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**Committee on Technical Barriers to Trade** 

# **MINUTES OF THE MEETING OF 4 NOVEMBER 2004**

Chairperson: Mr. Sudhakar Dalela (India)

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# I. ADOPTION OF THE AGENDA

1. The Committee adopted the agenda contained in WTO/AIR/2396, dated 1 October 2004.

# II. IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT

### A. STATEMENT FROM MEMBERS UNDER ARTICLE 15.2

2. The <u>Chairman</u> drew the Committee's attention to four new statements on Implementation and Administration of the Agreement, submitted by the Democratic Republic of the Congo, Madagascar, Georgia and Nicaragua, contained in documents G/TBT/2/Add.79, Add.80, Add.81 and Add.82, respectively. He also noted that Armenia and Malaysia had submitted revisions to their previous statements, contained in documents G/TBT/2/Add.75/Rev.1 and G/TBT/2/Add.9/Rev.1. A full list of statements made under Article 15.2 was contained in document G/TBT/GEN/1/Rev.1 and Corr.1. The latest list of enquiry points was contained in document G/TBT/ENQ/25, dated 13 October 2004.

### B. SPECIFIC TRADE CONCERNS

3. The <u>Chairman</u> 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.<sup>2</sup>

### 1. New Concerns

# (*i*) *Mexico: Pre-packaged products(G/TBT/N/MEX/95)*

4. The representative of the <u>European Communities</u> reminded Mexico that, on 14 September 2004, it had submitted comments concerning G/TBT/N/MEX/95 on pre-packaged products. Concerns had been expressed on the fact that the Mexican law differed from the revised version of the international standard OIML R 87, which had been approved in November 2003. She stressed that according to Article 2.4 of the TBT Agreement, when international standards existed, Members should use them, or the relevant parts of them, as a basis for their technical regulations.

5. The representative of <u>Mexico</u> pointed out that the comments received from the European Communities were being considered and that a written reply would be provided. He stressed that the technical regulation was at a draft stage and that all the comments, not only those of the European Communities, were being discussed in a working party; the results would be made public on completion of work.

# (ii) European Communities: Hip, knee and shoulder joint replacements(G/TBT/N/EEC/70)

6. The representative of the <u>United States</u> raised concerns on G/TBT/N/EEC/70, in which the European Communities had announced its intention to reclassify or up-classify hip, knee and shoulder joint replacements from Class II b to Class III, under Directive 93/42/EEC on Medical Devices. The US and European medical device industry had expressed strong concerns about the lack of a comprehensive scientific review of total joint replacements to substantiate the EC's planned up-classification. She also noted that the EC's proposed action diverged from regulatory treatment of these medical devices in the United States, where the US Food and Drug Administration (US FDA) had down-classified many joint replacement products. She urged the European Communities to carefully consider comments from all interested parties and to consult with the US FDA and other regulatory authorities. She explained that under the US FDA's classification system, devices with

<sup>&</sup>lt;sup>2</sup> G/TBT/13, paragraph 28.

different characteristics but in a single category could be in different classes, depending on the degree of regulatory oversight necessary to achieve safety and effectiveness. This flexibility had enabled FDA to maintain the Class III classification for some joint replacement devices that posed a higher risk, while down-classifying other joint replacement devices that presented a lesser risk.

7. The representative of the <u>European Communities</u> stated that the comments received by the United States were being reviewed and a written reply would be provided shortly.

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

8. The representative of the <u>European Communities</u> reminded the Peruvian delegation that, on 25 February 2004, her delegation had submitted comments on G/TBT/N/PER/4, concerning the labelling of footwear. She welcomed the fact that the notified text took into consideration previous comments made (G/TBT/N/PER/1). However, it still required the label to contain information on the country of origin of the good, and the corporate tax number of the manufacturer or importer. The European Communities reiterated the concerns that these mandatory requirements might impose significant costs on producers and exporters. She believed that the same objective might be achieved by a less trade restrictive measure, in accordance with Article 2.2 of the TBT Agreement; the country of origin labelling could be made voluntary, for example. Moreover, she considered that the requirement to indicate the tax number was irrelevant for the purpose of consumer information.

