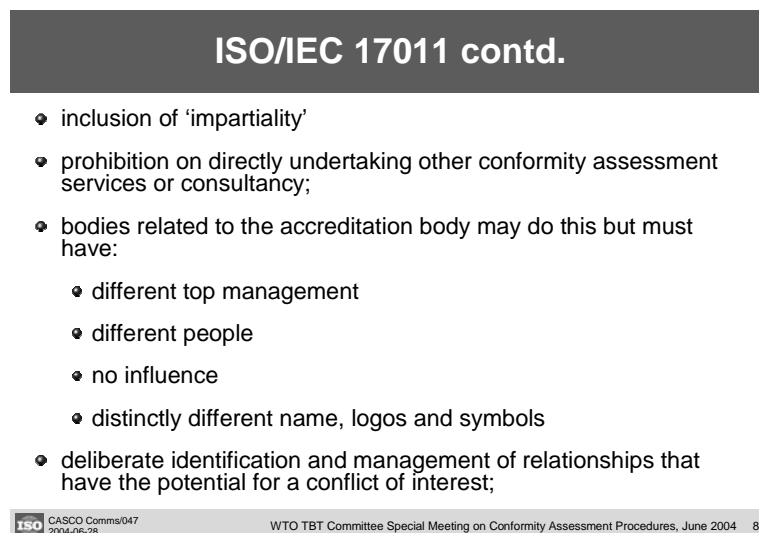
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92. The representative of the ISO noted that there was a new international standard on accreditation that had been approved in 2004. The final vote on this document, ISO/IEC 17011, had been completed in May and had received over 92 per cent approval from the voting Members of ISO and IEC. For an international standard, this was high. ISO/IEC 17011 would replace the current suite of documents which accreditation bodies used for their daily operations; these would probably be withdrawn at the end of 2004 (listed in the Figure 13). Once published, ISO/IEC 17011 would contain the future requirements on accreditation. The full scope of the standard was covered by the following points:

- (a) scope;
- (b) normative references;
- (c) terms and definitions;
- (d) accreditation body;
- (e) management;
- (f) human resources;
- (g) accreditation process; and,
- (h) responsibilities of the accreditation body and the conformity assessment body.

93. In essence, the new international standard set out what an accreditation body was supposed to do, or not supposed to do. It set out how accreditation bodies should manage themselves: what human resources they should have; what the generically approved process for accreditation was. At the end, the standard defined and separated out various responsibilities. Finally, it set out what an accreditation body was responsible for and what the responsibilities of a conformity assessment body, accredited by an accreditation body, were.

Figure 14



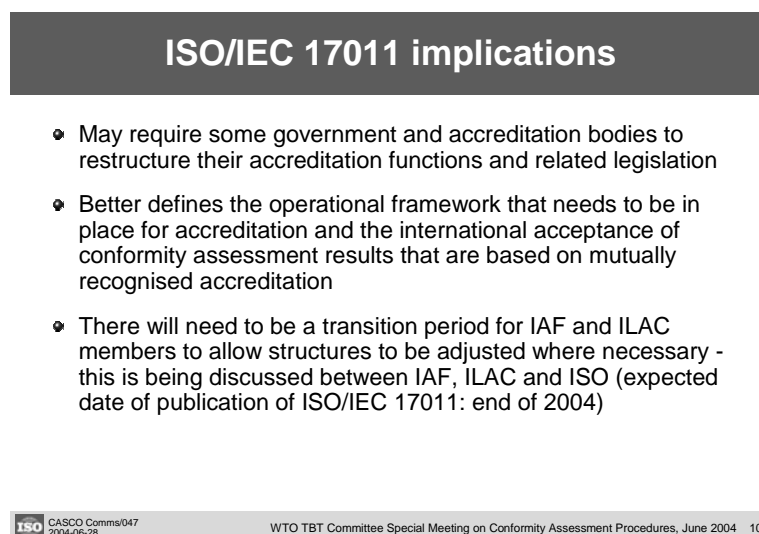
94. The new standard had underscored, very clearly, the need for accreditation bodies to show and demonstrate that they were impartial. This concept was not quite the same as 'independence'. Yet impartiality had been generated as a requirement in the new standard in a number of ways. Effectively, accreditation bodies that wished to hold themselves out in the market place as meeting the requirements of the international standard 17011 in the future could not, themselves, undertake any form of conformity assessment activity that they would otherwise be accrediting. It was this separation of responsibility which was important: one could not have accreditation bodies accrediting

in a particular field of conformity assessment and, at the same time, have another unit within that same body which actually operated in their field of conformity assessment. These two had to be separate.

95. This posed quite a lot of problems for some of the current accreditation bodies in the world. This was particularly so for those accreditation bodies which were part of their own government. Applying ISO/IEC 17011, in theory, meant that the accreditation part needed to be sucked out of the government and set up as a separate entity. For many developing countries, but also for many developed countries, this was problematic and sometimes politically unacceptable; it might not either be the most efficient method of operation for a particular market.

96. As a result, it had been recognized (third bullet point Figure 14), that it was possible to have bodies related to the accreditation body, that did provide conformity assessment services, but through having: different top management; different staff; no influence on the accreditation decision; and distinctly different names and logos. Taking these points into account, it was believed that the impartiality and the separation was enough to make sure that through this standard, accreditation remained isolated or independent so that it could then be impartial when it undertook accreditation activities. To underscore the above stated, there was now also a requirement in the standard that made it the accreditation body's own responsibility to analyse all its relationships, and to manage conflicts of interest, if they existed. This was something that *other* accreditation bodies could contest.

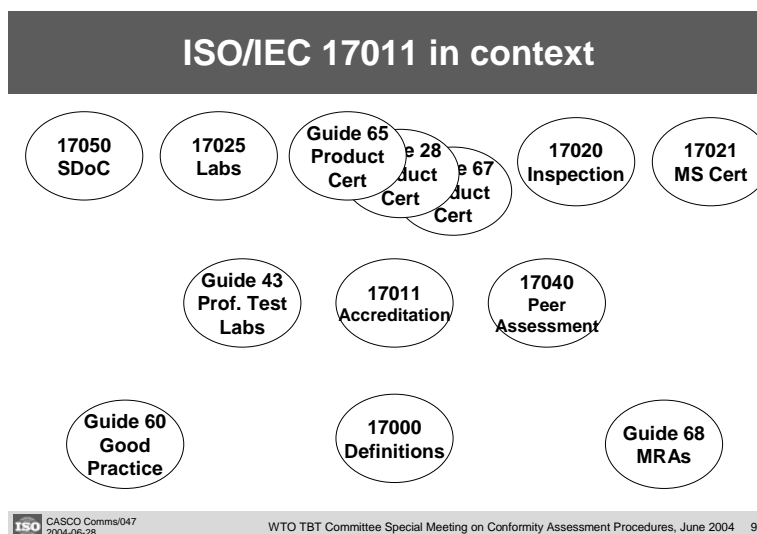
Figure 15



97. The ISO/IEC Standard 17011 was, in some senses, a ground breaking document. It would require questions to be raised about the placement of the accreditation activity within a country: whether it was inside or outside government, and how separation and impartiality was ensured. This would also be the future basis for the accreditation members of the IAF and ILAC.

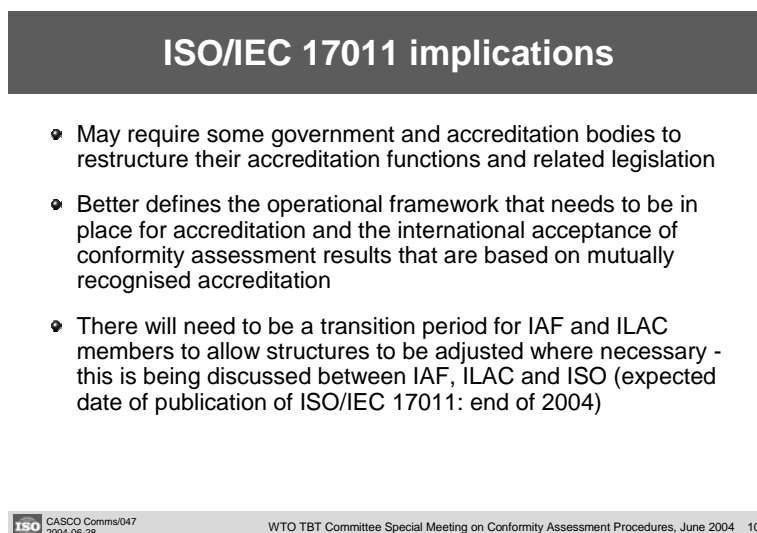
98. In terms of implementation, there would have to be some form of transition period. The current accreditation bodies set up around the world were based on the three previous guides (Figure 13) and there would be a need for time for those systems to adjust to the requirements of the new standard. In some countries, these were already in place while in other countries this was not the case. Although no transition date had been set yet, this was likely to be done when ILAC, IAF, and ISO met at the highest level in Cape Town, South Africa in October 2004.

