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Committee on Technical Barriers to Trade

MINUTES OF THE MEETING OF 22-23 MARCH 2005

Chairperson: Mr. Sudhakar Dalela (India)

Note by the Secretariat[1]

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

I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/2517.

II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

A. STATEMENT FROM MEMBERS UNDER ARTICLE 15.2

2. The Chairman drew the Committee's attention to three new statements on Implementation and Administration of the Agreement, submitted by Sierra Leone (G/TBT/2/Add.83), the Former Yugoslav Republic of Macedonia (G/TBT/2/Add.84) and the Republic of Rwanda (G/TBT/2/Add.85).[2] He informed the Committee that the latest information on Members' enquiry points was available on the TBT webpage.[3]

B. SPECIFIC TRADE CONCERNS

3. The Chairman drew the Committee's attention to the recommendation of the Third Triennial Review, that encouraged Members to share with the Committee, on a voluntary basis, any follow-up information on issues that had previously been raised in regard to their technical regulations and conformity assessment procedures.

1. New Concerns

(i) Indonesia - Mandatory Standard for Tyre (G/TBT/N/IDN/13)

4. The representative of the European Communities noted that the above notified Decree on compulsory implementation of the Indonesian National Standard on Tyre had been adopted on 23 September 2004. It allowed for a six month delay for implementation. Following bilateral consultations with the Indonesian authorities, the European Communities had requested confirmation that the entry into force of the Decree would be postponed until January 2006, rather than implemented on 23 March 2005 as originally foreseen. The European Communities reiterated its request that the technical guidance be simplified in order to facilitate the implementation of the decree. Clarification was also sought as to whether the Indonesian authorities would accept tyres complying with the UN-ECE regulations.

5. The representative of Indonesia confirmed that his authorities were planning to postpone the entry into force of the Decree.

(ii) European Communities: Restrictions on the Use of Certain Phthalates in Toys

6. The representative of the United States expressed her delegation's concerns about restrictions on the use of certain phthalates in toys. The directive at issue restricted the use of phthalates in toys and childcare articles for children three years and younger that "can be put into the mouth". Although the European Communities had notified a similar, but less restrictive technical regulation in 1999 (G/TBT/Notif.99/578), the United States requested that the proposed amendment to Council Directive 76/796/EEC, of 28 September 2004, also be notified to the TBT Committee given the significant revision and its potential to affect international trade. The European Communities also needed to explain the rationale and justification for the proposed amendment. The US concern was that the new provision greatly expanded the potential list of products in the industry directly affected by the directive. The representative of the United States was of the understanding that the EC legislation

[2] A full, updated list of statements under Article 15.2 is contained in document G/TBT/GEN/1/Rev.2 and an updated list of enquiry point contacts is contained in G/TBT/ENQ/26.

[3] http://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_points_e.htm.

was in the second reading by parliament and she noted that the U.S. Consumer Product Safety Commission had been in contact with its counterpart in the European Commission.

7. The representative of the European Communities confirmed that the proposal was being examined by the European Parliament and the Council of Ministers and that it had been substantially amended. The adoption of the Common Position by the Council of Ministers was expected to take place in April 2005. After adoption, the draft would be notified under the TBT Agreement and a sufficient time period for comments would be provided.

(iii) China: General Standard for the Labelling of Pre-packaged Alcoholic Beverages (G/TBT/CHN/72)

8. The representative of the European Communities recalled that his delegation had previously expressed concerns regarding the Chinese TBT notification on labelling for pre-packed food G/TBT/CHN/33. The European Communities now wished to raise similar concerns with respect to the above notified measure on alcoholic beverages as it was the EC view that this measure could create difficulties for the EU manufacturers of alcoholic beverages when exporting their products to China. The representative of the United States associated herself with the comments made by the representative of the European Communities and recalled that she had raised this issue in the context of China's Annual Transitional Review Mechanism at the last meeting of the Committee.[4]

9. The representative of China noted that, as had been requested by the European Communities, her authorities had agreed to extend the comment period until 31 March 2005, even though adoption of the measure had been set to take place 90 days after the circulation of the notification by the Secretariat.

(iv) Malaysia – Hologram Stickers on Pharmaceutical Products

10. The representative of the United States raised an issue regarding Malaysian requirements for hologram stickers on pharmaceutical products. It was the US understanding that on 26 June 2004, Malaysia's Ministry of Health had announced that it had approved implementation of a directive requiring the use of hologram stickers on pharmaceuticals, over-the-counter medications and certain herbal products. That regulation had never been notified as a proposal under the TBT Agreement and Members had therefore not been given an opportunity to comment. The US government and industry had raised the issue with their Malaysian counterparts and, in fact, implementation had been delayed on two separate occasions. Nevertheless, it was now scheduled for 5 May 2005. While the representative of the United States welcomed the cooperation that Malaysia had shown, she remained of the view that a notification needed to be made under the TBT Agreement.

11. The representative of Malaysia took note of the concern raised and informed the Committee that the notification was being prepared and would be submitted.

2. Concerns Previously Raised

(i) Korea: Import of Fish Heads

12. The representative of New Zealand reiterated that her authorities did not consider as legitimate the concerns raised by Korea in relation to the import of this fish heads: they were not justifiable, whether considered in terms of GATT Article XI or under the relevant provisions of the TBT Agreement. In fact, the representative of Korea had informed New Zealand that his country would continue to prohibit imports of fish heads from New Zealand while allowing imports of edible fish heads from certain other exporting countries. This was despite assurances that New Zealand

[4] The US concerns in this respect are contained in G/TBT/W/245.

could process hake heads to an edible standard. Provided the product was accompanied by official certification giving assurance that the product was fit for human consumption, it was New Zealand's view that Korea was obliged to allow the importation. This was the practice with most other sea food products exported to Korea and would seem to be an appropriate and adequate way of ensuring that any human health or safety concerns were addressed.

13. The representatives of Iceland, the European Communities and Norway expressed similar concerns and hoped that a solution could be found pursuant to bilateral consultations.

14. The representative of Korea noted that there had been some positive progress achieved in bilateral consultations, particularly with the United Kingdom. More discussions were needed with Norway, Iceland and New Zealand.

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

15. The representative of Japan noted that her delegation remained concerned about the trade-restrictiveness of the proposed measure. In particular, the provisions for the registration of substances in articles were obscure and implied a heavy burden on registrants. In consultations, the European Communities had responded that there was ample time for manufacturers and importers to get acquainted with this system and that the guidance on substances in articles would be developed. However, Japan could not judge from such expectation-based explanations that an excessive burden to the registrant would not arise. Japan had also emphasized many times the need to avoid duplicative registrations. Regarding the formation of consortia, it was not clear whether every manufacturer and importer who wanted to join a consortium could do so in a timely manner and under fair cost-sharing. In respect of Article 6.5, Japan had emphasized that this provision could be disadvantageous to articles produced outside the European Communities and had not yet received a clear explanation from the European Communities why the phrase "by an actor up the supply chain" was necessary. Nevertheless, Japan appreciated the EC's efforts to explain the proposal in response to Members' concerns.

16. The representative of the United States noted that the record of the last meeting extensively described Members concerns; the United States would not repeat their own. She thought that it had been helpful to have the EC Commission's experts present at the last meeting and emphasized that given the on-going discussion of the proposal by the European Parliament and Member States, it was premature to draw conclusions and interpretations in particular about compliance with WTO rules, such as those of the TBT Agreement. The United States remained hopeful that the EC Commission would revise its proposal and ensure that it did not become an unnecessary barrier to trade.

17. The representative of Australia noted that while her delegation supported the basic objectives of the draft regulation, and, in fact, welcomed the harmonisation of chemicals regulation across the European Union, her delegation remained concerned that it was more trade restrictive than necessary to fulfil its objectives; it did not focus on substances that presented the greatest risk. Australia was particularly concerned about the unintended negative consequences of REACH for the minerals and metals industry. An unintended consequence of the legislation was that it was discriminatory in its application to raw inorganic imports such as imports of minerals while exempting organic imports such as coal, gas and oil. This placed the inorganic industry at a competitive disadvantage to the organic sector. To maintain consistency and fair competition the same approach needed to be taken for alloys as for polymers i.e., to register (and authorise) the use of metal in the alloy but to exempt the requirement to register and authorise the metal in the downstream uses of the alloy. The special qualities of alloys needed to be recognised: they could not simply be treated as the sum of their constituent parts. The inclusion of secondary raw materials in the scope of REACH would discourage recycling within the EU of some metals and alloys and would further disadvantage the metals sector. In Australia's view, REACH had to allow for currently available assessments and data sets, and

consideration needed to be given to the use of internationally agreed definitions determined in other fora. The extra requirements imposed by REACH could result in some products, which Australia wished to continue to source, becoming uneconomic to produce and hence being withdrawn from the market. This was of particular concern to Australia as a net importer of chemical substances from the EU. The draft legislation exempted from registration substances in articles that had already been registered for a specific use by an actor of the supply chain. This could induce manufacturers within the EU to source their imports for the registered use from the EU rather than third country suppliers.

18. The representative of Mexico echoed the concerns voiced by the preceding delegations and agreed, in particular, with the point made by the United States: it was premature to analyse the compatibility of the draft regulation with EC commitments under the TBT Agreement. On special and differential treatment, Mexico recalled that his delegation had indicated that this type of regulation would have an impact on exports from developing countries and that it would therefore be important to take account of the special circumstances prevailing in developing countries so that they would not be unduly affected. On technical assistance, Mexico was of the view that the complexity of the system and the difficulty of implementing it made it clear that technical assistance would be needed. He recalled that his delegation had commented on the original REACH proposal in May 2003 but had still not received any response to those comments.

19. The representative of Chile noted that her country shared the concerns of previous speakers, particularly those of Australia. Without prejudice to any possible future modifications to the draft regulation, Chile was interested in knowing how the European Communities would extend technical assistance in order to facilitate compliance. It was particularly important that the rules be specific in order to avoid different interpretations and arbitrary implementation. Chile continued to be concerned that REACH seemed to work as a function of production and export volumes, rather than the risk associated with the product. For instance, as an exporter of minerals to the European Union, the impact of REACH could mean that each shipment would need to be registered. This entailed significant costs.

20. The representative of Cuba reiterated the concerns expressed by his delegation at the last meeting of the TBT Committee.[5] While the European Communities had recognised their obligations under Article 11.3 of the TBT Agreement to provide guidance material regarding the implementation of REACH, as well as technical assistance, the representative of Cuba was unaware of any specific action in this respect. He pointed out that the non-existence in the REACH text of any unified list of chemical substances or products made it difficult to comply with the requirements for registration; such a list needed to be created and disseminated. Finally, it was requested that the EC Enquiry Point make public the replies to the comments made on the second notification of REACH.

21. The representative of Korea noted that his country's chemical industry was concerned about the burden created by REACH, especially with respect to the possibility that confidential commercial information could be released in the process of registration. Also, many countries faced problems in implementing Good Laboratory Practices (GLP) and the representative of Korea hoped that the European Communities would take this into account.

22. The representative of China suggested that the European Communities should assess the negative impact of REACH regulations on developing countries and add provisions in REACH specifying the special and differential treatment for chemicals from developing countries. Secondly, there was a need to simplify the requirements of registration and authorisation as well as to cut down application fees to reduce the burden on industry. Small and Medium-sized Enterprises (SMEs) in developing countries needed to be exempt from such expenses. Finally, it was suggested that the European Communities clarify the coverage of REACH on waste chemicals and how duplication or overlap was avoided when other regulations or directives were applicable.

[5] G/TBT/M/34, para 48.

23. The representative of Uruguay stressed the issue of market access effects on products exported from developing countries and emphasized the need for technical assistance in order to facilitate the implementation of the system.

24. The representative of the European Communities reminded Members that the proposed REACH regulation was being examined by the European Parliament and the Council of Ministers under the Co-Decision Procedure and the Commission would update its notification to the TBT Committee if there was any major change to the proposal. Moreover, the European Communities would continue its efforts to explain REACH to WTO Members and to develop guidance as well as pursue bilateral and multilateral dialogues. Concerning the request from Mexico to have a written answer to the comments made, the European Communities had not replied formally to any of the 6,000 comments that had been made in response to its internet consultation. In effect, the response to these comments was a change to the proposal itself and the way in which those comments were being taken into account was set out in the explanatory memorandum accompanying the proposal. Nevertheless, the European Communities remained willing to continue the dialogue on outstanding questions. Regarding the point made by Cuba, the answers to the comments received by WTO Members had been made public and were available on the EC TBT website.

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

25. The representatives of New Zealand, Australia, the United States, Uruguay and Mexico recalled their delegations' concerns with the EC Regulation 753/2002 and 316/2004 relating to wine labelling, and stressed that concerns regarding the creation of unnecessary obstacle to trade remained unresolved. They did not find it necessary to repeat concerns raised at every meeting of the TBT Committee since June 2002. For New Zealand it sufficed to note that her delegation continued to seek written responses from the European Commission on the full range of issues that were both substantive and procedural in nature. The representative of the United States expressed frustration at the fact that the European Commission did not seem to appreciate the concerns that had been raised: responses had not been adequately answered and the European Communities appeared merely to be restating that comments had been taken into account and that the wine labelling rules at issue were justified. The representative of Mexico remarked at the difference in openness and transparency, as well as willingness for dialogue, in the case of REACH compared to wine labelling.

26. The representative of the European Communities stressed that the European rules on labelling had been amended on 20 February 2004 in EC Regulation 316/2004. This amendment had taken into account the comments relating to the previous regulation (753/2002). The European Communities had taken note of further comments made since those amendments were adopted, however, it was their view that the current legislation was legitimate.

(iv) Switzerland: Ordinance on the Emission Level of Passenger Cars with Compression Ignition Engines (G/TBT/N/CHE/39)

27. The delegation of Switzerland wished to update the Committee on an issue raised by the European Communities at the last meeting. This was specifically about Point 12 of the above-mentioned TBT notification on requirements for diesel filters used in motor vehicles. Switzerland was not yet in a position to give a definitive response to the comments made by Members as the legislative process in the Swiss parliament was currently underway. Nevertheless, the concerned Members would be informed of the outcome once this process had been completed.

(v) United States: Measure on Refillable Lighters

28. The representative of the United States reverted to an issue raised by China regarding a US regulation on refillable lighters. China had asked a specific question about the possible use of the

ISO 9994 standard, a safety specification for lighters. The United States informed the Committee that the U.S. Consumer Products Safety Commission was currently considering the issue and her delegation would report back when a final decision had been reached.

29. The representative of China reiterated her country's concerns as expressed at the previous three meetings of the TBT Committee regarding the US safety standard on lighters. China had also requested that the United States notify the measure to the WTO, in accordance with Article 1.6 and 2.9 of the TBT Agreement. While China was pleased to hear that US government agencies were working on the possibility of taking the afore-mentioned international standard into consideration, China was also concerned that over the past two years, the US child resistant standards had been followed by some other Members of the WTO. The representative of China strongly urged the United States to abide by the rules of the TBT Agreement and to amend the standard so as to bring it in line with ISO 9994:2002.

30. The representative of the United States reminded the Committee that the regulation in question had originally been published in 1993 and that the ISO standard which China had refered to dated to 2002. The United States had provided Chinese officials with the original documentation and studies that supported the approach taken by the U.S. Consumer Products Safety Commission which, in fact, showed that price had a relationship to safety. In terms of the notification, in April 2004, the U.S. Consumer Products Safety Commission had published a notice which was about an inflation-related adjustment (change in the whole-sale price index). This did not in itself constitute a change in the regulation, nor was it an amendment to the regulation. The fact that a notice had been published was simply an additional measure of transparency; the regulation, as published in 1993, remained unchanged, and, accordingly, the United States did not think that there was a basis for making an additional notification.