9. The representative of <u>Peru</u> recalled that the regulation on labelling of footwear had been notified twice, in G/TBT/N/PER/1 and G/TBT/N/PER/4. It had been adopted six months after the last notification, and the competent authority in Peru had taken into account the comments received when the first regulation had been notified. On the issue of the tax number, her understanding was that this information could be obtained at a later stage from the importers.

#### *(iv)* Belgium: Ban on the Importation and Commercialization of Seal Skins and Seal Derived Products

The representative of Canada drew the Committee's attention to a Belgian draft legislation, 10. which banned the importation and commercialization of seal skins and seal derived products. She was disappointed that Belgium had not notified the draft bill under the TBT Agreement, thus preventing Members from submitting comments. In her view, this draft bill would have the effect of creating an unnecessary barrier to trade, as the prohibition of all imports of seal skins and seal derived products was more trade restrictive than necessary to fulfil the draft bill's objective of the protection and of the seal population. Pursuant to the UN Convention on the Law of the Sea, seals were a living marine mammal resource under Canada's jurisdiction. She explained that Canada managed this resource on a sustainable basis, in accordance with its rights and obligations under international law. Its practices were based on scientifically proven and sound conservation principles, as determined by internationally accepted standards and guidelines. Canada also acted to ensure that sealing was humane by implementing strict regulations in this regard. She requested, under Article 2.5 of the TBT Agreement, that Belgium explain its justification for the draft bill, including any risk methodology used as a basis. She also asked Belgium to reconsider its proposed ban on the import and commercialization of seal skins and seal derived products, taking into account all relevant facts.

11. The representative of the <u>European Communities</u> took note of the concerns raised, and informed Canada that the draft bill in question was being examined at the European level, to asses its compatibility with both Community and international law. In light of this internal discussion, his delegation was not yet in a position to respond substantively to the comments of Canada.

### (v) Jordan: International Product Conformity Certification Program - DAMAN (G/TBT/W/241)

12. The representative of the <u>United States</u> raised concerns on Jordan's International Product Conformity Certification Program, known more commonly as DAMAN, a system which included testing, certification and accreditation. She recalled that Jordan had issued a document on its conformity assessment program (G/TBT/W/241). Bilateral discussions had been held with Jordan on this program. In particular, the United States had sought fairer treatment in fulfilment of Jordan's legitimate objectives and had asked to look at alternatives and at truly risk-based post inspection systems. Several suggestions had been proposed, but no changes had been made to the program.

13. The representative of <u>Jordan</u> took note of the concerns expressed by the United States.

### 2. Concerns Previously Raised

(i) 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.)

14. The representative of the <u>European Communities</u><sup>3</sup> made a presentation in response to comments submitted by Members under G/TBT/N/EEC/52. The European Commission had made the REACH proposal because it had found that, over the years, the current European legislation on chemicals was not effective. It had been difficult both to properly identify the risks arising from the use of chemicals and to manage them. This was largely because, for many chemical substances on the market, there was a relative lack of information.

15. Under the current EU law, there was no obligation on industry to provide information about the properties of the vast majority of chemicals. Existing legislation put the burden of proof on public authorities to demonstrate the safety of the use of a substance. In addition, there was no efficient instrument to deal with the most problematic substances. In the current system, so-called new substances, i.e. substances which had been on the market since 1981, were subject to much stricter testing and notification requirements than all of the other substances that had been on the market before 1981. This discouraged the development of new, potentially "greener" substances, thus entailing a lack of incentives for innovation.

16. The purpose of the REACH proposal was the creation of *one* system that covered *all* chemical substances. Its most significant element was the requirement for substances that were produced or imported into the European Union in quantities above one tonne per manufacturer or per importer per year, to be registered at a Central Agency. This obligation, spread over a period of 11 years, to provide data for about 30 chemical substances, was placed on EC manufacturers and importers alike. This information was also required to be passed down to users of chemicals in the European Union. This would allow downstream users of chemicals to manage and control the risks from exposure to those substances more easily. An evaluation stage whereby a certain number of substances would be examined in more detail by the member States' authorities, was also proposed.