Figure 16



99. In relation to Figure 16, accreditation bodies that met 17011 accreditation (centre of the slide) could accredit the top level (laboratories, product certifiers inspection and management systems certification). The whole conformity assessment system was based on ISO/IEC Guide 60 on Good Practice, which would be published in 2004 along with ISO/IEC 17000 on Vocabulary and general principles for conformity assessment. ISO/IEC Guide 68 was about Mutual Recognition of Conformity Assessment results (MLAs, MRAs, etc) and had been published in 2002. This has previously been reported the WTO TBT Committee.⁸

Figure 17



100. In respect of developing countries and conformity assessment work, one of the criticisms which had been levelled at ISO, or in particular the Committee on Conformity Assessment, was that there was not enough developing country input. Much had happened however, over the last five years to ensure developing country participation. The current Chairman of CASCO was from a developing country (Mr. Mario O. Wittner from Argentina). Moreover, in CASCO, there were approximately

⁸ G/TBT/W/73/Add.1.

100 countries with voting rights and half of these were developing countries. There had been a big push to ensure that Membership in CASCO was not limited to North America, Europe and Australasia. This had led to the present situation where the dynamic in terms of the Members participating – writing comments and having their views understood – was more balanced.

101. Moreover, the ISO was currently in the midst of a two-year programme which involved regional workshops in developing countries on conformity assessment.⁹ One of these had been completed in Brazil in May 2004 for the Americas region, and the next one would take place in December, in India for the South Asia region.

2. Discussion

102. The representative of the European Communities asked, in respect of the MoU between ISO, ILAC and the IAF, whether ILAC and IAF cooperated in such a way that their guidelines were identical; or did they develop guidelines independently?

103. The representative of ISO said that the IAF and the ILAC would, on this particular subject (the one standard for accreditation) begin a process of writing what guidance was necessary in a joint group as of October 2004. There was still, however, discussion with respect to how much guidance would be required as there was a significant amount of detail in the international standard as it stood. Nevertheless, in relation to other conformity assessment standards, there could be specifics for laboratories, which ILAC would want to include, and, likewise, more detail in respect of certification bodies which IAF might want to address.

104. The representative of Egypt suggested that the ISO conduct a workshop on conformity assessment in Africa.

105. The representative of Canada asked how the development of an ISO standard or guide on conformity assessment differed from that of an ISO standard for a product. Also, what was the kind of status that international standards for conformity assessment had compared to those of standards for products?

106. The representative of ISO noted that the ISO was not the only international body that could offer globally relevant standards; this was evident in some sectors in particular. However, in the area of conformity assessment, the international standards and guides set by ISO/CASCO fully met the definition of international standards under the TBT Agreement. The process to develop such standards was set out in the ISO/IEC directives. Those who could participate in this work were all member countries of IEC or ISO. Moreover, a set of liaison bodies existed with any particular committee. In CASCO's case, there were 10 formal liaison bodies which included ILAC and IAF. These liaison bodies did not only consist of accreditors, but also of representatives of the certification bodies and the laboratories who were actually accredited. In sum, the CASCO documents resulted from a good degree of representation from all interested parties.

107. The representative of Australia asked, in respect of impartiality, whether there was a move to suggest that governments should separate themselves altogether from accreditation activities.

108. The representative of ISO clarified that this was not the case. There was no "master plan" that suggested that accreditation bodies could not be part of governments. Nevertheless, the accreditation *function* had to be able to demonstrate that it was impartial. To do this some countries had chosen to separate out the accreditation bodies from their governments thereby placing it under another operational framework. Others, however – and legitimately so – had kept it as part of the government (or even brought it inside government), but this was done together with the appropriate checks and

⁹ Further information on conformity assessment can be found at <http://www.iso.org/>.

balances so as to be able to demonstrate that the services provided by the accreditation body remained impartial.

III. OTHER ISSUES RELATED TO CONFORMITY ASSESSMENT

A. JORDAN

1. Statement

109. The statement made by the representative of Jordan was circulated in G/TBT/W/241.¹⁰

2. Discussion

110. The United States noted that Jordan seemed to be moving towards conforming to the new ISO/IEC Standard on accreditation and developing its independence. She asked about the rationale behind the choice the four groups of products for DAMAN certification: toys, electrical and electronic appliances, safety equipment, vehicles and tyres and food products on a voluntary basis. Had there been some study or evidence of problems that had underpinned this choice?

111. The representative of Jordan stated that the products were chosen because Jordanian authorities did not have the capability or testing infrastructure to verify the conformity of the compliance of these products to the technical regulations. Hence, to ensure protection of health and safety of Jordanian people, these products were subjected to mandatory testing.

112. The representative of Malaysia referred to the section on inspection and market surveillance and asked whether the inspection of factories was also undertaken at overseas producers exporting to Jordan. Second, in respect of the risk based system, was it intended to be an alternative to the DAMAN Program?

113. The representative of Jordan responded that Jordan was only interested in products that entered the Jordanian market. Hence, it was only the Jordanian factories that were subjected to the local visits. In respect of the second question, she noted that the risk based system could become an alternative to the DAMAN program in the future, if it was developed to include all the factors that should be considered when developing a system.

B. EUROPEAN COMMUNITIES

1. Statement

114. The representative of the European Communities¹¹ began by stressing that the European Union was a community of different countries. While the overall approach was to form an internal market with free movement of goods between these countries, the individual EC Member States had all started out with individual certification schemes, different technical regulations and conformity assessment procedures.

115. For conformity assessment, two main instruments were used: (i) mutual recognition in the sense that if a product was approved in one country, then other countries of the Community were obliged to recognise the conformity assessment results and allow the product to circulate freely, (ii) technical harmonization which entailed the establishment of European Directives, which basically harmonized or approximated the laws of the Members States.

¹⁰ Mrs. Rab'ah Al-Ajarmeh, Head of DAMAN Unit at the Jordanian Institution for Standards and Metrology.

¹¹ Mr. Brian Jenkinson, Deputy Head of Unit, Directorate General for Enterprise, European Commission.

116. With respect to pre-market assessment, the representative of the European Communities referred to the "New and Global Approach". These policies, which were complementary to each other, and developed in the mid to late 1980's, were designed to cover wide fields of products or risks with one piece of legislation and to impose generic essential requirements that would not become obsolete and that limited government intervention to what was essential.

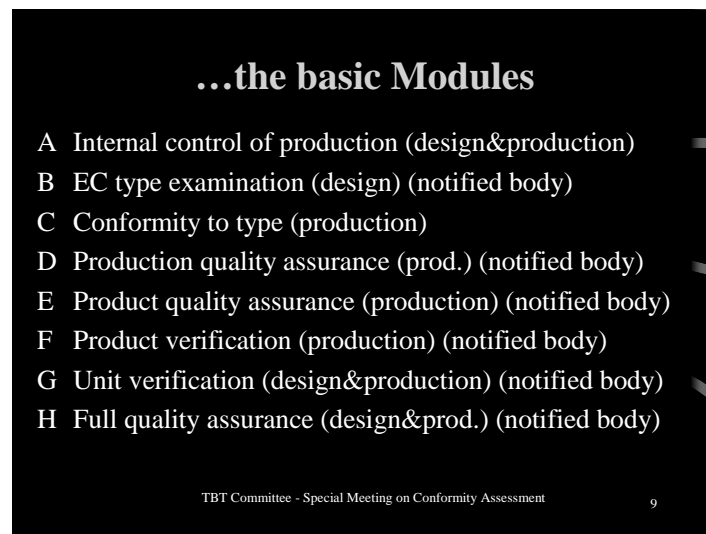
Figure 18



117. In respect of the Global Approach, which was relevant to conformity assessment, the fundamental point was that the manufacturer (or his authorised representative in the case of imported goods) was responsible for conformity. There was an effort to limit the number of different types of conformity assessment procedures to a reasonably small range (these were referred to as "modules" in the Global Approach). In most cases, the manufacturer was aided by a Notified Body (a certification body – or conformity assessment body) and there was an element of choice in that the manufacturer could choose any Notified Body.

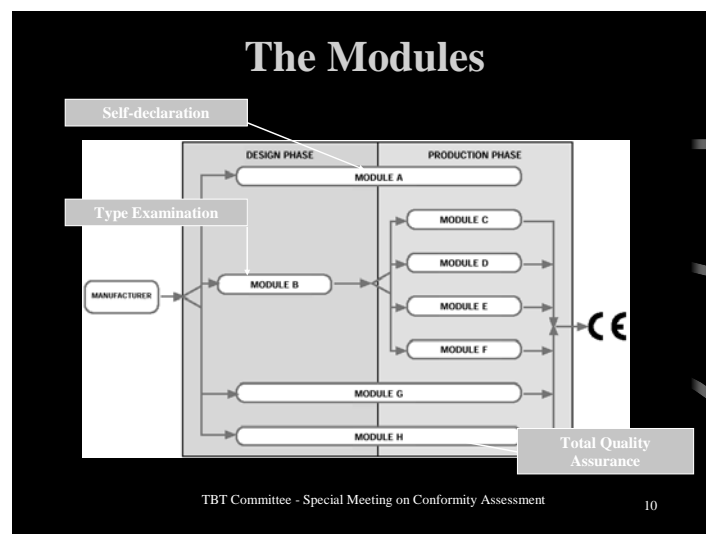
118. The key elements of the Global Approach were set out in Figure 18. It established eight basic modules to cover different situations (Figure 19). Each sectoral Directive specified which modules could be used. In some cases, it was just a single module or maybe two modules used in combination with each other. In other directives, there was a choice. Sometimes, the choice was not for the manufacturer to make; this depended on the type of product and the risk associated. Nevertheless, in general terms, every directive specified which modules applied. These covered the design and production phases and most modules required the use of notified bodies. Module A was the supplier's declaration of conformity (SDoC).