(vi) United States: Country of Origin Labelling (G/TBT/USA/25 and USA/83 and Corr.1)

31. The representative of Canada wished to raise a number of its ongoing concerns regarding the United States' mandatory country of origin labelling program set out in the US Farm Bill and referred to as "COOL". In particular, some aspects of the Bill affecting the imports of fish and seafood, were due to be implemented in April 2005. It was noted that the stated intent of the legislation was not to address food safety or animal health concerns but rather to provide consumers with additional information on which to base their purchase decisions. The Canadian government was of the view that COOL was inconsistent with the US obligations under the TBT Agreement as it was more trade restrictive than necessary to fulfil the stated objective. Canada had yet to be provided with evidence justifying the adoption and implementation of COOL. In Canada's view, mandatory COOL also ran counter to the US industry's long term interests and that of other countries, including Canada. As the USDA's own cost benefit analysis had indicated, the volume of US exports for all covered commodities would decline as a result of COOL as would US imports from other countries, and this would negatively affect the American food processing industry. The US government had not provided any evidence that mandatory COOL would benefit consumers as a retail labelling program. On the contrary, mandatory COOL in the United States could set a precedent for more extensive and trade restrictive non-food safety related labelling schemes internationally. There was evidence of this in the ongoing debates on the necessity of developing COOL standards in the Codex Committee on Food Labelling. The Interim Rule for Fish and Shellfish, due to be implemented on 4 April 2005 (all other covered commodities being delayed until 2006), would place that entire sector at a competitive disadvantage relative to the other covered commodities including the poultry sector which, seemingly arbitrarily, was *not* covered by the labelling program. It was requested that the implementation of the Interim Rule be delayed and the Final Rule repealed.

32. The representative of China supported the above-mentioned concerns raised by Canada.

33. The representative of the United States stated that she was aware of Canada's concerns and would revert to them.

(vii) Peru: Labelling of footwear (G/TBT/N/PER/4)

34. The representative of Peru wished to refer to comments made by the European Communities at the TBT Committee meeting of 4 November 2004. It was pointed out that the above-mentioned regulation had been notified twice; it had been adopted six months after last notification, and all of the comments to the first notified measure had been taken into account. In respect of the recent EC comments, the representative of Peru recalled that the labelling regulation stated that the country of origin information had to figure on printed, stamped or sewn labels. The information with respect to the corporate tax number could be struck on, or glued. Regarding imported goods, this same information could be given by the manufacturer or the importer once the goods had entered the territory of Peru.

(viii) Mexico: Pre-packaged products(G/TBT/N/MEX/95) and Mexico: Standard for Glazed Pottery Ware, Glazed Ceramic Ware and Porcelain Ware (G/TBT/N/MEX/69)

35. The representative of Mexico informed the Committee that with respect to both the above-mentioned technical regulations, bilateral consultations were ongoing and some agreement had been reached on how to deal with the comments previously raised by the European Communities.

C. OTHER MATTERS

1. Procedures established at the Codex Alimentarius Commission

36. The representative of Chile informed the Committee of her country's concern with respect to an ongoing situation in the Codex Alimentarius that had impeded adoption of certain modifications to a particular standard. She recalled that Codex standards were relevant both for the WTO SPS and TBT Agreements. Therefore, it was important that the procedures established by the Codex ensured credibility in the process of development of international standards. In the Codex, this process itself followed clear criteria and rules on the basis of scientific evidence.

37. In the specific case at issue, Chile had worked for a period of eight year to achieve the inclusion of a common Chilean species of sardines (*Clupea Bentincki*) in the Codex Standard for Canned Sardines and Sardine Type Products. Chile had complied with all applicable requirements for the inclusion of new species. These requirements themselves had been approved, in 1998, by the Codex Committee on Fish and Fishery Products with no opposition from any participating country. Nevertheless, when Chile's request was submitted to the Codex Alimentarius Commission for final approval, no consensus had been achieved. Some countries had asked for a revision of the procedures for the inclusion of new species because they felt that these were incomplete, and that the current standard did not meet the appropriate level of protection for the consumer. While Chile supported the initiative to review the procedures, it would not do so as a condition for the acceptance of the inclusion of the common Chilean sardine. Developing countries, such as Chile, needed to rely on clear and stable rules. The non-approval of Chile's request would mean ignoring current procedures, flouting the rights of those who had respected them (and sought to comply with them for eight years in Chile's case) and make it impossible to include new species in the short run. This would become a barrier to trade and would cast doubts on the procedures of the Codex itself as well as undermine the credibility of the Codex as a referenced standard-setting organization at the WTO.

38. The representative of Chile went on to suggest that, in order to ensure that these barriers to trade did not emerge in the standard-setting organisations, the TBT Committee could consider adding to those criteria that it had defined in the year 2000 in order to ensure that standards became relevant

international standards.[6] In Chile's view, these standards setting organizations needed to comply with their own agreed procedures. Chile would draw up a specific proposal on this subject for the next meeting of the Committee and hoped that it would be included in the up-coming Fourth Triennial Review.

39. The representative of Mexico was of the view that the matter deserved consideration by the TBT Committee and Mexico would revert to the issue with specific comments.

40. The representative of the United States stressed the need to understand what the facts at issue were, before attempting to establish whether the TBT Committee needed to amend its own work; it be so that the tools were already at Members' disposal.

41. The representative of the Codex informed Members that, at the Codex Committee on Fish and Fishery Products Committee held recently in South Africa, the inclusion of the specific type of sardine mentioned above had been raised but there had not been sufficient time to discuss this issue. The Committee had decided to extend the discussion until the next session of the Committee, to be held in 2006. At that point Codex members would discuss both the procedural matters as well undertake a more technical consideration of the standard itself.

III. TRIENNIAL REVIEW

A. ISSUES ARISING FROM THE THIRD TRIENNIAL REVIEW

1. Good Regulatory Practice

42. The Chairman began by recalling that the Committee's mandate on Good Regulatory Practice in the Third Triennial Review contained three elements. The Committee had, to date, held useful discussions pursuant to the first of the three recommendations contained in paragraph 14 of the Third Triennial Review, which was the exchange of national experiences related to the identification of **elements** of Good Regulatory practice at the domestic level.[7] In this discussion, a number of issues related to Good Regulatory Practice had been mentioned: these included issues such as transparency, harmonization, equivalence, regulatory impact assessment, consensus, representativness and non-duplication. The Chairman then went on to recall that, pursuant to paragraph 14, the Committee had agreed to pursue its work on two other elements. First, the Committee was to hold focused discussions "on, *inter alia*, choice of **policy instruments**, mandatory versus voluntary measures, and the use of regulatory impact assessments to facilitate Good Regulatory Practice" (emphasis added). Second, the Committee was to "initiate a process of sharing experiences on **equivalency** in the Committee particularly with regard to how the concept was implemented in practice" (emphasis added). The Chairman encouraged delegations to come forward with further submissions on each of the three elements of Good Regulatory Practice set out above (elements, policy instruments and equivalency) at the next meeting.

43. No further issues were raised in relation to the follow-up of the Third Triennial Review.

2. Transparency Procedures

44. The Chairman recalled that the Committee had held a wide ranging discussion on transparency in 2004. On one particular point, Canada had drawn the Committee's attention to a recommendation to examine the feasibility of creating a central depository for notifications on the WTO website, which would enable Members to complete notification forms on-line on the WTO

[6] The principles referred to are contained in G/TBT/1/Rev.8 under: "IX. Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement."

[7] See Colombia in G/TBT/W/239, Mexico in G/TBT/W/248 and Chile in Job(04)/163.

website. It had been agreed that the Secretariat would look into the feasibility of setting up such a facility.

45. The Committee took note of the information provided by the Secretariat in this respect (Annex 2, page 44, below).

46. No further issues were raised in relation to the follow-up of the Third Triennial Review.

3. Conformity Assessment

47. The Chairman recalled that in Paragraph 40 of the Third Triennial Review (G/TBT/13), the Committee had agreed on a Work Programme intended to improve Members' implementation of Articles 5-9 of the Agreement and promote a better understanding of Members' conformity assessment systems.

(a) SDoC

48. The Chairman presented his report on the 21 March 2005 TBT Workshop on SDoC.[8]

49. The representative of Grenada reiterated the difficulties faced by developing countries regarding their participation in the work of international standard-setting organizations. In her view, the high cost of such participation was a potential barrier to international trade in that it made the recognition of conformity assessment more difficult. The Committee needed to find a way of addressing this issue because, in fact, in order to benefit from the system one had to be a Member of it. The representative of Antigua and Barbuda supported this point and added that ISO/IEC Standard on SDoC seemed to be proceeding the same way as ISO 9000: although purported to be voluntary, market forces were making it *de facto* mandatory.

50. The representative of the United States stressed that SDoC had originally been a tool for the market place, used for compliance with voluntary standards as a communication vehicle between buyers and sellers. One important lesson from the discussion of the workshop was that the updating of the ISO standard had been an attempt by industry to make the document more usable as a tool for regulators. Nevertheless, she stressed, there was no requirement for any government to use an international standard that was not effective or relevant for its domestic regulatory purposes.

51. The representative of Mexico stressed the point he had made at previous day's workshop (see Annex 1, para. 143, on page 43).

52. The representative of Egypt stressed that there was a need to look at how developing countries could benefit from SDoC. For instance, it had been made clear from the discussions during the workshop that there was a need to establish market surveillance systems when introducing SDoC. Yet the capacity to set up such systems in developing countries was missing; the two issues needed to be considered together.

53. The representative of Brazil stressed that SDoC was a market-based solution to a problem of certification, which could have different impacts according to levels of development among countries, as well as the size and repute of the companies using it. It was therefore important to consider the views of certification bodies and those of SMEs.

[8] The Chairman's summary is contained in paragraphs 135-142 of Annex 1 (page 18).

(b) Accreditation Fora

54. The Chairman recalled that, during 2004, pursuant to Paragraph 40 of the Third Triennial Review, the Committee had heard presentations on the operation of accreditation fora and the participation of Members, in particular developing country Members, in these fora.[9] He noted that Paragraph 40 also contained another recommendation which stated that "users, such as certification bodies, should also be invited to share their experiences in this respect". He suggested that at the next meeting of the Committee Members would provide information on the experiences of *users of* accreditation, such as certification bodies, in their respective countries.

55. The representative of the United States pointed out that, with respect to the recommendation relevant to users of accreditation bodies, such as certification bodies, since these were private bodies, it seemed that a good opportunity to follow-up would be in the context of the planned March 2006 workshop. She suggested that this be one element to consider in the preparation of a draft programme of that event (see paragraph 57, below).

(c) Other Issues related to Conformity Assessment

56. The Chairman recalled that the Committee had discussed other issues relevant to conformity assessment during 2004.[10] For example, the European Communities had spoken about their "New Global Approach" and the representative of Jordan had informed the Committee about its international product conformity certification programme (DAMAN[11]). Likewise, the BIPM and OIML had spoken about metrology and the IEC and the OECD had provided substantive input on relevant on-going work in their organizations.

57. It was agreed that the Secretariat would prepare an outline of a draft programme for the planned March 2006 workshop on conformity assessment.

4. Technical assistance

58. The Chairman reported on his consultations held on an "issues and options paper" aimed at facilitating further discussion on the subject of transparency in TBT related technical assistance and which sought to find possible ways forward for the Committee.[12]

59. He began by noting that there had been general support for Option 2. Members had felt that this was a simple, pragmatic and forward-looking approach and offered the most viable course of action for the Committee. There had also been a feeling that Option 2 presented an opportunity for the Committee to commence work in the short term and that it could prompt the Committee to have a substantive discussion based on concrete, specific and current concerns. Moreover, in the sense that Option 2 could create an incentive for follow-up, feedback and discussion of specific needs by the Committee, it could contribute in operationalizing Article 11. Information made available would be complementary to existing databases.

60. Nevertheless, some Members had clearly felt that Option 2, by itself, was not sufficient, and that there was merit in pursuing the other Options in parallel. In terms of Option 1, the door needed to be kept open: in the SPS area, the STDF facility was already functional and it could be useful for the Committee to learn from developing countries' experience in this regard, and what relevance this could have to technical assistance needs in the TBT area. On Option 3, it had been pointed out that

[9] The Committee heard presentations from the International Laboratory Accreditation Co-operation (ILAC), the International Accreditation Forum (IAF), the European Co-operation for Accreditation (EA). The Committee had also heard a presentation on the new ISO Standard for accreditation (ISO/IEC 17011).

[10] G/TBT/13, Para 40, first tiret, first part of sentence: "Exchange information and experiences on existing conformity assessment procedures and practices, the use of relevant international standards, guides and recommendations, ... ".

[11] International Product Conformity Certification Program.

[12] JOB(05)/20, 21 February 2005.

the Committee could address some of the elements under the existing standing agenda item on technical assistance. At a subsequent phase, the Committee could revert to the concept in this option in light of advances of work on Option 2. However, both with respect to Option 1 and Option 3, funding, as well as Secretariat resources, remained an issue. Hence, while the concepts in these options remained on the table, and needed to be further explored in light of further developments (the door was not closed), they appeared to be more long-term in nature.

61. In light of the above, the Committee agreed to proceed with the voluntary notification of specific technical assistance needs and responses (Option 2) while keeping Options 1 and 3 on the table. The Secretariat would, in cooperation with the Chairman, circulate a draft notification format (for both specific technical assistance needs and responses) for Members' consideration ahead of the next meeting

5. Other Elements

62. The representative of the ISO informed the Committee about the publication, in 2004, of the new standard ISO/IEC 17000:2004 (Conformity Assessment – Vocabulary and General Principles) and its relation to the revised Guide 2 (ISO/IEC Guide 2:2004). He explained that the revised Guide 2 replaced all previous editions of the Guide; it had replaced clauses 12-17 with a cross-reference to ISO/IEC 17000. This maintained the necessary linkage between the two base vocabulary documents for internationally accepted standardization and conformity assessment practices. He suggested WTO Members could consider referencing ISO/IEC Guide 2:2004 which included the cross-reference to ISO/IEC 17000:2004. Apart from the above-mentioned change, there were no other differences between the new 2004 edition of Guide 2 and the previous edition published in 1996. In other words, Clauses 1-11 remained in ISO/IEC Guide 2:2004 unchanged. It was noted that the new ISO/IEC 17000:2004 provided internationally accepted definitions for terms that were, *inter alia*, found in Articles 5, 6, 7 and 8 of the TBT Agreement.

63. The representative of the United States stressed that there was a need to understand better the differences between the 1991 version of Guide 2 and the 1996 version of that same Guide, which itself had now been replaced by the above-mentioned 2004 version. This was an issue the Committee would have to look in to.

64. The representative of Mexico stressed the possible legal implications arising from a change to an international standard that defined the terms used in implementing the TBT Agreement. In addition, reference was made in the latest revision of Guide 2, to terms used to define conformity assessment which were not currently referenced in the TBT Agreement at all. He raised the question as to whether that, *per se*, had any consequences on the implementation of the TBT Agreement's provision on conformity assessment. It would, perhaps, be better for TBT Committee to discuss the issue rather than leaving it for a possible future dispute.

65. The representative of the European Communities recalled that this had been discussed at a previous meeting of the Committee.[13] The key was how to deal with a situation where an existing agreement was out of date: it could make sense to change the Agreement so as to bring it up to date.

66. The representative of Cuba suggested that a factual document be prepared which compared the TBT Agreement with the international guide.

67. The representative of Mexico was concerned that the Committee would enter into any exercise which would entail a modification of the Agreement. That was not necessarily the best option. He recalled that Article IX of the WTO Agreement permitted the General Council to adopt

[13] G/TBT/M/32, para. 106.

authorised interpretations of the WTO Agreements. The representative of Australia shared Mexico's concern.

68. Referring to the question raised by the United States, the Chairman wondered whether the ISO wished to comment on the feasibility of comparing the 1991 and 1996 versions of Guide 2.

69. The representative of the ISO noted that any work on terminology was long and tedious. The latest revision had been made necessary by developments on the international scene relating to conformity assessment. Nevertheless, should the Committee so wish, the ISO could provide further detail, at a later date, on the differences between the various versions. He emphasized that the new version (ISO/IEC Guide 2:2004) only changed the terms relating to conformity assessment.

70. The Committee took note of the information provided by the ISO.

71. In concluding the discussion on the follow-up to the Triennial Review, the Chairman remarked that the Committee had now discussed the recommendations under each of the various headings of the Review, and taken action accordingly. Substantial progress has been made to give effect to the mandated follow-up on several elements of the Review. This would allow the Committee to gradually shift, in line with the Work Programme for the Fourth Triennial Review, into the preparation of the Fourth Triennial Review.