17. A White Paper<sup>4</sup>, which set out the overall aims and plans for REACH had been published in February 2001. Two years later, a first draft of the Regulation had been published on the Internet. The summer of 2003 had been given for comments to be provided. Over 6000 comments, many of which were from WTO Members, were received at that stage. Following this, some significant changes were made to the first draft proposal and the current proposal had been adopted on 29 October 2003 and notified to the TBT Committee in January 2004 (G/TBT/N/EEC/52). An extended period for comments, until June 2004, had been allowed. It was stressed that at the present time, the legislation was not finalized and that the European Parliament and the Council of Ministers

<sup>&</sup>lt;sup>3</sup> Mr. Nicholas Burge (DG Enterprise) and Mr. Mark Blainey (DG Environment).

<sup>&</sup>lt;sup>4</sup> COM (2001) 88 final, available on the Commission's website at <u>http://europa.eu.int/comm/enterprise/reach/index.htm</u> or <u>http://europa.eu.int/comm/environment/chemicals/whitepaper.htm</u>

were discussing the proposal in detail, under the co-decision procedure. The European Parliament expected the first reading of the proposal to be completed in Autumn 2005. Any major changes made resulting from the decision-making processes would be notified to the TBT Committee.

18. The representative of the <u>European Communities</u> recalled that one of the key goals for REACH was to improve the level of health and environmental protection within the European Union associated with exposure from the use of chemicals. The vast majority of WTO Members had recognized the legitimacy of such an aim, and most WTO Members had implemented national legislation to achieve similar objectives.

19. Written replies to the comments received had been sent out recently, accompanied by a substantive document which delved into the details of the proposal. Information was also regularly posted on the EC website. Specifically, the main concerns raised by WTO Members were related to: (i) alleged discrimination between EU and non-EU manufacturers, focusing in particular on Article 6 of REACH, which dealt with requirements for substances in articles; (ii) the principle of least trade restrictiveness; and, (iii) other concerns, including concerns related to inconsistent application by EU member States, compatibility with international efforts, effects on innovation, protection of confidential information, and technical assistance and capacity building for developing countries.

20. Starting with Article 6 of REACH, dealing with substances in articles, it was explained that the word "articles" included almost anything that was not a chemical substance or a mixture of chemicals. Although the main purpose of REACH was to focus on chemical substances, and the main obligations of REACH fell on the manufacturers and the importers of chemical substances in the EU, risks could also arise from exposure to substances that were *released from* articles. Article 6 of REACH imposed various obligations on the manufacturers or importers of articles. First, these substances had to meet the EU classification as dangerous. Second, they had to be present in quantities above one tonne per article type per manufacturer or importer per year. Action would only be required if the substance in that article had not been registered for that use further up the supply chain. If those first conditions applied, and the substance was intended to be released (for instance like ink is released from a pen), there would be an obligation to register it.

21. It could also happen that there was no intention for the chemical to be released, but it was known to be released anyway, for example into the environment or in contact with the skin. In such cases, a decision would have to be taken by the producer or importer of the article as to whether the quantity released could adversely affect human health or the environment. There would be an obligation to notify the Central Agency, which might then require registration. This obligation would only come into force 11 years and 3 months after entry into force of REACH, which would be in 2017 or later.

22. On the issue of alleged discrimination against non-EU producers of articles, it was stressed that the obligations in Article 6 applied both to EU producers of articles and importers of articles. A proposal had been made by some WTO Members to limit this requirement further by listing the substances to which the provision in Article 6 would apply. However, this was not possible because the purpose of REACH was to help to identify the hazards of substances, and it would be difficult to identify the substances in advance. In addition, this would be inconsistent with the principle of industry responsibility.

23. Another concern that had been raised was that REACH was more difficult for non-EU manufacturers to comply with than for EU manufacturers. In this regard, it was stressed that REACH applied throughout equally to EU and non-EU producers. Other concerns were related to confidentiality requirements. In this regard, Article 6(a) of REACH allowed non-EU manufacturers to appoint an single representative, who could, therefore, keep that information confidential, and only pass it on to the Agency (and not to its customers within the EU). In order to make the proposal easy to operate, the European Commission was preparing extensive guidance material, aimed equally at

importers and EU manufacturers which would be finished towards the end of 2005. It was the view of the EC representative that REACH was fully compatible with Article 2.1 of the TBT Agreement.