Figure 19



119. Figure 20 showed that SDoC covered *both* the design phase and the production phase (because the technical file associated with SDoC covered both these aspects). Some other modules, such as type examination, only related to the design phase and the production phase was covered by a second module. Module G and H also covered both phases.

Figure 20



120. In the EU there were about 1300 certification bodies. These were independent third party bodies, notified by the Member States whose responsibility it was to ensure their continuing competence. There was a system in place whereby the Notified Bodies met regularly to discuss problems of mutual interest. Hence, whilst there was cooperation, on the other hand, there was also competition, in that a manufacturer could go to the Notified Body of his choice. The designation process for the Notified Bodies themselves was supported by accreditation, although, in the EC system, this was not mandatory. The EN 45000 Series of Standards was used and these were usually identical to the ISO guides and standards.

121. Three of the modules referred to quality assurance. These were all optional – there was no obligation to always use quality assurance modules and what the ISO 9000 offered was only one solution, and it was not mandatory.

122. In the context of SDoC, it was the responsibility of the manufacturer to prepare documentation related to the product to demonstrate that the product complied with the requirements. This was done through the "technical file" which was basically a set of documents that had to be made available to the authorities and the Notified Bodies upon request.

123. The EC Declaration of Conformity was drawn up and signed by the manufacturer. It was a commitment to declare that the product conformed to the requirements defined in each Directive. This included items such as the product, information on the manufacturer, applicable Directives and standards.

124. Another part of the conformity assessment procedure was that the products be marked with a CE Mark. Such marking meant that the product met all the legal requirements and that it could be placed on the market. This was not a mark of origin or quality. It was simply a mark that indicated that the equipment complied with the legal requirements for it to be placed on the market.

125. Post-market control ensured that market surveillance guaranteed equal protection for citizens and a level playing field for enterprises. The objective within the EU was to achieve a uniform, high level of enforcement of internal market legislation. In the EU this was a national responsibility and it was carried out by government officials in the market place. The way in which this was carried out could vary. This was not a disadvantage in that if different countries applied slightly different procedures for market surveillance, there was a better chance of a product being found to be in non-conformity.¹²

2. Discussion

126. The representative of the United States noted that the EC approach allowed for competition amongst Notified Bodies, but, according to her understanding, there was no ability for a body located outside of the European Union to become a Notified Body; this was an internal EU matter – in other words, the competition did not extend beyond the European Union.

127. The representative of the European Communities confirmed the US understanding. The Directives required that the Notified Bodies had to exist in one of the territories of the Member States. In a union of 25 countries, it was difficult to imagine how the "community" could manage to assess the competence of a body outside the EU territories. However, this was an issue that was raised regularly and was therefore on the agenda, and the EU would be looking into what steps, if any, could be taken.

128. The representative of the United States recalled a point had been made to the effect that the ISO 9000 Standard was not mandatory; it was but *one* option. What were the other options and how did suppliers demonstrate that they had other credible quality assurance approaches? The US understanding was that this was done on a case- by-case basis with the Notified Bodies and that there was no centralized body informing suppliers of options (such as through the provision of a list of other available options).

129. The representative of the European Communities noted that the US question referred to quality systems in use (the different quality procedures within the 8 modules). The answer to this question was rather similar to the choice that the manufacturer had to demonstrate compliance with the essential requirements. If the manufacturer used European Standards, there was a "presumption of conformity" that the essential requirements in the directives had been met (because the European Standards covered the essential requirements). There was a similar concept for the application of the quality system standards. Normally, a manufacturer would seek certification from the Notified Body

¹² More information on the New Approach and the Global Approach (11 EU languages) can be found at: Internet (<http://europa.eu.int/comm/enterprise/newapproach/index.htm>).

of the quality system in place based on the international standard, but there was no obligation for him to do so. Hence this was similar to the notion of "presumption of conformity".

130. The representative of Brazil asked what criteria were used to demand accreditation for Notified Bodies.

131. The representative of the European Communities clarified that the designation of the conformity assessment bodies in Europe was a Member State responsibility and the use of accreditation was not mandatory. Nevertheless, in most Member States accreditation was used – but, again, it was the national responsibility of a Member State to take the appropriate measures necessary to ensure that the criteria for the designation of a Notified Body were met (and accreditation was one way of doing this). There was, in addition, an on-going discussion on the role of accreditation within the EU.

132. The representative of China asked whether the New and Global Approach also applied to the 10 new Members of the EU.

133. The representative of the European Communities noted that the accession process of the 10 new Member States had taken several years and that all new Members States had had to transpose the existing stock of Community law. Therefore, as of 1 May 2004, the rules on the New and the Global Approach applied to both old and new Member States.

134. The representative of India asked where the issue of recognition through mutual recognition agreements (MRAs) fit in the overall approach of the EU on conformity assessment.

135. The European Communities noted that mutual recognition agreements (MRAs) with countries outside of the EU, were based on the fact that the technical regulations in place and the way that bodies were notified in both parties were different: the MRA was not a tool which attempted to determine equivalence or harmonize. An MRA recognized the competence of each party. In this sense, when the EU negotiated MRAs with countries outside Europe, the EC explained how the designation of Notified Bodies worked in the EU. However, in any event, to operate under the terms of the MRA, bodies had to be designated specifically with the knowledge that they could approve products against a third country legislation. In principle these agreements, which had gone through a stage of negotiation and implementation, were now, by and large, operational and were working.

C. BUREAU INTERNATIONAL DES POIDS ET MESURES (BIPM)¹³

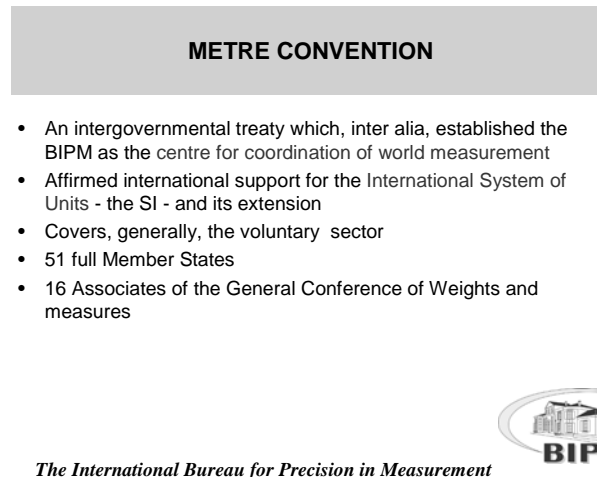
1. Statement

136. The representative of the BIPM¹⁴ noted that the BIPM had a very strong link with conformity assessment because, in essence, the BIPM covered the measurements that were necessary to show traceability to international standards so as to be able to comply and show conformity in a confident way. It was important to note that metrology, accreditation and standardization represented three groups of activities that were one consistent and coherent whole. All countries, of whatever stage in development, needed to have some aspect of each of those elements in place.

¹³ International Bureau for Precision in Measurement.

¹⁴ Professor Andrew Wallard, Director, BIPM.

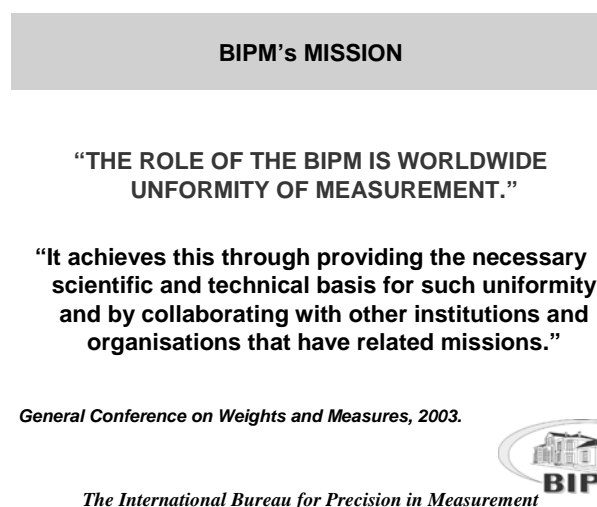
Figure 21



137. Established in 1875, the BIPM operated under the second oldest inter-governmental treaty in the world (only the International Telecommunications Union preceded it). The BIPM was set up by governments at a diplomatic conference to coordinate measurement worldwide. The heart of that Declaration, the Meter Convention (Figure 21), was the International System of Units. In general the BIPM covered what was referred to as the voluntary sector whereas the OIML dealt primarily with measurement which was part of legislation but there was a very close partnership between the two organizations.