B. PREPARATION OF THE FOURTH TRIENNIAL REVIEW

72. The Chairman recalled that at its meeting of 4 November 2004, the Committee had endorsed a Work Programme for the preparation of the Fourth Triennial Review of the Implementation and Operation of the TBT Agreement pursuant to Article 15.4 (Annex 3 on page 45). In that Work Programme, it had been agreed that the Committee would initiate the review work at the current meeting by making a preliminary identification of topics for the Review. The Chairman stressed that Members would be able to add on or to modify this list during the discussion phase of the review work and to revert to issues and submissions discussed on previous occasions. In addition to the point made by Chile in paragraph 36, above, the list of topics suggested by Members included the following (with the Member identifying the topic in parenthesis):

(a) Implementation and administration of the Agreement (US);
(b) Good regulatory practice (EC, US);
(c) Transparency (China, EC);
(d) Conformity assessment procedures (EC, US);
(e) Technical assistance (China, EC);
(f) Special and Differential Treatment (China);
(g) Intellectual property rights issues in standardization (China); and,
(h) Labelling (EC).

73. The representative of the United States noted that from her delegation's perspective, there was a need, under the *Implementation and Administration of the Agreement*, to continue the past practice of taking stock of which Members had submitted the statements on implementation, as well as established enquiry points. Moving on to the *Good Regulatory Practice*, this concept was not well defined in the TBT Agreement. Nevertheless, discussions in the Committee had provided an opportunity for Members to deepen their understanding of how domestic procedures were being implemented so as to ensure that regulations did not create unnecessary barriers to trade. Further discussions on this topic could give an opportunity to focus more deeply, for instance, on the issue of transparency and impact assessment. On *conformity assessment* the representative of the United States hoped that the Committee would, during the Fourth Triennial Review, be able to achieve greater focus and understanding than what had been achieved at previous triennial reviews.

74. The representative of China noted that his delegation had identified three areas for consideration in the Fourth Triennial Review: transparency, technical assistance and intellectual property rights issues in standardization. In respect of *intellectual property rights*, he stressed that there was a need to avoid conflicts between standardization and IPR. To enhance the efficiency of the international standards development process, and to facilitate Members' adoption of international standards, patented technologies that were necessary to meet the objective of a standard had to be treated appropriately to strike the right balance between the needs of international standards development and the implementation of adequate and fair protection of IPRs. Accordingly, the Chinese government perceived a need for the TBT Committee to discuss, in the framework of the Fourth Triennial Review, appropriate policies in this regard.

75. In particular, it was the view of the Chinese representative that international standardizing bodies such as ISO, IEC, ITU, ANSI, CENELEC and ETSI had established policies concerning patented technologies in standardization. In these policies, it had been deemed desirable that the full information of patented technologies on patented applications needed to be disclosed. It was also stipulated that once a patented technology had been promulgated in a standard, the patent holder was required to declare that it would accept the RAND Principle in patent usage negotiations (this principle, it was explained, entailed that IPR holders negotiated with applicants for IPR usage on reasonable and non-discriminatory terms and conditions). Such policies provided the Committee with a good technical base and a road map to follow. It was stressed, however, that there were many IPR policies of standardization that needed to be addressed. For example, although disclosure was important in standards development, some standardization bodies had declared that they would not be responsible for identifying patented rights. Moreover, there were no concrete measures to encourage IPR holders to disclose related information. Finally, there were no remedy provisions in cases where IPR holders would not accept the correct policies. There were several other technical questions that needed to be explored, such as: at what stage did information need to be disclosed? who bore the responsibility for information disclosure? who bore the responsibility for RAND terms arbitrage?

76. The representative of China stated that although the TBT Committee could not be expected to discuss all the above complex questions, since the Agreement encouraged Members to adopt international standards and the above-mentioned issues concerning IPRs were important for the efficiency and quality of international standards development, the TBT Committee needed to give them due consideration.

77. The representative of the European Communities noted that on *transparency*, it was his delegation's view that the systematic access to final texts of technical regulations and conformity assessment procedures notified under the TBT Agreement would be useful insofar as it would allow Members who had submitted comments on a notification to see how these comments had been taken into account. More discussion in the field of translation of notified texts could be useful. Regarding *technical assistance*, the Committee needed to continue its work in respect of the elaboration of the information coordination mechanism. Moreover, the Committee needed to explore ways in which to improve the participation of developing countries in the international standardization process. On *conformity assessments procedures*, it was stressed that these remained a substantial burden for exporters and importers, particularly in cases where there were a variety of procedures in domestic and foreign markets for similar products. The Fourth Triennial Review needed to promote the use of appropriate conformity assessment procedures, in particular with respect to Article 5.1.2 of the TBT Agreement which stressed that such procedures could not be applied more strictly than necessary. The use of accreditation needed to be examined in more depth. On *Good Regulatory Practice*, different approaches to regulatory practices needed to continue to exist. There was, perhaps, a need to increase the examination of ways in which an increase in the use of performance based regulations could be achieved. There could also be merit in developing the concept of regulatory cooperation, as well as exchanging experiences with respect to regulatory impact assessments. The European Communities also wished to raise the issue of *labelling* with the objective of improving Members' mutual understanding on the nature, scope and the impact of measures undertaken in this area.

78. The representative of Mexico noted that, with respect to labelling, his delegation had, on several occasions, indicated that labelling was either a technical regulation or a conformity procedure depending on the situation. It was not obvious to Mexico that there was a need to give a particular focus to labelling as such: it was a measure that was part of a wider universe of TBT measures that could, perhaps, be debated under the heading of Good Regulatory Practice. Regarding the issue proposed by China on intellectual property rights, there was a need to analyse what actually China wished to discuss. In the view of the Mexican delegation, intellectual property rights were not within the remit of the TBT Agreement. Mexico also wished to add an item to the list: the compliance with the obligations of the Agreement by authorities at a sub-national regional or local level. The representative of the European Communities supported this suggested addition.

79. The representative of the United States recalled, with respect to labelling, that much time had been spent on discussing the issue in the context of the Third Triennial Review, and that the result of these discussions was contained in paragraph 60 of G/TBT/13 where the Committee had agreed "to continue to consider labelling concerns in its discussions in the context of the implementation and operation of the Agreement". The intention had been to keep the discussion context specific which was the case when Members, on a regular basis, raised specific trade concerns at TBT Committee meetings. Hence, before considering this as a topic to be debated during the Fourth Triennial Review, there was a need for the European Communities to come forward with a substantiation of why they considered that labelling merited particular attention, and why it was not possible for the European Communities to address the issue in the context of the normal agenda of the Committee. The representative of the Australia associates herself with these comments as well as those put forward by Mexico on labelling.

80. The representative of Switzerland noted that her delegation supported the proposal to discuss conformity assessment procedures. She also supported the EC proposal on labelling.

81. The representative of the European Communities stressed that in the Third Triennial Review the Committee had agreed to continue to consider labelling concerns. It was his view that, given the number of specific trade concerns which involved labelling issues, it was something that the Committee needed to discuss. While the European Communities preferred that the issue be discussed in the context of the preparation of the Fourth Triennial Review, the discussion could also be done in the as a follow-up to the Third – in any case the issue could be raised.

82. The Chairman suggested that the Committee consider, at its next meeting, three topics: (i) the Implementation and Administration of the Agreement, (ii) Good Regulatory Practice and (iii) Transparency. It was so agreed.

83. The Chairman encouraged Members to table papers on the above-mentioned three topics to be discussed at the next meeting by 15 May. In respect of background papers, on Implementation and Administration of the Agreement, Members were referred to document G/TBT/GEN/2/Rev.1and G/TBT/ENQ/26. On Good Regulatory Practice, a factual note would be prepared by the Secretariat and made available to delegations ahead of the next meeting. On transparency, it was recalled that the Secretariat had already prepared a background note for the Committee's Fourth Special Meeting on Procedures for Information Exchange which was contained in document G/TBT/W/250.

IV. TECHNICAL CO-OPERATION

84. The representative of the International Trade Centre (ITC) informed the TBT Committee about a recent joint publication by the Commonwealth Secretariat and the ITC entitled "Influencing and Meeting International Standards: Challenges for Developing Countries". He also briefed the Committee on the organization of a workshop on the same topic which would be organized jointly with the Commonwealth Secretariat in Geneva from 22 to 24 June 2005. Aside from this Geneva-based workshop, other national workshops had been organized on the TBT Agreement in Kyrgyzstan

and Tajikistan in October 2004. A regional workshop had been held in Kenya in January 2005 and the ITC would be participating in regional TBT workshops under the JITAP in Malawi, from 31 May to 2 June 2005, and in Cotonou, from 13 to 15 September 2005. The TBT Committee was also informed about the ITC's Executive Forum which provided a venue for senior public sector decision-makers and business leaders to debate "best practice" in national export strategy design and management.[14]

85. The representative of the UNCTAD reported on the first substantive session of UNCTAD's new Consultative Task Force on Environmental Requirements and Market Access for Developing Countries (CTF), held on 5 and 6 November 2004 in Geneva. He also reported on a stakeholder discussion about the EC's draft REACH regulation organized with the Foundation for International Environmental Law and Development (FIELD) held in Brussels on 28 and 29 October 2004. Moreover, on 23-24 November and on 2 to 3 December 2004, the UNCTAD had organized national policy dialogues on environmental and related health requirements and market access for horticultural products in Phnom Penh, Cambodia, and in Manila, Philippines. On organic agriculture, the third and fourth meeting of the UNCTAD/FAO/IFOAM International Task Force on Harmonization and Equivalence in Organic Agriculture had been held on 17 to 19 November 2004 in Rome, and on 28 February in Nuremberg, Germany. As part of UNCTAD's UK-DFID-funded project, a regional workshop on environmental requirements, market access and trading opportunities for organic products, jointly organized by the Ministry of External Commerce (COMEX) and UNCTAD, took place in San José, Costa Rica, on 30 to 31 March 2005. Regarding forthcoming meetings, in co-operation with the UN Economic and Social Commission for Asian and the Pacific and the Federation of Thai Industries, the UNCTAD Secretariat was planning to hold a sub regional workshop in Bangkok, in May 2005, that would exchange national experiences among China, Malaysia, the Philippines and Thailand on pro-active adjustment strategies to new environmental requirements for electrical and electronic products.[15]

86. The representative of UNIDO drew the Committee's attention to a report on the "Relevance of UINDO Services to the Responses to the WTO Questionnaire G/TBT/W/178"[16] He stressed that the UNIDO approach to technical assistance included support to developing countries in improving their national quality policies, conformity assessment systems, standardization and methodology infrastructure. The Committee was also briefed on the implementation of the UNIDO/WTO Memorandum of Understanding (MoU) which established a strategic partnership between the two organizations for the purpose of implementing the Doha Development Agenda.[17] In this MoU, it was set out that UNIDO's main contribution focused on issues relating to developing countries' supply side capacity as well as conformity to standards.

87. The representative of the IEC updated the Committee on his organization's international standardization and assessment activities undertaken since the last meeting of the TBT Committee.[18] He drew WTO Member's attention to the IEC's Affiliate Country Pogramme, launched in June 2001 as a direct response to calls for finding ways and means for *all* WTO Members to use IEC international standards, as well as conformity assessment schemes, and to participate in their elaboration. This program was unique in that it was free: there was no charge and it operated in a full electronic environment, which allowed participants to involve themselves in the IEC's technical work according to the needs and the resources available. A workshop dedicated to the Affiliate Country Programme, would be held under the auspices of the IEC General Meeting, to be held in Cape Town, South Africa from the 16 to 22 October 2005.

[14] More information is available at http://www.intracen.org/index.htm.
[15] More information is available at http://r0.unctad.org/trade_env/.
[16] This report was made available as a Room Document.
[17] It was pointed out that the Second Joint Progress Report", 8 November 1994, WTO, UNIDO had been circulated at the last SPS Committee meeting as document JOB(05)/28.
[18] The IEC's full report had been issued separately as G/TBT/GEN/16.

88. The Chairman noted that a room document was available outlining the Secretariat's planned technical assistance activities.

V. TENTH ANNUAL REVIEW

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

89. The Committee adopted the Tenth Annual Review of the Implementation and Operation of the TBT Agreement contained in document G/TBT/15.

B. THE CODE OF GOOD PRACTICE (ANNEX 3)

90. The Chairman drew the Committee's attention to the Tenth Edition of the WTO TBT Standards Code Directory prepared by the ISO/IEC Information Centre which contained information received according to paragraphs C and J of the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 of the Agreement. He also drew the Committee's attention to two lists prepared by the Secretariat. The first list, contained in document G/TBT/CS/1/Add.9, compiled the standardizing bodies that had accepted the Code in the period under review. Since 4 March 2004, five standardizing bodies from five Members had accepted the Code of Good Practice. This included four central governmental standardizing bodies and one non governmental standardizing body. No standardizing body had withdrawn from the Code during the period under review. The second list, contained in document G/TBT/CS/2/Rev.11, compiled all the standardizing bodies that had accepted the Code since 1 January 1995. Since 1 January 1995, 147 standardizing bodies from 106 Members had accepted the Code of Good Practice.

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

VI. OBSERVERS

A. REQUESTS FOR OBSERVER STATUS

92. The Chairman drew the Committee's attention to document G/TBT/GEN/2, circulated on 4 March 2004, which set out the situation with respect to observership by inter-governmental organizations in the TBT Committee. There were still four organizations whose requests for observer status were pending: the *Office International de la Vigne et du Vin* (OIV), the *Bureau International des Poids et Mesures* (BIPM), the Gulf Organization for Industrial Consulting (GOIC) and the Convention on Biological Diversity (CBD). He noted that consultations were still needed on the issue of observership at the General Council level.

B. UPDATING BY OBSERVERS

93. The representatives of OIML and the Codex updated the Committee on relevant work in their areas. These reports are contained in G/TBT/GEN/17 and 18, respectively.

VII. ELECTION OF CHAIRPERSON

94. Pursuant to Article 13.1 of the TBT Agreement, the Committee elected Mr. Margers Krams (Latvia) as the Chairperson of the TBT Committee.

VIII. DATE OF NEXT MEETING

95. The Chairman announced that the next regular meeting of the Committee would take place on 16 to 17 June 2005.

ANNEX 1: TBT WORKSHOP ON SUPPLIER'S DECLARATION OF CONFORMITY

21 March 2005

1. At the Third Triennial Review of the TBT Agreement, concluded in November 2003, the Committee agreed to a Work Programme on conformity assessment to improve Members' implementation of Articles 5 to 9 of the TBT Agreement and, in particular, to promote a better understanding of conformity assessment systems.[19] In 2004, the Committee discussed the issue of conformity assessment under three sub-headings: (i) Supplier's Declaration of Conformity (SDoC), (ii) Accreditation and (iii) Other Issues Related to Conformity Assessment. The workshop, held in Geneva on 21 March 2005, focused on Supplier's Declaration of Conformity as *one* approach to facilitate the acceptance of conformity assessment results.[20] The participation of 93 representatives from developing country Members was sponsored by the WTO through the Global Trust Fund.

IX. GENERAL

A. OVERVIEW OF THE TBT COMMITTEE'S WORK ON SUPPLIER'S DECLARATION OF CONFORMITY

2. The WTO Secretariat[21] presented a background note contained in JOB(05)/30. It was emphasized that this note was intended to assist participants in preparing for the meeting and provided an overview of the key issues, submissions and statements made in respect of SDoC in the TBT Committee to date.

3. The representative of the European Communities made the point that while there were certainly benefits from the use of SDoC (costs for third party assessment were avoided), its use also entailed some administrative costs. For instance, market surveillance could be needed in some circumstances and there had to be procedures in place for follow-up in cases of product failure.