24. On the principle of least-restrictiveness, the EC representative noted that some of the concerns raised included the potential for duplication of testing and risk assessment, the authorization procedure, and more general concerns about workability and the burden that REACH would have on industry. The European Communities was of the view that individual registrations were necessary and that, as designed, the authorization procedures were limited in scope, workable, and that the decision were taken based on risk. An extensive impact assessment on the proposal had been conducted, which had demonstrated that the benefits from the proposal outweighed the costs.<sup>5</sup> It was concluded that REACH was fully compatible with Article 2.2 of the TBT Agreement.

25. On the issue of registration, it was explained that its aim was for each EU manufacturer and importer to take responsibility for the substances they produced or imported. This could be done in a number of ways. First, by obtaining information to assess the intrinsic hazards of a substance. In this regard, animal testing should only be undertaken as a last resort. The use of existing data, sharing of data, and other techniques should be considered by the manufacturer or importer before any new testing was carried out. The second main task for the manufacturer or the importer was to assess the risks arising from identified uses of the substance, and to put in place or to recommend risk management controls for that substance. Producers or importers had to demonstrate that this had been done by sending all the information necessary to the new European Chemicals Agency in the form of a registration dossier. REACH encouraged manufacturers and importers to come together in voluntary consortia to provide joint registrations. The European Commission had considered the suggestion made by some EU member States of having a "one substance, one registration" system (OSOR) when the proposal was being designed, but a number of concerns had been raised about its workability in practice, particularly on the compulsory requirement to agree on core data, and about confidentiality.

26. It was reiterated that the authorization component of the REACH proposal applied only to substances of very high concern, and that its aim was to ensure that these substances were properly controlled, or substituted. These substances, about two and a half thousand, had certain properties, such as being carcinogens, mutagens, or toxic to reproduction (the so-called CMRs), or persistent, bio-accumulative and toxic (PBTs) or very persistent and very bio-accumulative (vpVbs). There was a safety-net in REACH known as the "restriction" part of the process, which enabled the EC authorities to place use or marketing restrictions on certain substances where this was scientifically justified, based on risk.

27. To ensure workability of the system, the substances of very high concern would be prioritised, and progressively authorized as EC resources allowed. Each substance would be given an individual deadline for the authorization process, but its continued use would be allowed until any decision was made. Decisions on authorization would be taken by the Commission and would be based on expert opinions. Any down-stream user could use an authorization gained by their supplier if the specific use is covered, and for transparency, the applicant and other interested parties could comment during the process. The system was designed to be risk-based, and authorizations would be granted if an applicant could adequately control the risk and may be granted if it was demonstrated that social and economic benefits outweighed that risk.

28. Another issue that had been raised was the possible inconsistent application by EC member States, which could lead to uncertainty and trade barriers. They believed that this would not happen, since the legal instrument chosen – a Regulation – would be directly applicable in Members States. Furthermore, the European Chemicals Agency ("the Agency") had been given the power to take decisions in certain cases, and to ensure consistency, particularly in the registration and evaluation

<sup>&</sup>lt;sup>5</sup> This is also available on the Commission's website at the address given in footnote 4.

elements of REACH. The Agency would also have a forum for exchange of information on enforcement where Members States could discuss these issues. In order to promote consistent interpretation of REACH, guidance for authorities would be provided and an appeal would be possible both within the Agency and to the European Court of Justice. They believed that REACH would improve consistency of enforcement within the European Union and facilitate trade flows.

29. A concern had been raised that REACH was incompatible with international initiatives, such as the ICCA HPV programme and the UN's globally harmonized system for classification and labelling (GHS). The European Communities believed that REACH was complementary to such programmes. For example, information generated under the HPV programme could be used for REACH under certain conditions. Information generated under other programmes could also be used if appropriate. They noted that the European Commission was also planning to implement GHS.