138. There were 51 Full Member States of the BIPM, some of which were developing countries and 16 Associates. The "Associate" group was specifically set up to cover developing countries and *groups of* developing countries (this was relevant to the US delegation's question at the end of paragraph 80, above and paragraph 146, below).

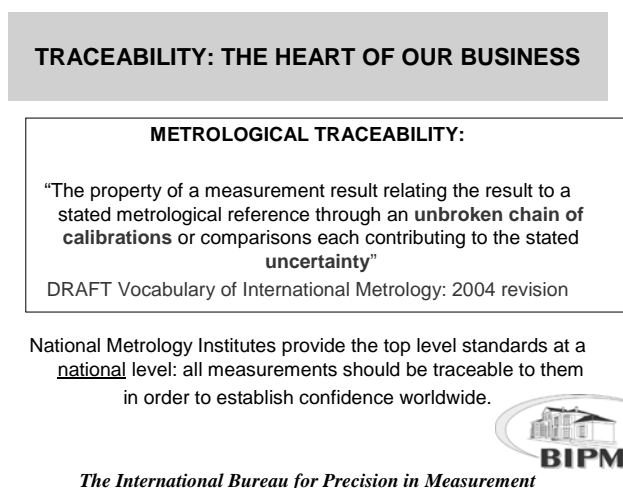
Figure 22



139. The BIPM mission statement was worldwide uniformity of measurement (Figure 22). This could not be done by the BIPM alone. The BIPM was a small organization and it was inevitable that there was a need for partnerships, MoUs, and other types of close relationships with specialist bodies

in their own areas. So, whilst the BIPM had MoUs with ILAC and the WHO, it was essential that there were also partnerships with organizations like the Food and Agriculture Organization (FAO), with ISO, IEC, ITU and specialised technical bodies in a number of areas. This was particularly important as the BIPM moved from traditional activities in physics and engineering to cover areas like food and chemistry.

Figure 23



140. The representative of the BIPM stressed that the International System of Units was at the heart of the BIPM's work. It had provided the international system of units in physics and engineering for over 125 years. Although still lively and meeting new challenges, the huge growth area was now in the area of chemistry, medicine, food and environmental measurements. While it was not always easy to achieve traceable measurement worldwide to unique and agreed measurement standards in these areas, it was the best way of achieving technical confidence. Hence, for the BIPM, the concept of traceability was the selling point; metrological traceability was the process of tracing the result of a measurement through unbroken chains of comparisons or calibrations (Figure 23). In most cases, and in most countries, there would be a national body which provided the top level standards at whatever level of accuracy was appropriate to what was needed in the countries. Ideally, in each country all measurements would be traceable to these national standards.

Figure 24



In 1999 the CIPM developed an MRA between NMIs to address technical barriers to trade caused by lack of traceability and equivalence.

Complying with the MRA means that an NMI's calibration certificates are acceptable world-wide with a validated accuracy.

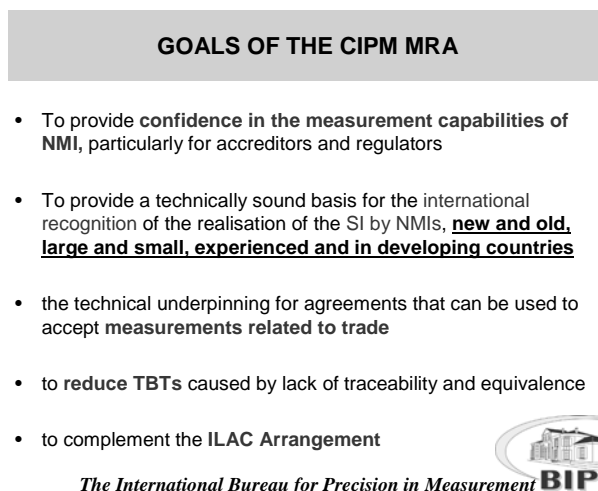


The International Bureau for Precision in Measurement

141. The work of the BIPM was to coordinate the international measurement system. A measurement made by an industrial company needed to be traceable to the standards which were held in that particular country. Here the work of ILAC and ISO/IEC 17025 was important in giving confidence in the traceability of measurements made in accredited laboratories to national standards. However, if the top level standards were not equivalent to similar standards held in other countries, then the whole system that a country might be trying to put in place could be weakened, because there would be no confidence that the top level measurement standards were equivalent.

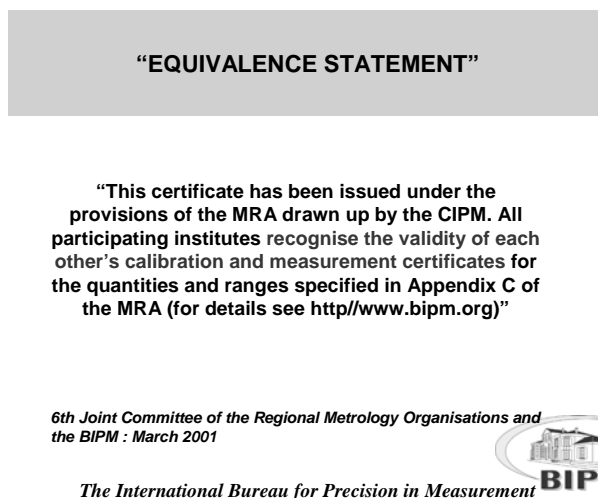
142. However, if ILAC provided the confidence of traceability to national standards for accredited laboratories, how did national metrology institutes prove technical competence and equivalence? This was the role of the BIPM. Up until a few years ago, there had been no formal system in place for doing that. To respond to that challenge, the CIPM (International Committee for Weights and Measures) produced, in 1999, a mutual recognition arrangement (CIPM - MRA) that was aimed at providing technical confidence at that highest level (Figure 24). It was very much driven by the needs of regulators and accreditors, as technical barriers to trade could be caused by lack of equivalence of national measurement standards. The bottom line was that the signatories to the CIPM - MRA accepted each others calibration certifications worldwide.

Figure 25



143. The goal was to provide international confidence in traceable measurement, and in what national laboratories said they could achieve in their measurement processes. The CIPM - MRA provided a technically sound basis for the international recognition of the activities of national metrology institutes from all countries and so helped reduce unnecessary technical barriers to trade caused by the lack of traceability and equivalence.

Figure 26



144. To be part of the CIPM's Mutual Recognition Arrangement, a national laboratory had to (i) have its calibration and measurement capabilities (CMCs) validated by others based on objective evidence (peer assessment); (ii) take part in key comparisons that gave technical confidence in the day-to-day measurements at the NMIs (National Metrology Institutes) worldwide; and to (iii) implement a quality/management system (which was essentially based on ISO/IEC 17025). This was applicable to countries at any stage of development. Whilst this might appear a complicated system, it had the benefit of enabling countries to relate the measurements made, say, in Chinese Taipei, to those in Brazil, Egypt, Germany or Kenya, for example, through the BIPM's international framework. In addition, an NMI which complied with this arrangement could put, on their calibration certificates, a statement like the one set out in Figure 26.

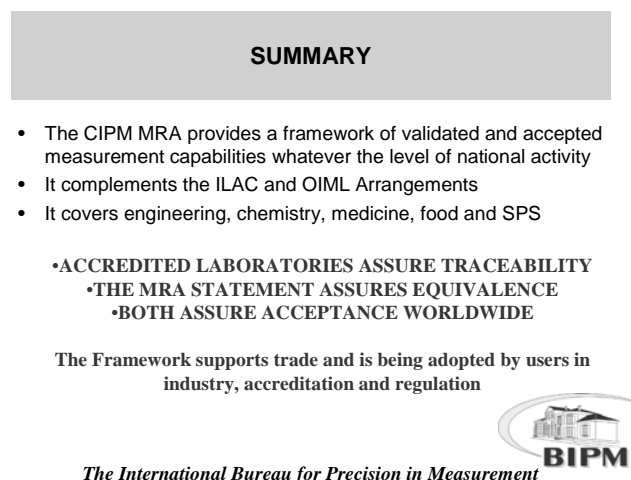
145. The BIPM also maintained a database of fully reviewed and internationally accepted NMI measurement capabilities, including any differences between National Standards (18000 validated and peer reviewed entries). This was the only database of NMI calibration services that assured traceability to the SI units and quantities. As a result, a degree of competition had been created between National Metrology Institutes services in that an accredited laboratory or other user could go to any national institute which was a signatory to the CIPM MRA and ask for a measurement to be made. That measurement would be accepted worldwide.