B. THE ISO/IEC STANDARD ON SUPPLIER'S DECLARATION OF CONFORMITY (ISO/IEC 17050)

1. Statement

4. The representative of the ISO[22], stated that with regard to SDoC, there had initially been an ISO guide on SDoC: Guide 22 (published in 1996). This Guide had constituted the starting point for elaborating a fully-fledged international standard addressing SDoC: the ISO/IEC 17050 (published in 2004). There were two parts to this standard. Part One contained general requirements for companies and organisations making their own claims on conformity. It covered: (i) the indication of the general responsibilities of the issuer; (ii) the content of the Declaration of Conformity (DoC); (iii) accessibility to the DoC; (iv) marking and labelling of products with the DoC; and, (v) the duration of the validity of the DoC. An annex provided an example of the DoC.

5. In respect of the content of an SDoC itself, the representative of ISO stressed that it had to contain, as a minimum: (i) a unique identification (that related the declaration to a given product or process); (ii) the name, contact address and signature of the issuer; (iii) an identification of what the declaration covered (for example, product description, type and extent of management system); (iv) the complete list of specified requirements, including standards, that the declaration was based on; (v) the date and place of issue; and, (vi) any limitation related to the validity of the declaration.

[19] G/TBT/13, para. 40.
[20] The full program is contained in G/TBT/GEN/15.
[21] Mrs. Ludivine Tamiotti, Legal Affairs Officer, Trade and Environment Division.
[22] Mr. Allan Bryden, Secretary General, International Organization for Standardization (ISO).

6. Regarding marking, it was pointed out that product marking had to be done in such a way that it would not be confused with any certification mark (third party conformity assessment). Moreover, such marking had to be traceable back to the issuer. The issuer had to have procedures in place to re-evaluate the validity of the declaration of conformity when: (i) there were changes that affected the object's design or specification (for example the changes to the actual product, management system etc); (ii) there were changes to the specified requirements (including standards) that related to the object of the declaration; (iii) there were changes in the ownership or management of the issuer; (iv) there was any relevant information which indicated that the object no longer fulfilled the specified requirements.

7. Part Two contained guidance that covered the content of supporting documentation. This guidance included: (i) the description of the object of the declaration of conformity, including design documentation; (ii) the conformity assessment results, such as a description of the method used to determine conformity, the actual results (for example, audit reports and test results) and records on the evaluation of those results which had led to the declaration of conformity; and, (iii) details of the relevant qualification and technical competencies of those involved in determining conformity. Document management was key to the efficiency of any requirement. Thus, Part Two also related to the management of supporting documentation in terms of: (i) traceability for the declaration of conformity; (ii) the availability of any supporting documentation; and, (iii) the retention of supporting documents for conformity assessment.

8. Regarding the use of the SDoC ISO/IEC Standard, the representative of the ISO stressed that SDoC could be a cost effective conformity assessment method. It could also be used as a method for achieving public policy goals when risks associated with product failure were considered low.

2. Discussion

9. The representatives of Antigua and Barbuda and Grenada expressed concern about the fact that WTO Members, who were not full members of ISO, were limited in their participation in the standards development process. They stressed that becoming a member of ISO was a costly process and many could not afford it. Thus, they could not directly influence the standards development process. This was troubling as the TBT Agreement made specific reference to the use of international standards and Members were expected to use those standards.

10. The representative of the ISO stressed that the minimum membership fee of ISO had to be seen against the background of the benefits that membership offered. Some 149 institutes or organisations responsible for standardization in their home countries were currently members of ISO. Through their participation in ISO they received access to knowledge and expertise which had been developed and was contained in the standards themselves. Furthermore, ISO produced about 1,100 international standards per year. Nevertheless, the representative of ISO acknowledged that for smaller economies it could be difficult to take an active part. In 2004, ISO had therefore adopted a five-year action plan to increase the participation of developing countries in its work. Since then there had been a significant increase in developing country membership.

11. The representative of the United States asked for more information on the extent to which there had been developing country participation in drawing up the particular standard on SDoC. Moreover, the US representative asked how the SDoC-mark, which needed to be traceable back to the issuer, could be distinguished from a certification mark.

12. Regarding participation, the representative of ISO indicated that 99 of the 149 members of ISO were members of its Conformity Assessment Committee (CASCO). Though he was unable to provide Members with exact figures regarding the vote on the SDoC standard, he assured the Committee that developing countries had had the opportunity to be involved. Regarding the mark, it was clarified that the standard did not indicate that there needed to be a mark, but merely that, if there

was a mark associated with it, it would have to be clearly distinguishable from any third party certification mark. The mark for a SDoC would be the mark of the supplier and a statement that the DoC had been carried out according to an international standard in terms of the content, the layout, etc.

13. The representative of Mexico asked why ISO CASCO had developed the standard on SDoC in the first place: had there been a petition or concern on the part of the private sector, or had the incentive come from somewhere else? Also, Mexico asked whether the ISO, in the course of its regular review[23], would carry out an evaluation on how many countries had actually adopted the standard.

14. The representative of the ISO noted that there was an ISO policy on the development of a standard when there was a clear recognition of the need to do so. The way the ISO formally recognized such a need was through national votes on the creation of a "new work item". In the case of SDoC, the incentive to take the vote had come on the one hand from the private sector, because of the various practices of SDoC which could lead to confusion in the market, and, on the other hand, from regulatory authorities, which had also been interested because they desired some formal guidance on how to use SDoC. Regarding the review, it was confirmed that the review of ISO's standards took place at least every five years, unless there was a reason to start earlier. In this context, the use of the standard would certainly be checked. However, it was pointed out that not all countries formally adopted the ISO standards. A number of countries made direct reference to ISO's standards by referring to them as "international publications". Hence, actual use of the document in the market could be greater than what would be reflected in a count of the number of national "adoptions".

15. The representative of Argentina asked how significantly the use of SDoC contributed to cost reduction and whether there were any studies which addressed the average reduction in cost across sectors compared to third party evaluation of conformity (certification).

16. Regarding the incentive to develop ISO/IEC 17050, the representative of the United States[24], recalled that the original Guide 22 had been used successfully for many years via voluntary adoption by industry and also by some regulators in the EU, Australia and New Zealand. The incentive to further develop it had come from industry when it was trying to persuade more governments to use SDoC. Some of the feedback that had been given by the governments was that the original standard, ISO/IEC Guide 22, was not rigorous enough and that it had to be updated and revised to add more substance to it. The US industry raised the issue through its national body to ISO and requested a revision to that standard. Now that more requirements had been added to make it more rigorous, ISO/IEC 17050 gave more confidence to the regulators.

17. The representative of Guyana stressed the need for more technical assistance in terms of implementing the new standard and putting in place the appropriate regulatory infrastructure. He was concerned that in the absence of such assistance, small economies would not benefit from the standard. In fact, the Workshop was probably the first time many developing countries had heard of the ISO/IEC 17050. It was unclear to what extent the standard had been implemented so far and what kind of institutional arrangements and infrastructure had been established by those countries that had done so.

18. The representative of China noted that SDoC could be combined with many other conformity assessment methods, such as second and third party evaluation. In any case, the supplier had to retain the choice of deciding which measure should be applied.

[23] Which was due in 2009 for ISO/IEC 17050:2004.
[24] Mr David Ling, Hewlett Packard.

19. The representative of the ISO, emphasized that the choice between the different approaches to conformity assessment depended on many factors and, from a regulators point of view, risk was a dominant one. Moreover, the decision of the regulator could depend on its capacity to organize market surveillance. It was recognized that the use of SDoC depended to some extent on the possibility to act through market surveillance to avoid faulty declarations of conformity. At the end of the day, the central question was how to make sure that what entered the market complied with the requirements placed on that specific product or activity. The use of SDoC was not exclusive vis-à-vis other forms of conformity assessment: it was one option.

X. MEMBERS' EXPERIENCES

A. THE GOVERNMENT'S PERSPECTIVE[25]

1. New Zealand's Experience with Regard to Electrical Equipment

(a) Statement

20. The representative of New Zealand[26] stressed that his country's electrical safety regulatory system in the field of electrical equipment was fundamentally based on consumer protection and safety and was closely harmonized with the regulatory system of Australia.[27] It had three tiers: (i) a universal requirement for compliance with essential safety provisions, which was based on the European Low Voltage Directive (LVD) and had been in place approximately since 1988; (ii) a formal SDoC requirement for a selected range of medium-risk products (these products were selected jointly with Australia, according to the risk they constituted to the public); and, (iii) for a very small range of products that posed a higher risk for a variety of reasons, a pre-market approval regime was in place. All Australian approvals were accepted into the New Zealand marketplace. Thus, the two countries' regimes for electrical safety were completely harmonized.

21. New Zealand's SDoC regime had been introduced in the late 1990s to implement the Trans-Tasman MRA with Australia; it required the strict pre-market approval for fewer products than Australia and the SDoC regime was applied to those products requiring pre-market approval in Australia but not in New Zealand. SDoC existed in New Zealand in the form of four different regimes: (i) a generic regime for supplier liability that, although it required no formal declaration, still held suppliers accountable for safety; (ii) a formal declaration of compliance regime for electrical safety which required the supplier to make a declaration and keep it on file; (iii) a gas equipment web site, which was based on formal declarations; and, (iv) an EMC[28] regime where the supplier also kept the formal declarations. That EMC regime was aligned with those of Australia and the European Union. Hence, EU certification was accepted.

22. In addition, New Zealand operated a performance-based regulatory regime to support technical innovation. This added some complications to the SDoC system because it raised the question of which standards might be applied. If the standard was not clearly mandated, the supplier had some flexibility to choose alternative standards to fulfil the performance objectives. Also, there was the question of who could certify to the fundamental safety parameters. New Zealand was currently grappling with this issue, because it had few technical certification agencies that could do so and it was unclear how other global and regional standards applied. New Zealand mainly used

[25] Speakers in this section were asked to address, *inter alia*, the following issues: (i) what reasons and factors (such as risk) should be taken into account when deciding to apply SDoC in a particular sector (and not in others); (ii) whether SDoC should be used alone or in combination with third party assessment; (iii) how, in applying SDoC, international standards are taken into account; (iv) what basic institutional and legislative infrastructure needs to be in place to use SDoC (for example in respect of product liability law and consumer redress); (v) how compliance is ensured and what experience exists with respect to surveillance and enforcement (incentives that could be used to encourage compliance and experiences with penalties for non-compliance); (vi) how the use of SDoC by developed country Members can facilitate imports from developing country Members (G/TBT/GEN/15).

[26] Mr. Peter Morfee, Principal Technical Advisor at the New Zealand Energy Safety Service.

[27] Further information on the New Zealand system can be obtained from the web address *www.ess.govt.nz.*

[28] Electromagnetic Compatibility.

Australian and its own standards, but also accepted some international and other regional standards as being equivalent.

23. The aim was to achieve an effective reduction in technical regulatory intervention. The most serious challenge in this regard, when introducing a system of SDoC, particularly where a pre-market approval system was being replaced, was how to justify failures of compliance in the case of an incident of serious consequence. New Zealand's Energy and Safety Service had come to the conclusion that in order to address this challenge, there needed to be some form of risk balancing factor available for implementation as part of the change to a SDoC regime.

24. Compliance in the New Zealand marketplace was generally good; this was a consequence of an effective post-market monitoring regime which consisted of a number of components. First, sharing of market compliance information with the Australian and other regulators, resulted in very low costs for monitoring efforts. In fact, 90 per cent of the cost of surveillance in the New Zealand marketplace was borne by Australia, the European Union and other parties. Hence, particularly where there were common standards, SDoC had some significant enforcement benefits. Second, surveillance of the market by industry parties: New Zealand's Energy Safety Service had found that much of its market surveillance was in fact carried out by the competitors in the marketplace. It was not unusual that suppliers tested their competitor's products and then informed the regulator about the results. Third, targeted auditing programmes: an Incident Reporting and Investigation Scheme as well as the responsible attitude of most suppliers contributed to satisfactory compliance.

25. In New Zealand's experience, SDoC worked well under certain circumstances. First, one precondition was a well-known, internationally aligned and recognized standard for the product in the marketplace. This made it easier for the suppliers to declare exactly what they were complying with. Second, regulatory control over the product in a parallel market that used the same standard, including the manufacturer's economy. In New Zealand's case, these markets were Australia or Europe. Third, a good relationship between the manufacturer and the supplier. There had been some serious problems in New Zealand where the manufacturer was not aware of the standards that the supplier was declaring against. New Zealand's Energy Safety Service agency had also found that large companies complied particularly well when they were involved in the actual product distribution (either importation or sale). Finally, SDoC performed well when functional MRAs with other regulators existed and when SDoC regimes had harmonized provisions.

26. However, New Zealand also found that SDoC did not work well under certain conditions. In particular, when there were alternative global standards with deficiencies in safety outcomes, or when recognized standards were not available. In these cases, problems tended to arise. Moreover, products which were from suppliers who manufactured to a different voltage or frequency requirement constituted a difficulty for New Zealand's electrical safety regulator. This occurred when the manufacturer was not the supplier or not knowledgeable of the market requirements. When small-scale importers and small-scale retailers were involved, SDoC had also not yielded the desired results.

27. New Zealand and Australia were reviewing their regulatory regimes and proposed to introduce a common mandatory SDoC scheme for all products. Currently, Australia did not yet have an SDoC regime and New Zealand only applied its regime to a small number of products. In the future, it would be likely that Australia and New Zealand would apply a mandatory SDoC scheme to all products, supplemented by a pre-market approval system for high-risk products.

28. From the New Zealand Energy Safety Service's experience, there would be merit in having an "international regulators' forum". Also, a global product hazard alert system, which would inform regulators of product failures in the marketplace, could also be useful. In fact, the idea of a global, internet-based SDoC system needed to be explored. It was stressed that New Zealand had a very small and open market – there were few manufacturers in the marketplace and these often served

niche markets, so most products were imported. In a narrow sense, this implied that New Zealand's problems in regulating its economy were common to those of developing economies.

(b) Discussion

29. The representative of Mexico stressed that SDoC could not function if there were no well-developed post-market surveillance mechanisms. Regarding the three-tier system for electrical product safety, Mexico asked on what basis a particular system was chosen. What analysis was carried out to decide this? Mexico emphasized that the relation of *trust* – in this case between Australia and New Zealand – was a very important element.

30. The representative of Chile asked for some clarification of the term "pre-market approval".

31. In response to Mexico regarding the three-tier system, the representative of New Zealand said that the choice of intervention was based on a number of risk criteria which were evaluated jointly with Australia. The most important criteria were: the occurrence of unsatisfactory products in the marketplace; the way in which the domestic market behaved in terms of compliance aspects; and, a safety assessment of the product itself, taking into account the product category. For example, electric fence energizers were potentially quite dangerous because they had exposed components on them. Regarding the enforcement infrastructure, it was stressed that it was possible to use other markets' non-compliance information, if their standards were acceptable and if products were shared. Thus, a regime could include enforcement but would still not need a very strong compliance infrastructure within its own economy. New Zealand had very few test labs and accepted testing from other countries around the world. Regarding "pre-market approval", it was pointed out that New Zealand had a mandatory standard: it required testing in an accredited testing facility of a sample of the product. This was not a batch testing regime. Such testing could be carried out in a number of internationally accredited testing laboratories worldwide. If the product had been found to comply, the pre-market approval could be issued by (i) the regulator in New Zealand or Australia, or (ii) agencies with whom New Zealand had an MRA. Hence, testing could be done within New Zealand or within the economy of manufacture.

32. The representative of Trinidad and Tobago noted that his country's market was small and open so that almost all electrical products were imported. The problem it faced was that a wide range of products were imported, but in very small quantities each. The product standards used were mainly international standards for manufacturers. The representative thus wanted to know what type of standards the New Zealand regulator used for electrical products.

33. The representative of Grenada asked what had been meant by "small players" in the context of SDoC not working well. She also asked about the cost of implementing the global alert system that Mr. Morfee had recommended.

34. The representative of Egypt asked on what basis New Zealand differentiated between medium-risk products and high-risk products. Also, he wanted to know which types of risk were addressed by the auditing programmes Mr Morfee had mentioned when talking about compliance.

35. The representative of the United Nations Economic Commission for Europe (UNECE) suggested that Members prepare a list of practical problems impeding the use of SDoC in order to further the discussions and find concrete solutions for particular problems.

36. Regarding "small players", the representative of New Zealand stated that his statement had been based on the analysis of cases where problems occurred. For instance, there had been major problems with very high technology, specialist equipment of which only *one* exemplar each had been imported. The general problem with that kind of small batch imports was that in order to make a profit on the deal, companies tended not to spend much time on securing documentation from their

suppliers. So, in fact, it was the size of the manufacturing base that mattered. Nevertheless, even if import quantity was small, by networking with other regulators, it was possible to find out the problems of specific products.[29] It was stressed that most problems occurred when products were manufactured in deviation from the usual standards. On the issue of the cost of the global hazard alert system, Mr Morfee pointed out that the system New Zealand already operated with Australia, which had ten different regulators on board, cost very little – this was simply an e-mailing list and did not need a large database. Also, each economy kept track of all its hazard information and posted it on a web site where other regulators could access it.

2. Market Surveillance Mechanisms for Industrial Products in Chinese Taipei[30]

(a) Statement

37. The representative of Chinese Taipei[31] explained that for each product that fell under mandatory SDoC, the Chinese Taipei Bureau of Standards, Metrology and Inspection (BSMI), announced which standard applied and which technical documents were to be prepared. Products that posed low safety risks, such as computer components, had been selected as the first group for which SDoC had been implemented. The testing which was required before making a declaration had to be carried out either by the BSMI itself or by testing laboratories it recognized. A complete SDoC would hence include necessary technical documentation as well as a signed declaration of conformity regarding the applicable standards. Moreover, the technical file had to be retained for at least five years after the product was taken off the market.

38. Should the BSMI carry out a check of the product in the course of market surveillance, the SDoC would have to be presented to the BSMI within 24 hours; for the technical documents the time-limit was ten days. Specialized personnel collected information on non-compliance, analysed risk factors, conducted product checks, supervised the recall or improvement of products by manufacturers and provided information and advice to consumers and suppliers. Market surveillance took place where products were displayed and sold, at production or storage sites as well as in locations where the products were in use, such as work places. Market surveillance plans were drawn up on an annual basis. These were elaborated by taking into account risk assessments, lessons-learnt from previous surveillance activities and the characteristics of products and product areas. Also, information on compliance was gathered from the public via volunteers that were selected to help monitor consumer goods and also from consumer protection groups.

39. The implementation of market surveillance in Chinese Taipei entailed drawing up inspection plans, education programmes for manufacturers and distributors, sample purchases in the market place as well as sampling from the production or storage sites. Sampling was done in order to check whether commodities had passed the required tests, whether the appropriate mark or label had been affixed and so as to monitor imposed recall time limits or violations of display prohibitions. Penalties for non-compliant products were bans on production, sale or import, requiring corrective action within a time-limit, or fines.

40. Two market surveillance plans had been implemented in 2003 and 2004, respectively. Appearance checks (whether the mark was affixed or not) yielded a non-compliance rate of ½ per cent in 2003 and one of 6 per cent in 2004. Sample Testing (regarding the declaration of conformity, technical documentation and EMC testing) revealed a non-compliance rate of 47.7 per cent and 24 per cent respectively. Hence, Chinese Taipei's experience with SDoC had not been particularly successful as the non-compliance rate was relatively high compared to the rate under other conformity

[29] For instance, a multinational manufacturer was unlikely to produce only twenty or fifty items for a one particular economy. This meant that there would probably be thousands or tens of thousands in other markets. If a regulator could find out where were and what problems they caused, a small import quantity would not matter.

[30] For more information, consult: http://www.bsmi.gov.tw.

[31] Mr. Bing-Yuan Liou, Senior Specialist, BSMI, Ministry of Economic Affairs.

assessment procedures. Factors that had possibly affected the success of SDoC included the completeness of the legal framework, how manufacturers interpreted that legal framework, the government's financial, human, and informational resources, consumers' awareness about and confidence in product certification, a lack of confidence on the part of the regulators, or the effectiveness of the market surveillance mechanism.

41. The representative of Chinese Taipei stressed the need to share experiences on how post-market surveillance was conduced in an effective way. In his opinion, market surveillance was key to a successful SDoC regime: meaning one that ensured the safety of consumers and yielded benefits for manufacturers through deregulation and simplified procedures.

(b) Discussion

42. The representative of India asked how it was possible that in 2003, for the "sample testing" a non-compliance rate of close to 48 per cent had been discovered given that a ½ per cent non-compliance rate in the "appearance checks" had pointed to almost full awareness about the SDoC requirements on the part of the suppliers and importers. He also asked what the increase in non-compliance in the "appearance checks" from ½ per cent to 6 per cent between 2003 and 2004 was due to.

43. The representative of Barbados asked how the length of time for testing and inspection of products had been decided. Barbados had come across cases where a trade-off had to be made between thorough, lengthy testing on one hand and not impeding business development on the other. On penalties for non-compliance he noted that small countries, such as his own, sometimes had no choice other than completely banning a non-complying product from the markets because foreign manufacturers were not always willing to make adjustments to products for a country that constituted such a small share in their revenues. Taking that decision was, however, not necessarily in the overall interest of the country.

44. The representative of the United States asked if penalties had actually been imposed by the authorities in detected cases of non-compliance.

45. The representative of Chinese Taipei confirmed that a company that had actually affixed an SDoC label showed that it understood what the government's requirements were. In assigning penalties, his agency distinguished between offences of labelling requirements and non-compliance regarding standards. A fine was applied if non-conformity with standards was detected, while faulty labelling was dealt with by merely imposing a time limit for corrective action. Turning to Barbados, it was stressed that Chinese Taipei required imports to comply with government rules. If this was not the case, importation would be held up. In the case where the manufacturer of a non-compliant product was located in Chinese Taipei, the BSMI would immediately stop production.

46. The representative of Antigua and Barbuda noted that this second presentation had once again confirmed that SDoC would only work well in economies with sufficient resources for implementing the necessary infrastructure. Similarly, the representative of St. Lucia noted that in the experience of Chinese Taipei, there had apparently been instances where suppliers were declaring conformity to standards which the manufacturers themselves were unaware of. Hence, the emphasis on market surveillance. Yet this was costly – and additional procedures themselves could constitute unnecessary barriers to international trade.

47. The representative of Japan inquired if the BSMI disclosed information on non-compliance rates, such as the result of the sample testing in 2003, to the public and, if so, whether it also informed consumers about which products were affected and who manufactured or imported them. Furthermore, Japan wanted to know on what legal basis market surveillance was carried out and whether the BSMI was founded on a form of general product safety law.

48. The representative of Chinese Taipei said that enforcement of SDoC involved considerable human resources but that the BSMI was, nevertheless, coping. In fact, type testing and SDoC had officially been introduced in the course of a very rapid transition from batch inspection as early as 2000, which had caused some resource problems for Chinese Taipei's regulators.

3. The Brazilian Experience with Supplier's Declaration of Conformity

(a) Statement

49. The representative of Brazil[32] explained that INMETRO (the Brazilian National Institute of Metrology and Quality) was responsible for the Brazilian Conformity Assessment System and was also Brazil's official accreditation body.[33] Brazil employed all the traditional means of conformity assessment such as certification, supplier's declaration, labelling, inspection and testing. Depending on the applicable method, monitoring or products in the market could be done in two ways: by *inspection* carried out by a network of public bodies under the supervision of INMETRO, which established inspection procedures and provided training for the inspectors. INMETRO verified that products bore the Brazilian conformity mark. In the event of irregularities, the inspectors could seize products or prohibit their sale as well as impose fines (up to around $US 1 million). The other approach was *market surveillance*, which involved the periodical testing of samples of conformity-assessed products collected at the point of sale. If non-conformance was detected, an analysis of the cause would be performed.

50. It was stressed that SDoC was applied in Brazil only to products or services that posed medium to low risks to the health or safety of the consumer or the environment. The objective was to ensure, with an adequate level of confidence and with the lowest cost to society, that products and services were compliant with the requirements of standards and regulations. In adopting SDoC, maturity of the consumer relations, record of quality in the sector, the related costs as well as the international standard ISO/IEC 17050 had been taken into account. INMETRO's regulations stipulated that products which were subject to conformity assessment based on SDoC needed to be periodically verified via market surveillance – and more frequently compared to products subjected to third-party conformity assessment. A first verification would normally be performed no later than six months after the introduction of the product and subsequent verifications would take place at least annually thereafter.

51. It was stressed that SDoC was being implemented gradually in Brazil and was currently used in the following sectors: disposable cigarette lighters; installation of vehicular natural gas systems (VNG); angle iron made of hot-rolled steel; and, welded or seamless, carbon or micro-alloyed steel tubes for use in the structure of transmission towers. Applying SDoC to fire extinguisher powder and plastic chairs had already been recommended by feasibility studies.

52. Brazil's market surveillance programme gave priority to the assessment of requirements related to health, safety and the environment. Products would be collected at the retail level and submitted to INMETRO-accredited testing laboratories. A market survey regarding points of sale in the country would be conducted at the same time in order to identify and chart the distribution of manufacturers, importers, brands and models. This survey ensured that the sample was representative regarding its size and its regional distribution. The most recent results for some of the products under the SDoC regime are set out in Table 1.

[32] Mr. Alfredo Lobo, Director of Quality at the Brazilian National Institute of Metrology and Quality (INMETRO).

[33] The Brazilian Conformity Assessment System is a sub-system of the National System of Metrology, Standardization and Industrial Quality (SINMETRO). SINMETRO is ruled by the guidelines of the National Council of Metrology, Standardization and Industrial Quality (CONMETRO). The National Institute of Metrology, Standardization and Industrial Quality (INMETRO) is the central executive body of SINMETRO. It manages the conformity assessment programmes and is also the official accreditation body in Brazil.

Table 1

Market Surveillance – Supplier's Declaration Results	
Name of the Product	**Non-Conformity**
Disposable Cigarette Lighter	0%
Installation of Vehicular Natural Gas Systems	14.1%
Angle Iron made of hot-rolled steel	0%

53. In Brazil, there was a trend towards a higher incidence of non-conformities in services compared to goods. However, the results presented in the chart were similar to those made in third party assessments. In general, Mr. Lobo considered the use of SDoC in Brazil to have been very positive. He noted that Brazil did not yet have any experience regarding the use of SDoC by developed countries in order to facilitate imports from Brazil.

(b) Discussion

54. The representative of India understood that Brazil used specialized software for risk assessment and asked which parameters were used to measure costs and benefits.

55. The representative of Haiti asked if, in the case of a product not conforming with the quality standards, whether an importer or exporter should turn to the producer of that product or directly to INMETRO, in the case of Brazil.

56. The representative of Brazil stated that Brazil's risk analysis methodology used information related to the sociological, technical and economical aspects to select whether first, second or third party conformity assessment was to be employed.

4. The Canadian Experience with SDoC in the Telecommunications Sector

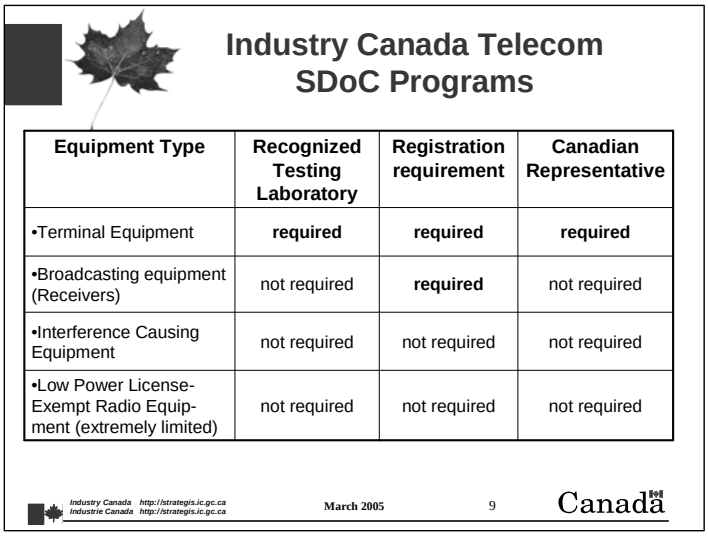
(a) Statement

57. The representative of Canada[34], noted that there had been three main areas of consideration when considering the use of SDoC in the Canadian telecom sector. First, the maturity of the technology and the industry determined how experienced the regulator and the companies were in a particular field. Second, low risk of the products covered was important. Regarding the telecom sector, this meant low probability of interference or damage. Third, the regulator's ability to monitor and enforce its regulation was key to the success of SDoC. This entailed the need for an appropriate legal framework which was conducive to the verification and enforcement of product compliance. Also, the regulator needed to have the internal capability to carry out the monitoring activities properly.

58. In the Canadian telecom sector, SDoC was used for four product groups: terminal equipment (meaning telephone, facsimile, etc.), radio equipment (albeit only with very low risk of interference), broadcasting equipment (mainly on the receiving end, e.g. TV sets) and interference-causing equipment (anything able to cause unintended radiation or radio frequency interference, such as computer equipment or spark ignitions). Each product group had different requirements (Figure 1, below). However, all schemes included mandatory marking. In none of the programmes were the requirements combined with any certification requirements: it was always either certification *or* SDoC.

[34] Mr. Claude Beaudoin, Industry Canada, Manager of Interconnection Planning and Coordination.

Figure 1



59. For terminal equipment, SDoC had been introduced in 2002. It had been based on ISO Guide 22 as the much broader ISO/IEC 17050 did not exist at the time. The program required: registration with Industry Canada; that testing be performed by laboratories recognized by Industry Canada; the marking of equipment (marking had to include the registration number and other information such as the model number and the manufacturer); and, a Canadian representative for audits and enquiries by the regulator. It was noted that the WTO ITA Committee[35] had developed four generic forms of SDoC regimes for EMC-EMI[36] products. In this respect, he pointed out that the Canadian regime for terminal equipment was "Type 1"; for broadcasting equipment it was "Type 3"; and, for interference-causing equipment "Type 4". In Canada, and for the Telecom sector, there was no implementation of what the paper referred to as "Type 2".[37]

60. The importance of good post-market surveillance was highlighted. Mr. Beaudoin explained that when the move had been made from certification to SDoC in 2002 for terminal equipment, employees in the regulator's certification engineering bureau (pre-market activities) had been given the responsibility of acting as a national centre to coordinate the monitoring programme (post-market) for all the equipment that was subjected to SDoC. Fines of up to Can$25,000 for individuals, and up to Can$250,000 in the case of corporations, could be imposed for non-compliance. Theoretically, even imprisonment was possible but in most cases the response to non-compliance by the suppliers was cooperative and punishment was a last resort.

61. On the results of verification of compliance, it was noted that each year, about 2 per cent of the roughly 2,000 newly introduced products would be audited and that the level of compliance since 2002 had been around 95 per cent. Cases of non-compliance were mostly of administrative nature, e.g. faulty marking. Some audits were also conducted on the base of complaints from a competitor or consumer. In the case of terminal equipment, market surveillance was facilitated by the registration system which gave the regulator detailed information about the products in the market and provided

[35] Information Technology Agreement. It is noted here that the Committee of Participants on the Expansion of Trade in Information Technology Products formally adopted, on 24 February 2005, "Guidelines for EMC/EMI Conformity Assessment Procedures". These are contained in G/IT/25, 17 February 2005. For more background, see also G/TBT/M/33/Add.1, 21 October 2004, paras. 192-197. It is noted here that the representative of Chinese Taipei informed Members that Chinese Taipei was in the process of implementing what those guidelines classified as a "Type 3" SDoC regime.

[36] Electromagnetic Compatibility, Electromagnetic Interference.

[37] The representative of Chinese Taipei informed Members that Chinese Taipei was in the process of implementing what, under those guidelines, were classified as a "Type 3" SDoC regime.

contact information. Equipment was selected for audit purposes based on interference investigation, complaints from competitors or on a random basis.

62. In concluding the representative of Canada stressed that converting to SDoC did not mean giving up regulation. However, communicating properly with the industry was of major importance when introducing an SDoC regime. The use of SDoC could be facilitated by using international standards, adapted to different levels of risk. The system could be implemented progressively. Moreover, SDoC was consistent with the TBT principles, and, compared to the time-consuming involvement of a certifier, time-to-market could be significantly reduced. In general, Canada considered that SDoC functioned well.