146. With respect to developing countries, it was stressed that the MRA applied to all countries. The status of "Associate of the General Conference on Weights and Measures" had been created within the Metre Convention to deal with developing countries (currently, he noted, there were 16 such members). Economic groupings were eligible and the BIPM had a strong regional organization within which Regional Metrology Organisations arranged for the participation for many developing countries.

147. On the issue of how regulators used the results, it was stressed that more and more regulations required accurate measurement. Regulators first needed to be confident that measurements made in ISO/IEC 17025 accredited laboratories were traceable to National Standards at an NMI. The CIPM MRA then provided the evidence that Regulators needed to have confidence that the standards at NMIs were equivalent. Hence, there was no need to specify that measurements were traceable to any given NMI.

148. The representative of the BIPM gave an example that related to the In Vitro Diagnostic Devices Directive of the EU. This Directive was about traceability of values to reference measurement procedures, and materials of a higher order, but the Directive itself did not specify what was meant by that. The BIPM was asked to step in and the result was: (i) a data base of agreed and validated higher order reference materials for use by the industry and which was likely to be accepted by the European Commission; (ii) a common data base of reference methods, validated and agreed against objective criteria; (iii) a set of reference laboratories that could perform the measurements and that had an appropriate quality system. This was underpinned through a series of comparisons which were designed to validate technical capabilities and which resulted in a framework which could be used in organic and biological reference materials and measurements, and in food.¹⁵

Figure 27



¹⁵ More information on the BIPM can be obtained from www.bipm.org.

2. Discussion

149. The representative of Canada asked the representative from the BIPM whether he could provide any examples of where there had been problems with measurement and how these may have impeded trade.

150. In response, the representative of the BIPM noted that one example was a discussion between Canada and Germany on the whiteness of paper the origin of which was the fact that the standards that were held by Canada differed by those which were held by Germany. By making the comparisons the dispute had been resolved, and, the Canadian industry had saved about \$40 million in doing so. There were other examples, for instance with respect to the level of pollutants in fish that had come from certain African countries, and there were levels of contaminants in chicken carcasses which were traded between Southern America and the EU, where, again, the testing methods differed. Without going into further detail, he stressed that there were a number of well-documented case-studies that showed that a lack of equivalence of national standards at the top level could cause problems. This was especially likely when the industrial need for accurate measurement was very close to the levels of accuracy which NMIs could provide.

D. IEC SYSTEM FOR CONFORMITY TESTING AND CERTIFICATION OF ELECTRICAL EQUIPMENT

1. Statement

151. The representative of the IEC¹⁶ noted that the IEC was founded in 1906 to promote international co-operation on all questions of standardization in the field of electrotechnology (electrotechnology being anything with electricity running through it). The IEC also promoted co-operation in areas related to standardization, including with respect to conformity assessment.

Figure 28

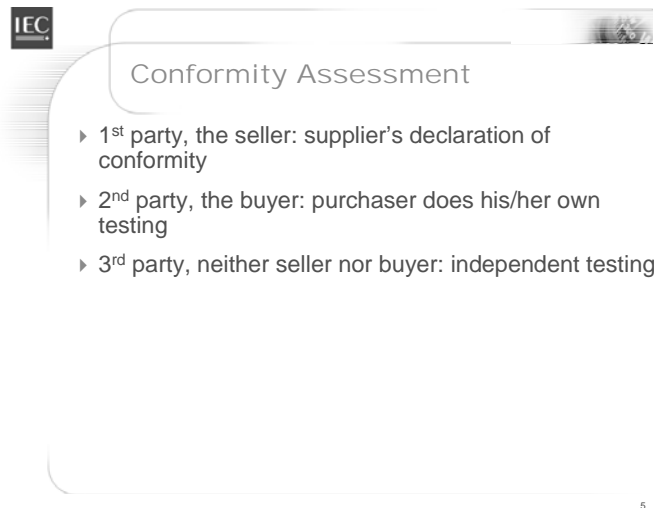


152. Regarding the "IEC family" set out in Figure 28, the representative of the IEC noted that the difference between an Associate Member and a Full Member was essentially one of voting rights on technical work (Associate Members had limited voting rights). The IEC's Affiliate Country Programme had been organized as a direct response to a call from the TBT Committee to increase the participation of developing countries in the standard-setting work of organizations such as the IEC. This Programme had been launched in 2001 and there were currently 68 participating countries.

¹⁶ Mr. Jonathan Buck, Head of Communications, IEC Central Office, Geneva.

Essentially, it provided guidance on the selection of appropriate standards and focus of relevant technical work in developing countries.

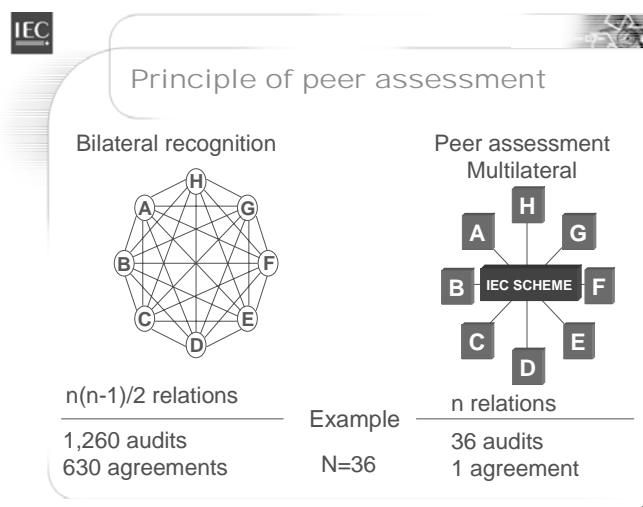
Figure 29



153. With respect to the basics on conformity assessment, there were three different types of schemes (Figure 29). He would only focus on the schemes of the IEC which dealt with third party (i.e. independent) testing, although the IEC did provide international standards in the other two areas. Reiterating the point that conformity assessment schemes could make a contribution to facilitating trade, it was noted that there was a growing emphasis on world markets and, in response to market needs, global conformity assessment ensured that time was saved and costs were cut – also at the global level. The key issue was: increasing *confidence* in products and services.

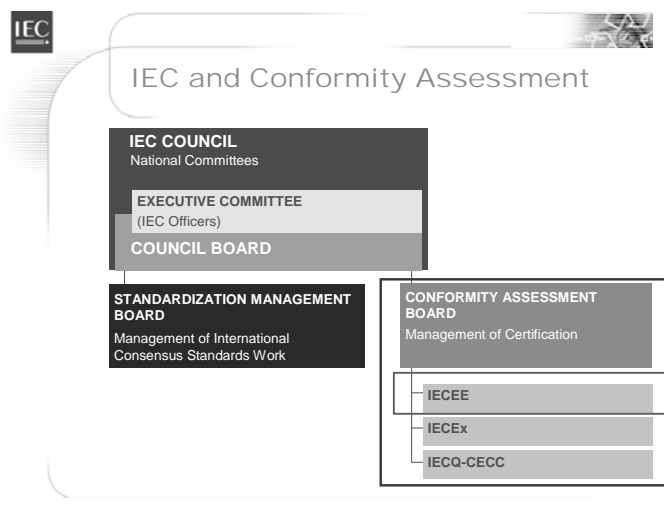
154. The IEC had three conformity assessment schemes which all fell under a Management Body known as the Conformity Assessment Board. These were the IECEE, the IECQ-CECC (dealt with quality conformity of electronic components in the non-regulated areas) and the IECEx (dealt with electrical equipment for operation in explosive atmospheres, heavily regulated). All of the schemes, including the IECEE, had common objectives. These could be summarized as: (i) flexible national representation from both government and private sector; (ii) open to members and non-members; and, (iii) the use of the principle of Peer Assessment. Regarding the latter, Figure 30 compared multilateral Peer Assessment with the alternative of concluding a series of bilateral agreements.

Figure 30



155. The schemes were all based on IEC international standards. Nevertheless, while they encouraged the harmonization to these standards, they accommodated national differences. The IEC schemes were product-focused, not system-focused. The schemes endeavoured to eliminate the multiple testing of products (except where there was a need to test for national differences) and they covered regulated as well as non-regulated areas.

Figure 31



156. The functioning of the schemes was illustrated in Figure 31. Basically, on the top, the governing body within the IEC was the IEC Council. The Standardization Management Body looked after the technical development of the standards and, underneath that, there were 175 Technical Committees, and about 15,000 experts around the world writing the international standards. On the right-hand side, there was the Conformity Assessment Board, which oversaw the running of the three schemes.