(b) Discussion

63. The Chairman asked why a requirement for a Canadian local representative had been included in the newest programme for terminal equipment (paragraph 59, above).

64. The representative of Canada replied that, as a regulator, the primary concern was about risk and, for that reason, when starting the most recent programme, the idea had been raised to include the local representative requirement. However, since it was considered an evolving programme and countries aligned their requirements with each others, this requirement could be changed or removed in the future.

65. The representative of the Democratic Republic of Congo asked how the distributor and the manufacturer cooperated when taking corrective action in the case of non-conformity.

66. The representative of Canada noted that in most cases, once notified, a supplier or distributor would quickly comply and remove the product off the market voluntarily.

5. The Korean Experience with SDoC in the Automotive Sector

(a) Statement

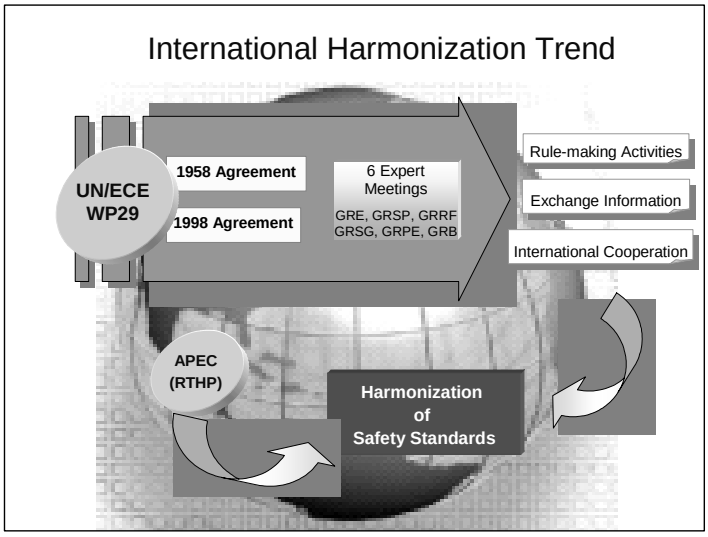
67. The representative of Korea[38] began by noting that in his country only vehicles that met safety standards in conformity assessment procedures were licensed to operate. As Korea's automobile imports and exports had risen rapidly since the 1990s, differences in safety standards and conformity assessment procedures had become an important and growing problem. Manufacturers at home and abroad had felt an increased burden of complying with additional certification costs. Complaints from foreign automobile manufacturers and looming trade concerns had persuaded the Korean government to take action.

68. First, Korea had harmonized its safety standards with international standards by joining the UN-ECE W29[39], which was the leading body in international harmonization of vehicle safety standards (Figure 2, below). Korea also began participating in the APEC road transport harmonization project in forming cooperative relationships with other countries (the European Communities, the United States and China). In 2003, in an effort to rationalize its conformity assessment procedures in the automotive sector, Korea had switched from type approval to SDoC. However, prior to adopting SDoC in 1992, Korea had introduced a recall system. This had proved very useful in establishing an efficient quality control system for manufacturers, and, it had the added benefit of increasing consumer awareness.

[38] Mr. Woo-Jin Jung, Deputy Director, Ministry of Construction and Transportation (MOCT), Republic of Korea.

[39] It was pointed out that the UN-ECE W29 was originally a group working to harmonize safety standards among European Countries. In 1995, it opened itself to non-European countries. W29 included two Agreements, one from 1958 and the other from 1998. In 2001, Korea acceded to the 1998 Agreement and in 2004 to the 1958 Agreement. W29 had six expert groups under it that established vehicle standards, exchanged information and promoted international co-operation. There was a special APEC group within W29 named RTHP, which Korea had attended since 1996.

Figure 2



69. In Korea's view there were several important benefits to using SDoC. Cost savings could enhance market flexibility and enable the government to cut its budget without undermining its policy objectives. International trade of automobiles had been significantly facilitated and there was no discrimination of geographic location.

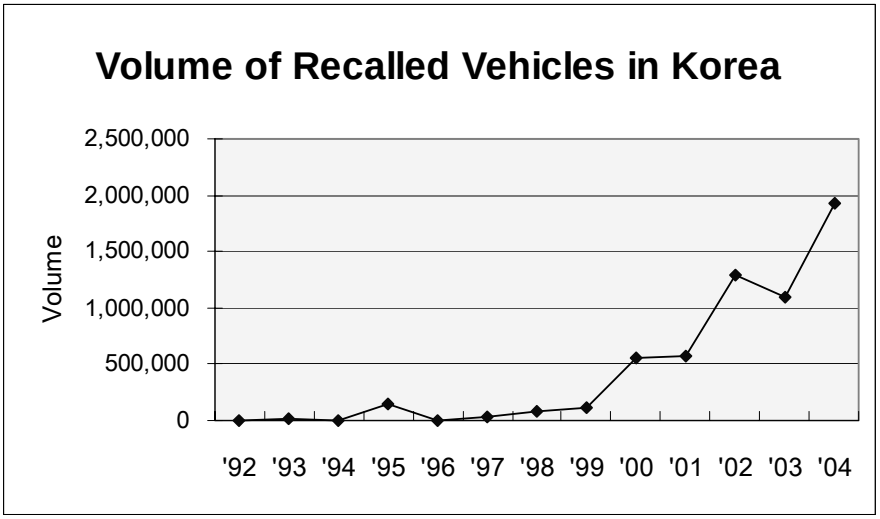
70. The necessary steps to declare conformity in the Korean regime were simple. First, the manufacturer or importer had to register the testing facilities with the Ministry of Construction and Transportation (MOCT). After successful testing, the manufacturer would declare compliance and affix the relevant labels to the automobiles. As a last step, the MOCT needed to be notified of the vehicle model's specifications. In the Korean experience, the prerequisites for the adoption of SDoC included the level of technical know-how of the manufacturers, the degree of consumer awareness and the existence of an effective market surveillance mechanism. With respect to the latter, an active consumer role was an important component.

71. It was stressed that especially in relation to such safety risks as in the area of automobiles, it was absolutely necessary to ensure compliance by the manufacturers. This was done through a recall system. Vehicles were recalled when they did not comply with all the required safety standards or a safety related defect was found. This process worked in a number of ways: In a *compliance test* a vehicle was randomly selected[40] and tested. Alternatively, a *defect investigation* was initiated when a vehicle was suspected of having defects because of consumers' complaints or reports from vehicle inspection centres. If a non-compliance was identified, the manufacturer would be given a chance to present a defence and a recall order would be given. Also, voluntary recall by the manufacturer was possible if the manufacturer found non-compliance or defects. Manufacturers could be fined up to $US 1 million.

72. The outcome of the recall system since 1992 had been a surge in the number of recalled vehicles (Figure 3). According to Mr. Jung, reasons for this included enhanced consumer awareness as well as active monitoring. Most of the recalls were due to safety defects rather than non-compliance with safety standards. Moreover, most recalls had been voluntarily conducted by the manufacturers. Mandatory recalls by the government were rare.

[40] Vehicles were usually selected from models with high sales volume.

Figure 3



(b) Discussion

73. The representative of Argentina asked whether the SDoC covered, apart from the issues related to safety requirements, also pollution-related issues and if those were also enforced.

74. The representative of Korea confirmed that the SDoC included pollution standards.

75. The representative of the United States asked whether – given the success of SDoC in the automotive industry – Korea would apply this scheme to other industry sectors, such as information technology (for electromagnetic interference) or private safety, where there was less risk than in the automotive industry.

76. The representative of Korea confirmed that his government would be implementing SDoC for electronic products in 2006.

77. The representative of Guyana asked if SDoC applied to used vehicles being exported to Korea.

78. The representative of Malaysia asked about the apparent contradiction in that Korea had introduced SDoC even though it was a member of the 1958 Agreement of UN-ECE W29 which required third-party certification.

79. The representative of Korea clarified that in order to adhere to the 1958 Agreement, Korea ran a two-tier programme. Although SDoC was used for vehicles for domestic use, vehicles *for export* would still be certified by the Korea Government.

6. The EC Experience with SDoC in the Electrical and Mechanical Sectors[41]

(a) Statement

80. The representative of the European Communities[42], Mr. Georg Hilpert from the European Commission, recalled that Article 28 of the EC Treaty stipulated free movement of products on the European internal market. It prohibited all quantitative restrictions on imports and all measures having equivalent effect between member States. Article 95 of the EC Treaty provided for technical harmonization of European legislation. These two Articles were the basis of the so-called "New Approach" Directives such as the Low Voltage Directive or the Machinery Directive. The main elements of the New Approach Directives were conformity assessment, technical documentation, "CE" marking and – most importantly – market surveillance.

81. The Low Voltage Directive (LVD) 73/23/EEC[43] had been adopted by the European Council on 19 February 1973 with the aim of harmonising the laws of the Member States relating to electrical equipment designed for use within certain voltage limits. In 1993, that Directive was amended by Directive 93/68/EEC(5), the so-called "CE marking Directive", solely in respect of the procedures for conformity assessment and conformity marking. The objective of this amendment was to align the provisions concerning conformity assessment and the CE marking of electrical equipment on those introduced for the "new approach" directives.

82. It applied to all electrical equipment designed for use within the "low voltage" range. The LVD was a so-called "total harmonization" and "total safety" directive. "Total harmonization" meant that there were no other legal requirements allowed in Member States; "total safety" meant that the directive regulated all safety aspects of products which it covered. Under the LVD there was a large system of European electro-technical standards; of the approximately 700 European harmonized standards, 75 per cent were identical or at least based on international standards.

83. Regarding the conformity assessment under the LVD, the manufacturer had two possibilities. The manufacturer could either apply his own technical specifications to comply with the directive or he applied the relevant European harmonized standards. This gave the manufacturer the opportunity to find alternative ways to fulfil the requirement of the directive, and, therefore, facilitated innovation. When applying the harmonized standards, however, a manufacturer had to ensure *and declare* that his product fulfilled the requirements of the LVD. Annex 4 of the LVD mentioned the procedure of internal production control. The manufacturer had to prepare a technical documentation – which was to be kept for ten years – that would enable the assessment of conformity of the electrical equipment to the requirements of the directive. The manufacturer's declaration of conformity (SDoC) was part of that technical file. In the case of LVD, the SDoC did not need to be delivered with the product under the LVD. The completion of the conformity assessment process was signalled by the mandatory CE marking which was affixed before the product was placed on the market. In cases where there was more than one applicable directive, the SDoC needed to refer to all applicable directives.

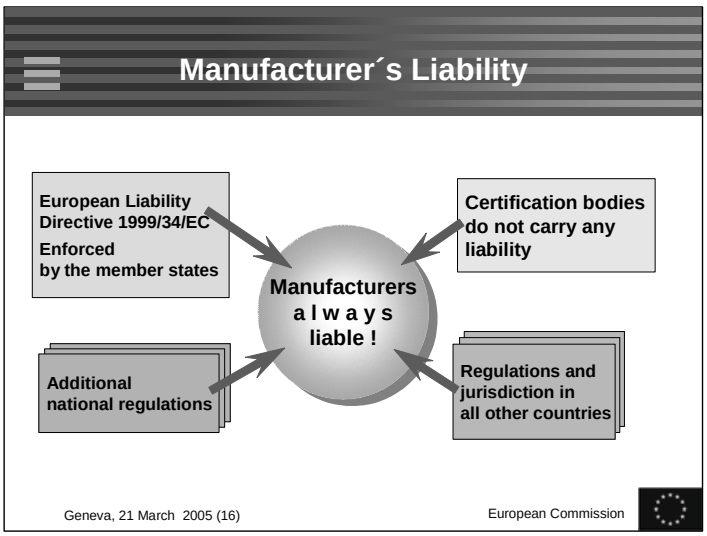
84. Regarding SDoC in the EC, this had to identify: (i) the directives according to which it had been issued, (ii) the manufacturer or his authorized representative, (iii) the "notified body", if applicable, (iv) the product itself, and – where appropriate – a reference to harmonized standards or other normative documents which had been applied. For electrical products covered by the LVD, there was only SDoC. Hence, there was no third party involvement in the electrical area even though the products could represent a high-risk (LVD covered voltages up to 1000 volts). However, over the last 20 years, fatal electrical accident numbers in Europe had fallen dramatically. Hence, in the view of the representative of the European Communities, having third-party involvement did not

[41] For more information see: http://europa.eu.int/comm./enterprise/electr_equipment/lv/index.htm, /comm./enterprise/newapproach/legislation/guide/legislation.htm or /comm./enterprise/networks/eic/eic.html.
[42] DG Enterprise and Industry, mechanical and electrical engineering and radio and telecom terminal equipment industries.
[43] OJ No L 77, 26.3.1973, p. 29.

necessarily increase the safety of products. In contrast, the Machinery Directive provided for self-declaration in some product areas and for third-party certification in high risk areas and the Pressure Equipment Directive had an even larger variety of different conformity assessment procedures with third party intervention.

85. It was stressed that neither SDoC nor third-party certification systems worked without market surveillance. On the issue of liability, it was stressed that the manufacturer always bore the burden (Figure 4, below). According to the European Liability Directive (1999/34/EC), certification bodies did not carry any product liability.

Figure 4



(b) Discussion

86. The representative of Egypt asked, given the statement that third-party conformity assessment was not necessarily needed for high-risk electro-technical products, what other factors could affect the choice of conformity assessment method. Also, was it correct that products destined to Europe from developing countries would not need third-party conformity assessment if they were not included in the directive's listing of products for which third-party conformity assessment was mandatory?

87. The representative of the European Communities stated the need for third-party intervention was not necessarily correlated the level of risk. With respect to safety of electrical appliances there was already a long history and tradition of standardization in Europe which had lead to many well-established technical rules in the member States. When drawing up the LVD the application of these rules without third party intervention had been recognised as one way to comply with the directive's safety provision. For other areas however, such as the Machinery Directive, there was not much experience and only a few technical rules in the Member States, and, therefore, it had been decided by the legislator when drafting the Machinery directive to require third-party certification for high risk machinery.

88. The representative of Argentina asked whether, based on the EC perception that SDoC did not necessarily affect product risk, it could be expected that the European Communities would introduce SDoC into other sectors in which it had broad regulator experience. Secondly, she asked whether the requirement for a legal representative continued to exist for areas where there were mutual recognition agreements.

89. The representative of the European Communities replied that the European Communities was in the process of revising the "New Approach" and that this revision could also affect existing conformity assessment procedures. The objective was to eliminate differences between the various directives as far as possible as well as to reduce, if appropriate, the number conformity assessment procedures. Moreover, new mutual recognition agreements with non-EC countries were not a high priority because the European Commission had realized that they did not help to achieve worldwide technical convergence. Rather, they cemented existing legislation.

90. The representative of Mexico asked what exactly had been meant in terms of SDoC incurring lower costs: was this in terms of the product price or the costs in implementing that type of system? Clearly, if conformity assessment cost were to be borne by the government, there would be a transfer away from the manufacturers, which imposed costs on the consumers via taxation.

91. The representative of the European Communities reiterated that it was the manufacturer who was responsible for ensuring that his or her product was compliant with the requirements of the directive. This was done through the application of either harmonized standards or internal technical specifications. Since SDoC was merely a document on which the required information needed to be set out, costs were low. The costs for the conformity assessment itself were of course higher but had to be borne by the supplier, not the government – and these costs were lower than the costs incurred from third-party conformity assessment. Regarding the costs for member States, the SDoC regime could be costlier *for the administration*, because a functioning market surveillance system was needed. However, market surveillance was necessary for all different types of conformity assessment procedures, not just for SDoC.

92. Regarding market surveillance, the representative of Malaysia asked whether there was any formal mechanism for coordination and co-operation between member States, such as information-sharing, and, if so, how it was organized.

93. The representative of the European Communities explained that European market surveillance authorities met at least twice a year in a so-called administrative co-operation working group to coordinate their activities.

94. The representative of Kenya asked if there was any possibility of information-sharing between developed and developing countries with regard to market-surveillance so that countries with weak surveillance infrastructures could provide their consumers with safe products while introducing SDoC.

95. The representative of the European Communities reiterated that, in his view, even with third-party intervention necessitated market surveillance infrastructure, such as testing facilities.