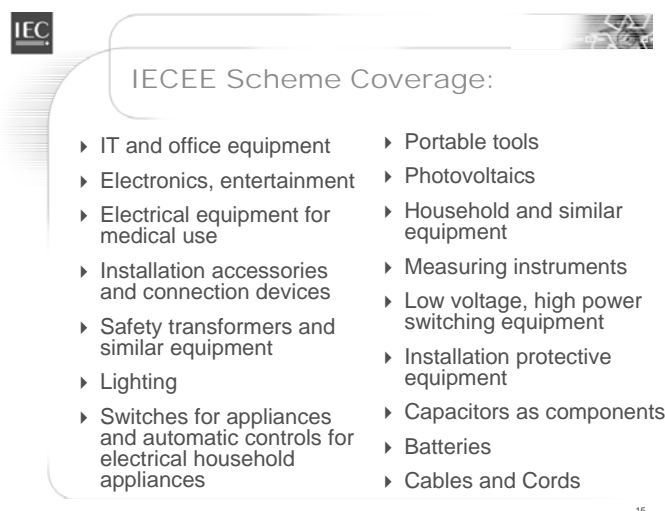
157. It was noted that the IECEE Scheme was a multilateral certification system based on international standards. It dealt with the safety of electrical and electronic products and its aim was to

facilitated trade by promoting harmonization of national standards with international standards. It was managed by the Certification Management Committee which reported to the Conformity Assessment Board. The Scheme was also known as the "CB Scheme" which stood for Certification Bodies Scheme. Within the Scheme there was a "Member Body" (or the National Certification Body – which could either be recognizing or recognizing *and* issuing), the Testing Laboratories, the Test Certification (which was the proof the product conformed to the IEC Standard), and, finally, there was a Test Report, which was the report of the test, given to the National Certification Body in order to issue the certificate. The Membership of the CB Scheme was set out in Figure 32 and Figure 33 listed the full range of subject matters covered by the Scheme.

Figure 32



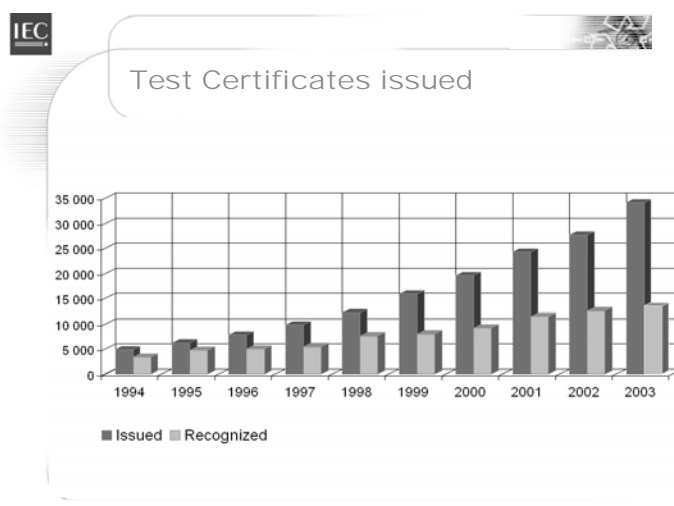
Figure 33



158. How did this work? The manufacturer of equipment wishing to export that equipment to a country would send the equipment for testing to obtain a certificate. The laboratory would test the equipment for conformity to the relevant IEC International Standards. A CB Test Report would be issued and sent to the NCB which would, subsequently, issue a certificate (CB Test Certificate). Then the manufacturer who wished to export the equipment would send the CB Test Certificate to the

National Certification Bodies (NCBs) in other countries. The NCBs in those countries (Issuing and Recognizing) would issue the certificates without testing the equipment as they would recognize that testing and assessment had already been done. Next, according to the status of the NCB, the manufacturer would be able to affix other countries' national marks of conformity to its equipment and export this equipment to those countries (and/or receive a Test Certificate proving that they could enter that market). This saved both time and money, reducing overall manufacturing costs.

Figure 34



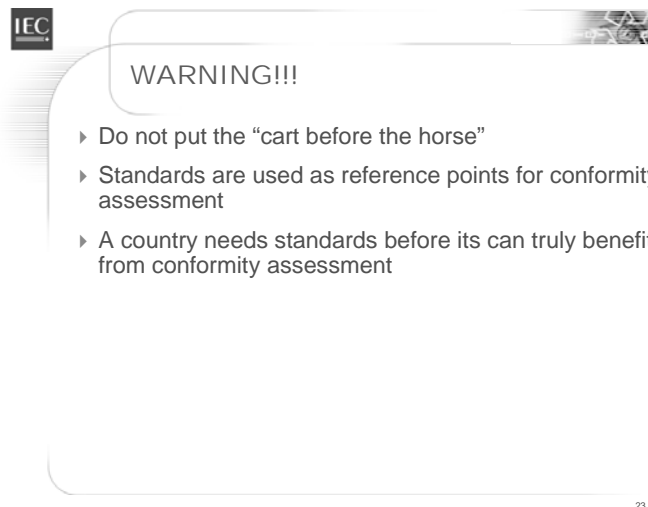
159. In terms of the evolution of the Test Certificates under the Scheme, Figure 34 showed the number of certificates that had been issued since 1994; these were now close to the 34,000. The lighter bar (to the right) showed the level of recognition by other national certification bodies (NCBs), in other words, other certificates being issued as a result of that recognition.

160. The IEC had an on-line system of registration of all the certificates. There were currently 45,000 certificates registered since 2002. This system gave the end-user full access to information on which certificates had been issued, where and by whom. It allowed all parties involved in the process to have immediate verification of the Test Certificates. More information was available on the web-site itself.¹⁷

161. What were the potential advantages of the Scheme? For the consumer, the Scheme offered confidence in compliance of imported products. A regular concern voiced in WTO workshops the IEC had participated in was the issue of "dumping" of poor quality goods. Developing countries wanted to use a scheme, such as the CB Scheme, in order to prevent the dumping of low quality goods on their territories. The Scheme also prevented "hiding" behind false origins (e.g. built in one place but trans-shipped through another). Moreover, the Scheme opened up the widest range of acceptable products to consumers. With respect to the benefits of the Scheme for the industry, the whole idea of the Scheme was about reducing manufacturing costs – it eliminated the need for repeated testing around the world. This could also mean that markets opened faster as the delays connected to testing would be reduced. For government, the potential advantage was that there was confidence that the imported goods were in compliance. Moreover, the Scheme offered an assurance of neutrality in that there would be no favoured supplier countries. In this sense, the CB Scheme offered the assurance that the issuer of the certificate did indeed conform to Article 6.1.1 of the TBT Agreement, regarding the phrase on "adequate and enduring technical competence".

¹⁷ www.iecec.org.

Figure 35



162. One of the problems the IEC had encountered with the Affiliate Country Programme, was that the countries tended to ask for information on the conformity assessment schemes without really looking first at the need for national standards. As underscored in Figure 35, there was a need for having an infrastructure in place at the national level relating to the *standards* required that best met a given country's particular needs. Standards provided the reference point for the conformity assessment. In other words, a country needed to establish its standards *before* it could truly benefit from the conformity assessment schemes.

163. The IEC Schemes were global in nature. The IEC endeavoured to provide the one-stop shop with the relevant international standards in its core competency area, as well as the relevant conformity assessment schemes. The IEC believed that the principle of Peer Assessment was proving to be a viable model and was, in practice, working well. The Schemes themselves were open to Members and Non-Members of the IEC. The CB Scheme was a particularly good example. Over the last ten years, the growth of the recognition of the Scheme – and the level of interest from all countries – had been remarkable. The IEC had tried to adopt a "building block approach" to encourage and help countries to establish their needs, first in terms of the standards, and then to identify which was the appropriate use of the conformity assessment scheme that best met the national needs and resources.

2. Discussion

164. The representative of Chinese Taipei asked whether there was an interface between the CB Scheme and the MRA operated by ILAC, or the MLA operated by the IAF. Was there an interface in the recognition of test reports or test certificates? Also, it had been mentioned that the Schemes were open to non-members and the representative of Chinese Taipei wished to have some further elaboration on this point.

165. The representative of the IEC noted that an active relationship already existed between IECEE and ILAC. The two bodies were collaborating on joint assessments, sharing common sets of documents, in addition to regular meetings under the auspices of the IEC Conformity Assessment Board and the ILAC Technical Panel. The IECEE and ILAC had established a Joint Working Group entitled "Uniform understanding of ISO/IEC 17025". In addition, the IECEE was currently considering signing a Memorandum of Understanding between ILAC members and IEC Schemes (essentially IECEE) members. The IECEE had also initiated preliminary discussions with the IAF

with a view to achieving similar objectives and procedures as those in place with ILAC. Regarding membership, it was noted that it was the IEC National Committee that designated the national certification body in their country. In terms of the application, non-members could simply apply to the IEC secretariat in Geneva requesting participation in the IEC Scheme and the IEC membership would consider that application.¹⁸

166. The representative of the United States wished for some more elaboration on the point that a country needed standards before it could truly benefit from conformity assessment. At a practical level what did this mean and what would the IEC advice be to a particular country?

167. The representative of the IEC stressed that the IEC was trying, through the IEC Affiliate Country Program, to demystify the world of electrotechnical standards. It had to be recognized that developing countries did not need full and comprehensive access and use of *all* 4,500 IEC international standards. What the IEC was trying to do was to work with participants to try to identify what were the areas of domestic interests and relevance to that country, both with respect to its domestic industry as well for the potential of importing electrical goods.

168. The representative of Switzerland asked what the exact requirements were for certification bodies to become a "national certification body". Was it so that smaller or medium sized certification bodies were unlikely to meet the criteria under the IEC CB scheme? In other words, how could it be avoided that the IEC CB Scheme became a "club" for larger certification bodies?

169. The representative of the IEC clarified that the terms of operation of the Scheme clearly stated that every country was permitted to participate at whatever level it wished. The level of benefits and the level of membership was determined according to the national needs of each country. In terms of the management of the Scheme, there was a Conformity Assessment Board which oversaw the functioning of the CMC running the CB Scheme so as to ensure that there was fair representation and that all applications and enquiries to the Scheme were handled in an appropriate manner.

E. ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

170. The representative of the OECD¹⁹ noted that in its successive reviews of the operation of the TBT Agreement, the TBT Committee had in the past noted concerns with respect to the restrictive effect on trade of diverse and often multiple conformity assessment procedure and requirements. As part of its ongoing work, the OECD was currently involved in the identification and analysis of the nature of non-tariff measures which had a potentially negative impact on market access, and could potentially cause difficulty to traders. In this regard, the OECD had launched a study which looked in particular at how conformity assessment procedures could facilitate trade on one hand, but could also cause some difficulties on the other. This work would involve some conceptual analysis, such as the identification of the players who operate in the field, and the costs and benefits which conformity assessment procedures entailed. It needed to be kept in mind, however, that conformity assessment procedures was "a big whole" whose parts could be quiet drivers, interrelated and each of which could individually benefit or hamper trade. The OECD would be looking at under what circumstances conformity assessment requirements can facilitate trade or create barriers.

171. Regarding the policy context, it needed to be kept in mind that conformity assessment procedures could provide substantial benefits for manufacturers, consumers, government regulators and for trade in general. The primary aim of the procedures was to prove whether products were safe and fit for use and consumption, or not so. This system therefore supported the role of regulators

¹⁸ This response was provided in writing by the IEC after the meeting. More detailed information can be found in the Basic Rules IECEE 01 and Rules of Procedure IECEE 02, available from <http://www.iecee.org/cbscheme/pdf/IECEE01.pdf> and <http://www.iecee.org/cbscheme/pdf/IECEE02.pdf>, respectively.

¹⁹ Ms. Barbara Fliess, Principal Administrator of the Trade Directorate.

responsible for protecting health, safety, environment etc. Conformity assessment procedures had a legitimate role to play in the overall context of regulatory regimes.

172. The OECD study would also consider the negative effects of conformity assessment procedures systems; these entailed costs to producers, importers, governments and society overall. There needed to be a cost-benefit analysis of each such system. And while conformity assessment was part of the normal costs of doing business, and necessary in both domestic and international trade, it could also present significant costs for traders that could arise in three ways: it could raise costs directly to business, it could delay market entry, and it could raise transaction cost, thereby reducing competition and retarding the development of economies. Duplicative testing was one example that could lead to all three of these cost outcomes.

173. It was noted that the data on costs of compliance and the different effects on market access that conformity assessment procedures presented in different countries, was scarce. Hence, the OECD's work would be a systematic effort to gather available data and perhaps even generate new data in this regard. The OECD would review WTO material, including submissions and discussions in the TBT Committee. From this review of WTO material, the OECD study aimed at producing a shortlist of key concerns and issues of importance to trade which would guide the subsequent part of OECD analysis which would, in turn, consist of conducting several case studies to document and illustrate the ways in which specific conformity assessment requirements impacted on trade, and the experiences with the tools which were available for action.

174. In addition, the OECD work would seek to determine the extent of cross-border conformity assessment activity today. It would seek to answer the question of whether conformity assessment activity was getting easier or more difficult. It would also examine whether conformity assessment barriers were the subject of significant concerns to businesses that engaged in trade. Given the lack of data, OECD would consider collecting data through a survey instrument, possibly by involving a sample of conformity assessment bodies, and the OECD would also conduct focused interviews with other stakeholders who were closely affected by conformity assessment requirements, such as manufacturers and exporters.

175. The OECD hoped that the study would provide useful background to the discussions in the TBT Committee. It could contribute greater specificity on information on national experiences that were being dealt with in the TBT Committee's work programme. The study could also benefit developed and developing countries which were in the process of developing or improving their existing conformity assessment infrastructure, programmes or policies. The OECD expected that the first report of the results of this research would be available at the end of 2005. The OECD would be pleased to share this with the TBT Committee.

F. INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY (OIML)

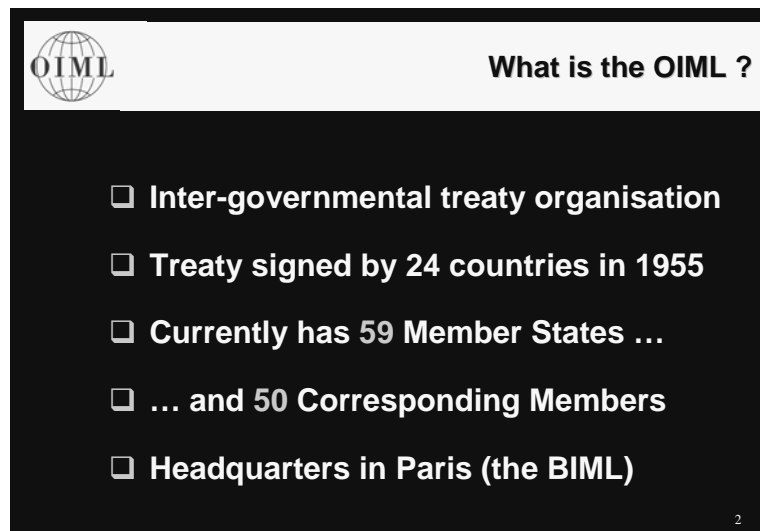
1. Statement

176. The representative of the OIML²⁰ noted that the OIML was a Paris-based inter-governmental treaty organization, which had been founded in 1955 and signed, originally, by 24 countries. When the Metre Convention (previously addressed by the BIPM, Figure 21, above) was established, it had been thought that this organisation would be able to solve all metrology problems. However, participants discussed a number of practical problems within an International Conference on Practical Metrology, and it was decided to establish the OIML as a separate organization to look at these practical problems pertaining to the regulated use of measurements and measuring instruments.

²⁰ Mr. Ian Dunmill, Assistant Director of the OIML.

177. Currently there were 59 Member States of the OIML and 50 Corresponding Members. The main difference between the two categories was one of voting rights (Figure 36, see also paragraph 191, below).

Figure 36



178. In distinguishing between the work of the OIML and that of the BIPM, the representative of the OIML referred to the definition of "legal metrology" and stressed that the key issue was that legal metrology was where governments became concerned with measurement, and this was where the OIML had a role to play whereas the BIPM was concerned with the primary metrological standards:

“Legal metrology comprises all activities for which legal requirements are prescribed on measurement, units of measurement, measuring instruments and methods of measurement, these activities being performed by or on behalf of governmental authorities, in order to ensure an appropriate level of credibility of measurement results in the national regulatory environment. Legal metrology is not a specific discipline of metrology, it makes use of scientific metrology to get appropriate references and traceability, and it may apply to any quantity addressed by metrology.” [emphasis added]

(Draft Revision of OIML D 1 *Law on metrology*)

179. In addition to the traditional areas of competence on weights and measures, a number of other fields now fell under the scope of legal metrology. In this sense there had been considerable change in the scope of legal metrology which had originally been focused almost exclusively on weights and measures in the marketplace. Today, legal metrology was applied to areas such as health and safety (for example, medical measuring instruments, equipment used to analyse samples taken in a medical context, or radiation dose meters); protection of workers in the environment from noise, vibration and radiation; measurements in the environmental pollution field (pollution of the earth, water and soil); and in the field of law enforcement (speed detectors and alcohol breath meters).

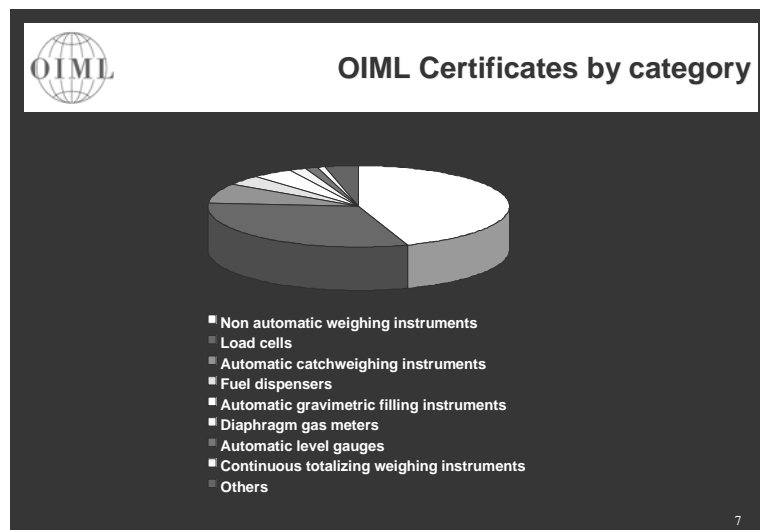
180. The OIML aimed at eliminating barriers to trade caused by metrology. It did this by harmonizing laws and regulations used in its Member States in the areas of measurement, pre-packages and measuring instruments. Pre-packages, which had not been one of the original considerations of the OIML, had become an important area for developing countries, where a large percentage of their exports were pre-packaged agricultural products destined for industrialized countries. In attempting to harmonize these laws, the organization produced "International

Recommendations", which were a form of international standard. There were currently over a hundred of these, covering all the different ranges of measuring instruments. These were intended to be model technical regulations that were developed by technical committees throughout all the Member States of the organization. They set out metrological requirements for the accuracy of the instrument, and technical requirements, where these were necessary. The OIML also produced standard test procedures and standard test reports, so that the same tests were applied in different countries.