96. The representative of Guyana asked about the occurrence of counterfeit CE markings on electrical products due to the implementation of SDoC.

97. The representative of the European Communities noted that market surveillance authorities could not identify counterfeit products, they needed the help of manufacturers to do this. The main concern was *compliance* with the safety requirements.

98. The representative of Trinidad and Tobago wished to know more about the "CE" marking.

99. The representative of the European Communities stated that the "CE" marking was essentially a statement from the manufacturer that it had fulfilled all the requirements which were necessary under the directive. It was not a quality mark.

100. The representative of Chile asked what function the "notified bodies" in the context of SDoC.

101. The representative of Egypt asked what incentives existed for suppliers to comply with the requirements, besides liability? In addition, as the SDoC subject-matter was a TBT implementation issue[44], he asked how developing countries exporting to markets of developed countries could benefit from such a mechanism. Technical assistance needed to be provided to developing countries so as to enable the setting up of needed regulatory and physical infrastructure (such as market surveillance systems). The representative of Egypt also asked what kind of special and differential treatment (S&D) could be granted to developing country exporters in the area of SDoC?

B. THE MANUFACTURER'S / SUPPLIER'S PERSPECTIVE[45]

1. Transition to SDoC in the IT/Telecom Sector in the European Communities[46]

(a) Statement

102. The representative of LM Ericsson, Mr. Per Döfnäs[47], explained how two fundamental factors had contributed to the simplification of product regulation in the European Union. One had been the realization of the EU Common Market and the other had been the move to SDoC on product regulation. The latter had significantly reduced technical requirements and simplified administrative proceedings when launching new products.

103. Efforts to establish a common internal market in the European Communities had started in the late seventies with the replacement of various national requirements by EC-wide requirements and alignment with international standards. From the manufacturer's perspective, this meant one set of requirements instead of the 15 (currently 25) national ones. The effect had been quite drastic: the overall time-to-market (for a product) had been significantly shortened as there was no longer any need to adapt the products to the different country-specific regulations. Previously, technical requirements had been highly detailed and difficult to understand, which meant that companies had to employ scarce expert resources, and parallel approval was impossible: products were introduced successively (in one country at a time).

104. The simplification process regarding technical requirements began in 1973 with the Low Voltage Directive (LVD) (previous speaker). For the first time, it listed *only safety* objectives and did not stipulate technical requirements as such. Then, the "New Approach" regulatory technique, developed in 1985, had provided for a separation of policy objectives (such as safety, interference problems) from the technical standards or technical means to achieve those objective. The LVD (previous speaker) had paved the way (in administrative terms) because it required no third-party intervention.

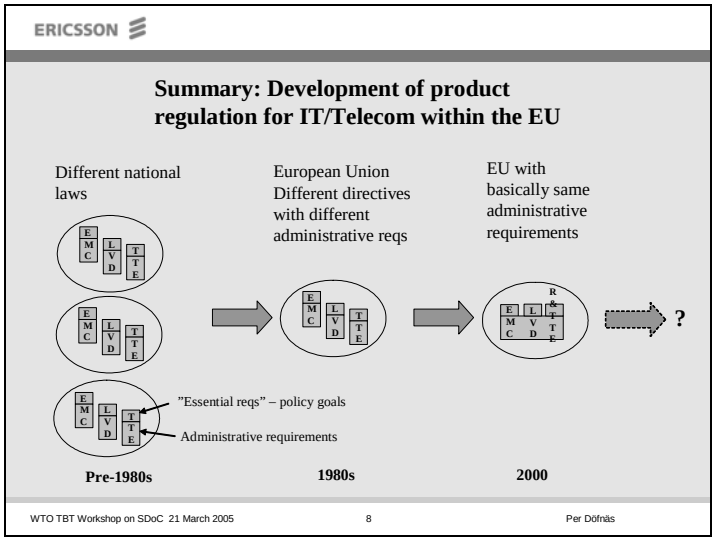
[44] The latest report on the TBT Committee's two outstanding implementation issues, including SDoC ("Tiret 34"), is contained in G/TBT/W/191, 23 October 2002.

[45] Speakers in this section were asked to address, *inter alia*, the following issues: (i) the reasons why manufacturers may prefer SDoC; (ii) the main problems encountered by the manufacturer in implementing SDoC; (iii) any specific problems relevant to SMEs. (G/TBT/GEN/15).

[46] For more information, consult: *http://europa.eu.int/comm./enterprise/electr_equipment/lv/index.htm, /comm./enterprise/newapproach/legislation/guide/legislation.htm or /comm./enterprise/networks/eic/eic.html.*

[47] Director, Technical Regulations, Government Affairs & Regulations, Telefonaktiebolaget LM Ericsson, Sweden.

Figure 5



105. The Radio Equipment and Telecom Terminal Equipment Directive from 1999 had aligned largely administrative obligations for radio and telecom terminal equipment with the safety/EMC directives. This was especially important for Ericsson due to its product portfolio. At that point, the SDoC regime for most IT and telecom products was complete. Some minor third-party involvement remained however, requiring the manufacturers to seek advice from the "notified body" in the case of some "non-harmonized" radio equipment. Nevertheless, the European regulatory system in the IT and telecom sector functioned well and improved the dynamics of the European market.

106. Regarding SDoC, the clear benefit from the industry's perspective was that it explicitly placed the responsibility of compliance on the manufacturer. Hence, somebody empowered by the company had to place a signature; this meant closer involvement of the management in the approval process. It also ensured compliance without the involvement of a third party. Cutting costs for approval had the effect of speeding up time to market and reducing prices of products for consumers.

107. Moreover, SDoC gave enterprises the possibility to integrate approvals into the design process of a product. This caused a wider diffusion of knowledge about regulatory compliance within the firm. The harmonized administrative requirements allowed optimized work organisation, tailored to a single set of rules. External testing laboratories, once only responsible for third-party certification, were now often partners on a commercial basis and constructively involved in the internal design by providing their expertise.

108. Generally, it was stressed that whether the approach used was SDoC or third party certification, it was always possible to cheat if a company had that intention. Therefore, regardless of which conformity assessment regime was being used, market surveillance was always of major importance. It ensured a level playing field and trust in the system. In a union of 25 countries, there was a good chance of realizing that objective at a low cost. Manufacturers expected that market surveillance would be done effectively, intelligently, and that it would concentrate on compliance with the policy objectives of regulation ("technical compliance").

109. For companies, it was important that when a new regulation came into force, it followed the simplest regulatory model already in place for that given sector, meaning that no administrative obligations would be added. An exemplary regulatory model consisted of objectives, standards,

conformity assessment procedures as well as information requirements.[48] In the global market, it was noted that technical requirements still differed across countries. While with respect to EMC and safety, the situation was improving towards the use of international standards, in other areas, such as telecom networks, there remained large disparities between countries. It was a fact that administrative requirements sometimes formed *de facto* barriers to trade which posed more difficulties to SMEs than to large enterprises. In particular this was due to overly burdensome conformity assessment procedures and varying requirements for the provision of technical information.

110. In concluding, Mr. Döfnäs stressed that a shift to SDoC without third-party intervention in all countries would remove most formal and *de facto* trade barriers. This was demonstrated by the positive experience in the EU. This system assigned clear responsibilities to the manufacturers and relied on international standards. It necessitated market surveillance by the authorities to ensure adherence to regulation.

(b) Discussion

111. The representative of Argentina asked if LM Ericsson had conducted studies on the potential reductions in consumer prices due to the introduction of SDoC.

112. Mr. Döfnäs replied that he did not have any data on that issue. This was because of the incremental, sector-by-sector character of the shift from third-party certification to SDoC – over a period of 10 to 15 years. It was difficult to make estimations. Mainly, the benefit lay in time saved for approval which meant that companies covered costs of research and development earlier. For economies, the benefits lay in the early availability of high-tech products.

113. The representative of Antigua and Barbuda sought clarification on the duration of the transition period Mr Döfnäs had just mentioned (to SDoC from third party certification). Was the time period of *15 years* particular to the telecom sector, or was it general?

114. Mr. Döfnäs clarified that he had been talking about the sector of radio and telecom terminal equipment. During the period from 1985 until 2000 the process of EC-wide harmonization and of introducing a new regulatory approach – which included the move to SDoC – had taken place. Other sectors that only fell under the LVD and the EMC Directive benefited earlier.

2. SDoC for Information and Communication Technologies (ICT) Regulations.

(a) Statement

115. The representative of Hewlett-Packard, Mr. David Ling[49] began by stressing the shared objectives between industry and regulators in the information and communications technology sector (ICT). These were: to provide protection, promote competition, allow growth in a global economy and keep regulatory intervention to the necessary minimum.

116. In particular, two trends needed to be kept in mind. The first trend was that both small and medium-size enterprises (SMEs) and larger multinationals might misconstrue the regulatory intent of "certification" and how to manage for it. Thus, regulatory requirements had to clearly place responsibility and accountability for safe and legal products *on the supplier*. SMEs in the ICT sector were often the original design manufacturers, the equipment manufacturers or contract manufacturers to larger multinational companies. They were typically located in America, Asia or Central Europe and, hence, offered advantages such as lower cost labour. When conformity assessment was based on

[48] Regarding the emerging legislation on environmental aspects (draft on eco-design, Common Position 9/2005 from the European Parliament), Mr. Döfnäs saw some "clouds in the sky". There were various deviations from the regulatory model of the New Approach. If implemented in this way, it would be very costly in administrative terms.

[49] Regulatory Policy and Strategy Manager, Hewlett-Packard, United States.

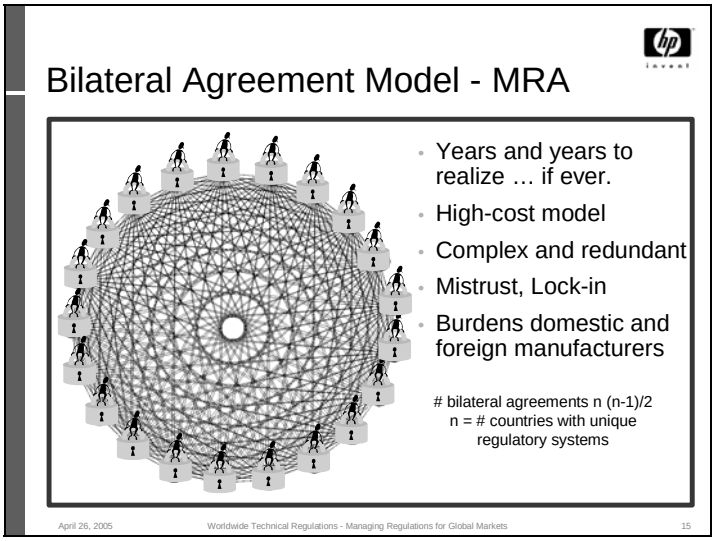
certification, SMEs might wrongly believe that it was the certification body that was responsible for ensuring that their products complied with relevant technical regulations. In contrast, when conformity assessment was based on SDoC, the SMEs clearly understood that it was the supplier who was responsible for compliance with the relevant technical regulations. Moreover, when coupled with effective surveillance, SDoC rewarded and motivated suppliers to improve programme management and make sound engineering judgments.

117. In addition, certification was not to be equated with the provision of safe products: surveillance was needed under any conformity assessment regime, not only under SDoC. Therefore, from an industry perspective, it was important that regulators highlighted the supplier's accountability and responsibility for safe and legal products. The way to do that was to set requirements for SDoC that rendered certification optional and stipulated supporting documentation. There was also a need to conduct post-market surveillance, and, enforcement via penalties would over time reduce the non-compliance rate across the industry.

118. The second trend was the prevalence of excessive conformity assessment requirements. This was in violation of Article 5.1.2 of the TBT Agreement which stipulated that conformity assessment procedures could not be stricter than necessary in order to ensure adequate confidence. While most countries referenced international standards – usually from the IEC – in some countries conformity assessment involved mandatory, in-country testing by a (third-party) and certification by an independent certification body before the launch of a product (pre-market approval). Moreover, many WTO members did not yet have *any* regulations in force, and, for those, it was important that they introduce international standards and *post*-market conformity assessment.

119. The difference between an adequate and an "overbuilt" system was that the latter imposed additional requirements (mandatory submission of samples, audits, government-designated test labs, obtaining pre-market certificates) which could delay a product's introduction into the marketplace by four to 12 weeks and make intergovernmental MRAs necessary. They constituted a burden in terms of the delay in revenue which was unrecoverable for the industry. Consumers also had less choice of products and had to pay higher prices. For a nations' economy this had an impact on trade. When conformity assessment was based on pre-market requirements, fulfilling the obligations under the TBT Agreement would mean having to conclude a bilateral MRA with every trading partner. That was providing an unrealistic salutation; a single MRA was a multi-year effort, and resulted in complexity, lock-in and mistrust. In contrast, if all trading nations based their conformity assessment procedures on SDoC, the doors would automatically be opened to foreign suppliers. Thus, SDoC (based on the international standard ISO/IEC 17050) was the lowest cost model for safe and legal products as it did not require any bilateral agreements.

Figure 6



120. The four types of SDoC recently adopted in the ITA's "Guidelines for EMC/EMI Conformity Assessment Procedures" were mentioned.[50] These four types were a good example of what was sufficient to provide a workable SDoC framework for many different countries. For the industry, which applauded the ITA Guidelines, either no regulation at all or one or more of the four SDoC types was acceptable.

121. In concluding, Mr. Ling stressed that know-how on the implementation of SDoC currently existed, and it had been shown to work effectively for IT regulations in many countries. It improved an economy's competitiveness and, hence, there was good reason to move into that direction. There were several ways of reducing the risk at the beginning of such a transition: using accredited labs; limiting the scope of SDoC to EMI and excluding safety; limiting SDoC to certain product types; creating a database of the mature companies allowed to use SDoC; and, sharing market surveillance data, as New Zealand had proposed (paragraph 24 and 28 above).

(b) Discussion

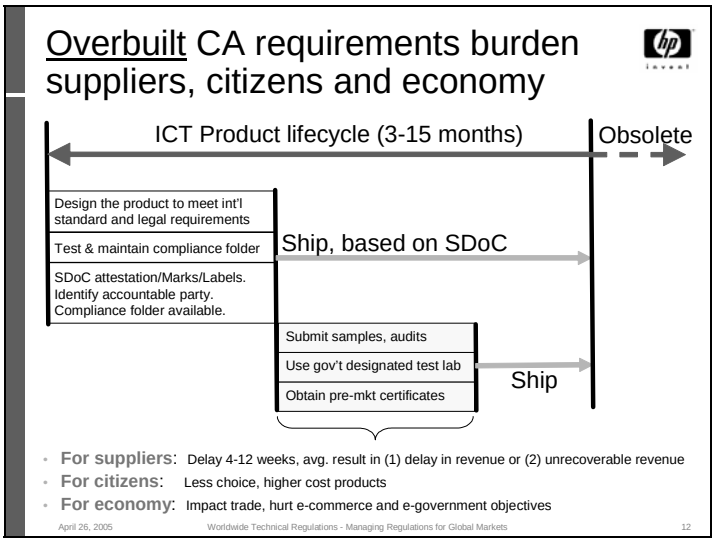
122. The representative of Mexico stressed that countries could be in compliance with the TBT Agreement but still have standards that deviated from the international ones – moreover, harmonization of standards could also be partial. Also, it needed to be kept in mind that although SDoC made trade easier in some sectors, Mexico had actually experienced import growth in products of the IT sector for which pre-market certification was mandatory. Lastly, he asked about the way in which the United States applied SDoC to products – not only in the ICT sector – imported from developing countries. It was evident that for products in which the developed countries had an export interest, SDoC was being promoted while this was not the case for those of export interest to developing countries.

123. In response Mr. Ling pointed out that while it could very well be the case that imports had increased without the use of SDoC, the question needed be posed as to how much better the performance might have been with it. SDoC needed to be recognized from any country, as long as the requirements were fulfilled. In fact, the US IT industry had consistently tried to persuade the United States Government to move towards an SDoC system without any restrictions on the manufacturer's location for the past 10 to 15 years. Regarding developing countries, it was stressed that there was no difference in approach for imports from developing countries and developed countries. The

[50] *Supra* note 35.

confidence in the system lay in the regulators' ability to enforce compliance with the regulations through market surveillance and penalties. Moreover, Asian developing countries were large suppliers in the ICT sector.