181. The *OIML Certificate System for Measuring Instruments* was set up in 1991. A certificate issued under this scheme stated that a particular measuring instrument complied with all the requirements of the appropriate International Recommendation. There was a supporting test report which gave all the details of the type approval tests which were conducted to gain that certificate. The OIML certificates were registered at the headquarters of the OIML against a fee paid by the issuing authority, and the certificate Issuing Authority usually passed that fee on to the company that was receiving the test certificate. This was a completely voluntary system; there was no obligation for any other Member State of the organization to accept that certificate.

182. This voluntary recognition had enabled developing countries to have a "ready-built" type approval system. Many developing countries accepted these certificates, even though they had neither any metrological infrastructure nor testing facilities themselves, to give a guarantee of the level of quality and accuracy of measuring instruments which they accepted to put on their domestic market. They would then require some kind of policing infrastructure, in order to ensure that the instruments on the market actually were the same ones.

Figure 37



183. About a third of all the certificates which had been issued were for load cells (large dark area in Figure 37), which were a module of weighing instruments. The other large sector (light-coloured) was for non-automatic weighing instruments (the kind of instrument commonly found in a grocer's store or supermarket, or a vehicle weighbridge). In other words, around two-thirds of the certificates which had been issued were for parts of, or whole, weighing instruments. Hence, although the System covered a large number of different categories of instruments, the vast majority of certificates which had been issued were for weighing instruments.

184. Although the system had worked well, and in practice there was a very wide recognition of the certificates amongst OIML Member States, it was decided that something else needed to be done.

With the objective of addressing the issue of acceptance of the certificates, in 2003, the OIML established a Mutual Acceptance Arrangement (MAA), which was a framework for the acceptance of certificates amongst Member States of the OIML. Issuing authorities in Member States would sign Declarations of Mutual Confidence (DoMC), of which there would be one for each category of instruments (one for non-automatic weighing instruments, another for petrol pumps, etc.). No one country had to sign up to all of them, so the groups of countries could be completely different, according to the category of instrument concerned. Nevertheless, the participants that signed these agreements agreed to accept and use test reports which were issued under the agreement in the production of their national type approvals, and not to repeat all the testing.

185. The representative of the OIML stressed that it was important to note the fact that DoMCs were engagements between the Issuing Authorities within countries; it was not the State that was engaging itself. There was still need for a type approval process in each country. This system only intended to harmonize the use of the test reports; it was not an acceptance of a certificate. In other words, because the OIML had no legal basis for issuing an international type approval, individual Member States would still have to issue type approval certificates of their own. Confidence was built-in either by accreditation (by signatories of the ILAC MRA) or by peer assessment – either approach was based on ISO 17025.

186. For each DoMC, a Committee on Participation Review (CPR) would be set up, consisting of representatives of those countries wishing to participate to consider whether they were all at the appropriate level to be accepted internationally amongst themselves. The OIML secretariat would participate in the CPRs to ensure that there was a consistent approach taken between different categories of instruments. For example, when a DoMC was signed for non-automatic weighing instruments, there would be a transition period where participants in that particular DoMC would issue all their OIML certificates based on that DoMC, but non-participants in the DoMC would still be able to issue OIML certificates under the old OIML Certificate System. After that transition period, those who were not participating in the DoMC would be stopped from issuing OIML certificates. It was noted that the arrangements for this had yet to be finalized. Moreover, this was a fee-based system, where it is proposed that the Issuing Authorities would be paying a fixed annual fee (€1200) to participate in each DoMC that they choose to participate in. It is also proposed that there will be an additional fee for registration of each certificate issued under that DoMC (€150). The first two DoMCs would be for load cells and for non-automatic weighing instruments. The first stages for setting these up (establishment of the CPRs and preparation for the signing of the DoMCs), would take place in the beginning of 2005, following the recruitment of a new member of staff at the BIML to take responsibility for this.²¹

2. Discussion

187. The representative of the United States enquired whether the concept of Declaration of Mutual Confidence was different from the concept of mutual recognition agreements / arrangements (MRAs)?

188. The representative of the OIML replied that there was no significant difference between the two terms and that it was basically a group of countries, or a group of Issuing Authorities in those countries, who got together to decide whether the test results produced within those countries were all acceptable to each other. The intention was to ensure that the countries were confident with their own results of measurement.

189. The representative of Canada asked what the procedure was for becoming a Member of the OIML?

²¹ More information is available at: www.oiml.org.

190. The representative of the OIML replied that there were two categories of membership according to the Convention which set up the organization: "Members States" and "Corresponding Members". The Corresponding Members had a higher proportion of developing countries than were included in Member States. There were slightly different requirements for each category of membership. In order to become a Member State, the country needed to be a signatory to the original treaty; this was a longer process (and of a more political nature). To qualify as a Corresponding Member, it was sufficient that the head of the national authority responsible for legal metrology sent a letter to the OIML requesting membership and furnished an undertaking to continue to pay the subscription, which was around a €1000 per year (for Corresponding Members). The minimum subscription for a Member State was around €12000.

191. Contributions from Member States were divided into classes as a function of population, with some derogation given to those countries with a large population but low GDP. In practice, the OIML encouraged the participation of developing countries in the activities of the OIML. Corresponding Members could participate practically in all the meetings and work of the organization. They could participate in all the technical work, providing comments which would be taken into consideration by Technical Committees. However, Corresponding Members were not eligible to vote on the acceptance of documents produced by the Technical Committees. Moreover, to encourage developing countries to make use of OIML publications, it was the intention of the OIML to make all its publications available free of charge to both Members States and non-members as from the beginning of 2005.

G. INFORMATION ON ITA FROM THE SECRETARIAT

192. The Chairman drew the Committee's attention to some other work in the WTO relevant to conformity assessment. He noted that it was his understanding that the Committee of Participants on the Expansion of Trade in Information Technology Products had decided to proceed by formulating "Guidelines" in the specific area of EMC/EMI (Electro-Magnetic Compatibility / Electro-Magnetic Interference) relating to conformity assessment procedures. He invited a representative of the Secretariat to brief the Committee on this work

1. Statement

193. The representative of the Secretariat noted that the Committee of Participants on the Expansion of Trade in Information Technology Products was a plurilateral group, currently representing some 63 WTO Members. Pursuant to paragraph 3 of the Annex of the Ministerial Declaration on Trade and Information Technology Products, this Committee had been encouraged to examine and consult on non-tariff barriers in IT products (tariffs were minimal in this area and being reduced or eliminated).

194. In November 2000, the Committee had launched a "Non-tariff Measures Work Programme", whereby it would identify NTMs that were impediments to IT trade. There were three components to this work: first the identification of NTMs that were impediments to IT trade; second, the examination of their impact on trade in IT products; and third, give formal consideration to the outcome of these two first phases.

195. During the first phase (identification of NTMs), 26 non-tariff measures had been notified by ITA participants. The vast majority of these were in the area of conformity assessment / testing and certification (nine particular notifications), and the second largest incidence of NTMs was in the area of standards and regulatory environment (eight notifications).²²

²² Document G/IT/SPEC/Q2/11/Rev.1 compiles this information on the NTBs identified.

196. As a practical way to proceed, one particular NTB was chosen for a so-called "pilot project". This was the EMC/EMI (electromagnetic compatibility/electromagnetic interference). As a first step, the Committee conducted a survey to get an idea of the different regulatory environments or regimes of ITA members. Following this, in 2003, a workshop was held specifically on EMC/EMI. At this workshop it was determined that while there was a large degree of harmony with respect to the standards, the problem was more one of conformity assessment procedures.²³

197. A paper on so-called "Best Practices for EMC/EMI-Related Conformity Assessment Procedures for IT Products", which highlighted many of the points from our workshop, took the matter to the next step (G/IT/24). At the last meeting of the Committee (June 2004), the Committee agreed to move forward and proceed by formulating "guidelines" for EMC/EMI-related conformity assessment procedures.

²³ An overview of the survey responses is contained in document G/IT/SPEC/Q4/19/Rev.2. More information on the workshop is contained in document G/IT/23 and the WTO web site compiles all the presentations made at the workshop.