Figure 7



124. The representative of Canada, asked whether there had been any cost analysis that could help regulators better understand the impact of "overbuilt" conformity on prices. She referred to the slide (Figure 7, above), which showed how such over-built conformity assessment requirement (i.e. pre-market, third-party certification) could lengthen the time-to-market by one to three months.

125. Mr. Ling noted that in one case a calculation had been made for a country which did not recognize foreign tests, hence required re-testing and demanded to have, *inter alia*, product samples. The result – based on current trade of IT products into that country – had been that due to that specific regulation, additional costs for the manufacturer amounted to US$ 90 million per year on an ongoing basis. Financial burdens to the manufacturers translated into disadvantages to the consumers in two ways. First additional costs of conformity assessment would be distributed among all purchasers of a certain product. Second, costly procedures led manufacturers to make an educated guess on which products interested clients most in each market. Thus it frequently happened that a manufacturer made only part of his product portfolio available to customers in a foreign market.

3. Implementing SDoC: the view of conformity assessment bodies in developing countries

(a) Statement

126. Mr. Rafael Nava[51], Mexico, stressed that it was mainly developed countries that owned technology and thus markets. Developing countries were constantly trying to win "a piece of the cake" while trying to develop technology as well. Therefore, developed countries had strong industries that had built confidence over the years and this enabled them to implement SDoC procedures. Industries in developing economies were generally small or medium sized (SMEs) and conformity assessment procedures were usually based on third party evaluation simply because there was not, as yet, enough confidence to move to SDoC – and, moreover, there existed serious problems with such practices as falsification, counterfeits or contraband.

[51] President of the Commission of Conformity Assessment for the Industrial Confederation of Mexico (Concamin).

127. For developing countries, hence, the key question was how their manufacturers and suppliers could access developed countries' markets despite the fact that most of them did not have a working conformity assessment infrastructure (i.e. testing laboratories and inspection bodies). Such an infrastructure was needed to enable them to, *inter alia*, test their products according to developed countries' technical regulations and standards. Moreover, there needed to be a strong market surveillance mechanism coupled with strong enforcement regulations in cases of non-compliance. For low risk products, legislation needed to provide for SDoC that was based on testing reports of accredited testing laboratories as an *alternative* to third party certification. When there were well-performing testing laboratories in developing countries, it would be easier to work with the developed trading partners and build trust.

128. Mr. Nava pointed out that if SDoC was implemented without meeting the above-specified conditions, there was a risk of the spread of informal commerce practices which could lead to unfair competition. Also, developing countries might receive products which had been rejected in other economies or products that – though meeting the requirements of other countries – were not suitable for a developing country operating environment (for instance, with respect to the use of electrical equipment in countries with highly varying electrical power supply).

129. The ways in which developed countries could facilitate a successful implementation of SDoC in developing countries included: (i) fostering the establishment of conformity assessment infrastructure in developing countries while recognizing the needed for time and resources; (ii) engaging in information exchange and the acceptance of testing reports by means of MRAs; (iii) helping developing countries to participate in drawing up international standards; and, by assisting developing countries to develop and implement local technical regulations and evaluation schemes.

(b) Discussion

130. The representative of Argentina noted that it was important to consider the cases where SDoC had been applied to products of export interest to developing countries. While some developed countries were willing to accept declarations of conformity from developing countries, if there was no appropriate infrastructure in developing countries, confidence could not be maintained in the long run.

131. Mr Ling noted that in the case of the IT industry, the bulk of manufacturing was actually done in developing countries such as Chinese Taipei and China and subsequently exported and accepted through SDoC procedures. Regarding the need for time, he stressed that the concept of SDoC had been refined over a long period of time and proven to work well in multiple countries. Therefore, developing countries could simply adopt it as it was, without having to go through the same steps of different conformity assessment methods which had taken developed countries decades to get though.

132. The representative from Antigua and Barbuda stressed that the issue was not time, but rather one of resources. In other words, technical assistance that merely helped understand ISO/IEC 17050 better was not sufficient. What was actually needed were resources to implement the appropriate infrastructure at the national level.

133. The representative of the European Communities pointed out that it was necessary not to forget the benefits of SDoC for a country's own national economy. The LVD in Europe was of great benefit primarily domestically: it was no so much about helping exports. In fact, exporters were in any case often faced with third-party certification in their export markets. The real boost to an economy arising from the use of SDoC came from faster access to more modern technology and cheaper prices for consumers.

134. The representative of the United States re-emphasized that there was no obligation whatsoever to impose SDoC in any country: it was merely an option. It was less bureaucratic and

less intrusive than some other approaches to conformity assessment, and it required less infrastructure. Whatever approach was used, effective enforcement would go a long way to enhance a domestic manufacturer's ability to compete in the global marketplace.

C. CONCLUSION

135. The Chairman recalled that, at the Third Triennial Review of the TBT Agreement, concluded in November 2003, the Committee had agreed to a Work Programme on conformity assessment to improve Members' implementation of Articles 5-9 of the TBT Agreement and, in particular, to promote a better understanding of conformity assessment systems (G/TBT/13, paragraph 40). Hence, in response to the recommendation contained in G/TBT/13 (paragraph 40, second tiret) the Committee had held a Workshop on this subject. This had, essentially, been a "learning event" where delegations exchanged information and experiences on the SDoC, which, he recalled, was one element of the Committee's broader work programme on conformity assessment.

136. In terms of the structure of the workshop, participants had heard two general presentations: the WTO Secretariat had given an overview of the key issues raised in relation to SDoC based on the submissions and statements made in the TBT Committee to date (JOB(05)/30). Second, the representative of the ISO had described the new ISO/IEC Standard on Supplier's Declaration of Conformity (ISO/IEC 17050). Subsequently, there had been six presentations on the "Government's Perspective" and three presentations on the "Manufacturer's or Supplier's Perspective" (industry), followed by a discussion.

137. It was emphasized that SDoC was **one option** among various approaches available to facilitate the acceptance of conformity assessment results (other approaches remain an option). In this regard, it remained the prerogative of governments to choose the type of regulatory regime to put in place to ensure (and achieve confidence) that products conformed to requirements and met legitimate policy objectives (such as the protection of human health or safety).

138. In making a decision as to whether to use SDoC or not, **several factors** could come to bear. One factor frequently mentioned at the Workshop was the level of risk involved in the area of application. While some speakers noted that SDoC was primarily used for products with low risk to the consumer or the environment (Chinese Taipei, Brazil and Mexico), others made the point that SDoC could also be adapted to risk (Canada) and be used in relatively high-risk areas (vehicle safety standards in Korea and electrical products in the EC).

139. For industry, SDoC could be **cost effective** in that, for instance, third party certification costs were avoided. This saved valuable time. SDoC could also facilitate the portability of results and avoid what one speaker had referred to as "over-built" conformity assessment requirements. In light of this, it was not surprising that industry was the main driver behind the development of the IEC/ISO Standard on SDoC. The point had been made by a number of speakers that in those countries (and sectors) where industry used SDoC there were potential benefits to consumers in terms of greater choice of products and lower prices.

140. However, there were potential **regulatory costs** as well – and these could be particularly burdensome for developing countries. It appeared that there was a need for each Member to find a balance between the benefits of using SDoC and the administrative or regulatory costs that were incurred in setting up the needed infrastructure. For example, in terms of infrastructure, several participants and speakers emphasized the need to establish a functioning **market surveillance** mechanism which would enable regulators to deal with non-compliance (enforcement). Participants had heard how this was done in the automobile sector in Korea, and with electrical products in the EU.

141. Moreover, a number of **developing countries** had stressed their need for technical assistance and resources both in order to participate more effectively in the international standard-setting process but also – and perhaps key – to be able to implement the use of SDoC (based on the international standard). In most cases, the industries in developing countries were small and medium-sized (SMEs) and it was felt by some that these countries had not, as yet, built enough confidence to make the transition (where it was desirable) to the use of SDoC. It was noted that the transition to SDoC, in certain sectors, from third party certification had taken many years (in the EU 10-15 years). Yet, for developing countries time was pressing: it was important to establish the appropriate conformity assessment infrastructure that would help establish confidence in markets for products of export interest also to their economies.

142. Finally, the Chairman stressed that discussions had been substantive and that, overall, the workshop had lent some more clarity to a complex and technical area of conformity assessment.

143. The representative of Mexico stressed that it was not possible to draw the conclusion that SDoC was better than certification. Although SDoC was certainly a useful tool, the usefulness of either procedure depended heavily on the policy aims, and each country's individual requirements. Finally, no Member opposed the use of SDoC as an approach to conformity assessment. The concerns were about obstacles to implementation. Much remained to be done regarding infrastructure, technical assistance, confidence-building as well as risk-taking.

144. Mr. Ling wished to clarify the difference between third party certification and SDoC. He emphasized that the former required manufacturers to submit documentation from a third party (confirming conformity) and the latter allowed the manufacturers to do that themselves. Testing needed to be viewed separately. It could be done by the manufacturer, an independent laboratory or an accredited laboratory. Hence, depending on the regulations, testing for SDoC could indeed involve a third party.

145. The representative of Grenada urged Members to consider the particular case of the Caribbean countries and stressed that the Caribbean did not have separate regulatory entities to deal with TBT and SPS related issues.

ANNEX 2: ON-LINE COMPLETION OF TBT NOTIFICATIONS[52]

At the Third Triennial Review the Committee agreed to examine the feasibility of creating a central depository for notifications on the WTO website. This would complement, not replace, the submission of notifications to the CRN (paragraph 27 of G/TBT/13 (first tiret)). At the November 2004 meeting, the representative of Canada drew the Committee's attention to this recommendation which had been based on a Canadian proposal and requested the Secretariat to look into the feasibility of setting up such a facility. This note has been prepared in response to this request.

The Committee may wish to note that, on the initiative of the Agriculture and Commodities Division, relevant work has commenced on an SPS information management system which is aimed, *inter alia*, at facilitating the Secretariat's tasks in the management of notifications. Examples of the types of tasks that the information management system will help the Secretariat deal with, include, the preparation of annual reports (summary statistics), and its responses to queries about notifications from delegations. Another key objective of this project is to improve coherence among Divisions of the WTO Secretariat which are involved in the management of notifications (operational Divisions, CRN, Documents-On-Line, etc.). As a first step, the WTO's IT team will establish this information management system for the Secretariat's own internal use ("Phase I" of the project). A second phase would entail providing Members query access through the WTO website. The funding for the creation of the software application to support the SPS information management system has been secured by the Agriculture and Commodities Division.

Since the last meeting of the TBT Committee, the Trade and Environment Division has discussed the subject with the IT team who have agreed to ensure that the software application developed is also adaptable to TBT notifications, or will be flexible enough also to include the entry of TBT notifications. However, for the development and entry of data for the TBT side of this information management system, additional resources would be needed (over 6100 notifications have been made since the entry into force of the Agreement). For this purpose, the Trade and Environment Division will seek funding for the TBT side of this project during this year's budget exercise.

Canada's proposal is about an on-line notification facility.[53] This is not, as yet, envisaged in the project that the IT team is working on. Once the information management system is set up, and subject to availability of funding and appropriate IT security measures, the possibility of developing such an application will be looked in to.

[52] At the time of the meeting, this information was provided in JOB(05)/33.

[53] The representative of Canada stated at the November meeting that: "The idea was to offer Members an alternative to the way in which they currently submitted notifications, by creating an electronic notification form which could be added on to the WTO website, filled in on-line and automatically sent to the CRN. The notification would be received by the Secretariat, scanned to ensure its completeness and accuracy and then forwarded through the usual channels. While recognizing that not all Members might be in a position to take advantage of an e-form, this was an attempt to maximize the amount of time to make comments on other Members' notifications." (G/TBT/M/34, paragraph 120).

ANNEX 3: WORK PROGRAMME FOR THE FOURTH TRIENNIAL REVIEW

1. Article 15.4 of the Agreement on Technical Barriers to Trade (TBT Agreement) provides that: "Not later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter, the Committee shall review the operation and implementation of this Agreement, including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of the Agreement where necessary to ensure mutual economic advantage and balance of rights and obligations, without prejudice to the provisions of Article 12. Having regard, *inter alia*, to the experience gained in the implementation of the Agreement, the Committee shall, where appropriate, submit proposals for amendments to the text of this Agreement to the Council for Trade in Goods".

2. The Committee concluded the First, Second and Third Triennial Reviews of the Operation and Implementation of the TBT Agreement on 13 November 1997 (G/TBT/5), 10 November 2000 (G/TBT/9) and 7 November 2003 (G/TBT/13), respectively. In light of the mandate quoted above, the aim is to conclude the Fourth Triennial Review at the Committee's last meeting in 2006.

3. Article 15.4 states that the Committee shall *at the end of* each three-year period undertake the review work. In order to prepare for this review work and to ensure efficiency, the work programme (overleaf) sets out three stages: identification, discussion and drafting. In essence, this approach means that, by mid-cycle (June 2005), the Committee would shift its focus from the follow-up of the Third Triennial Review to the preparation of the Fourth.

4. Three formal meetings of the TBT Committee have been scheduled for 2005 and another three are foreseen to be held in 2006.

5. It is proposed that the review work be initiated at the First meeting in 2005 with a preliminary identification of topics for review. It is stressed that this list will be preliminary and that Members would be able to add to or modify it during the discussion phase of the review work. At its Second and Third meetings in 2005, it is proposed that the Committee hold focused discussions on topics that have been identified. Members will be encouraged to submit papers on the issues identified for consideration. To facilitate the discussion, the Secretariat will prepare factual background notes on specific topics under discussion.

6. At its First meeting in 2006, the Committee should be in a position to take stock of the discussions. To assist the Committee in this stocktaking exercise, the Secretariat will prepare a summary of the key issues discussed, under each topic identified. This draft will be factual in nature and will not contain any recommendations.

7. The Second meeting in 2006 will mark the start of the drafting phase. For that meeting, the Committee will have before it a first draft of the Fourth Triennial Review, including both the factual elements *and* any recommendations on which there is general agreement.

8. In respect of the conduct of the review work itself, it is proposed that substantive discussions pertaining to the review will normally be held in formal mode under an agenda item dedicated to the review process (currently Agenda Item 3 "Triennial Review"). After circulation and discussion of the first draft of the Fourth Triennial Review, including both the factual part and any recommendations on which there is general agreement, necessary drafting will take place in open-ended informal meetings. These meetings will, to the extent possible, be held back-to-back with the regular meetings of the Committee. The Chairman will subsequently report on the results in the formal meeting.

9. The Committee to adopt the final text of the Fourth Triennial Review at its Third meeting in 2006.

10. The work programme should be seen as flexible and may be modified in light of any new developments.

Work Programme for the Fourth Triennial Review

Dates / Time Frame	**Proposed Action**
Identification phase	
mid-February 2005	Preliminary identification of topics for review by delegations
First meeting in 2005	Listing of topics and organization of discussion
Discussion phase	
end-April 2005	Circulation of Secretariat note on topics to be discussed at the next meeting
mid-May 2005	Submissions by delegations on topics to be discussed at the next meeting
Second meeting in 2005	Discussion on topics identified
mid-September 2005	Circulation of Secretariat note on topics to be discussed at the next meeting
mid-October 2005	Submissions by delegations on topics to be discussed at the next meeting
Third meeting in 2005	Discussion on topics identified
end-January 2006	Submission by delegations of proposals for recommendations
end-February 2006	Circulation by the Secretariat of draft of factual elements of the review
First meeting in 2006	Stocktaking: Discussion of draft of factual elements of the review as well as any proposed recommendations.
Drafting phase	
mid-June 2006	Circulation of first draft text of the Fourth Triennial Review, including both the factual part and any recommendations on which there is general agreement
Second meeting in 2006	Discussion of draft text of the Fourth Triennial Review
mid-September 2006	Circulation of the draft final text of the Fourth Triennial Review
Third meeting in 2006	Adoption of the final text of the Fourth Triennial Review