30. Other issues raised included that REACH was bad for innovation. While this was not a WTO issue, it was stressed that, on the contrary, a number of elements would encourage innovation, including greater exemptions for research and development. Concerns had also been raised about protection of confidential information. REACH tried to achieve a balance between giving information on chemicals on one hand, but making sure that confidential information was not disseminated on the other. Some key information would be made available on the Agency's webpage once it was established, but some information would always be treated as confidential. All other information could be made available by the Agency upon request, but only after consultation with the owner of the information.

31. One of the other concerns expressed was that REACH was very difficult for developing countries to apply. The European Communities recognized that it had obligations under Article 11.3 of the TBT Agreement. In this respect, extensive guidance material would be provided and technical assistance and capacity building was planned, for example through the Agency.

32. The European Communities concluded that REACH was WTO compatible and expressed their willingness to continue efforts to explain REACH to WTO Members, to develop good quality guidance and to pursue bilateral and multilateral dialogues.

33. The representative of Malaysia, in relation to the issue of registration, sought clarification on the approach that was used for the privatization of substances for restriction. He understood that production volume was the criteria for approximation for exposure. However, the approach preferred by industry was a risk-based one, where intrinsic hazard of the substances, and level of exposure to humans and the environment were taken into account. On the issue of data sharing and confidentiality, he noted that the proposal encouraged companies to form consortia for registration of the same substances which were manufactured or imported. He believed that this might have implications on intellectual property rights, because companies, as part of a consortium, needed to reveal proprietary details such as the manufacturing process that might not have been patented. His country's industry was particularly concerned that the information submitted should not compromise confidential data. In relation to the evaluation process, he believed that there could be inconsistencies from one member State to another, since member States needed to carry out their own evaluation. On the issue of authorization, he noted that some of the terms used, such as "adequate control", and "socio-economic benefits" that determined authorization to be granted were difficult to define. This could result in disagreements since two similar substances undergoing the same evaluation might have different outcomes or results. There was concern that it could happen that substances were withdrawn from the market for economic, rather than safety reasons, since the companies or manufacturers could feel that the costs outweighed the profits. He further wondered how and to what extent information was made available to Members and to the public. Data could be available on the internet, where they could be assessed by anyone. Although there was a need to have access to as much information as possible, the information classified as non-confidential should be restricted to essential items only. He noted that the European Chemical Agency would be funded from the income from REACH fees.

He believed that the role of ECA should be one of ensuring the harmonized enforcement of REACH across the European Union and that the fee structure should not be an additional burden to the chemical industry.

34. The representative of the <u>United States</u> thanked the European Communities for the written responses to the comments submitted, and believed that additional time was needed to evaluate the information received. She noted that extensive discussion on the issue had also taken place at the recent review of the EC's trade policy regime. It was her hope that the European Communities would take into account the questions and concerns raised in that context as well. Her delegations had further questions, on a number of the EC's assertions, notably their prioritization and the estimate of the impact of the proposed regulations. She believed that since the discussions continued with Parliament and member States, it was still too early to make assertions or draw conclusions on the WTO compatibility. She wondered if an additional communication to WTO Members would be made after the conclusion of the first reading, in Autumn of 2005, and if, at that point, there would still be an opportunity for additional comments to be taken into account.

35. The representative of <u>Japan</u> noted that his delegation was studying the replies received and might later raise some points for clarification. He thought that REACH raised some issues of trade restrictiveness from the perspective of the TBT Agreement.

36. With regard to substances in articles, he noted that in a previous EC response to Japan, it had been stated that obligations with regard to substances in imported articles were slightly easier than in the case of articles produced in the EU and left ample time for manufacturers and importers to get acquainted with the system. This reply, however, did not directly respond to the concern raised by Japan about Article 6.5 of the proposed regulation, for which the registration of substances in articles should not apply to substances that had already been registered for that use by an actor up the supply chain. This could be disadvantageous for non-EU article producers. He believed that there would be many cases where importers of articles containing chemical substances from non-EU manufactures might have to register the substances because the upstream suppliers had not registered the substance in question. He stressed that this situation might not be consistent with the principle of National Treatment stipulated by Article III.4 of the GATT 1994 and Article 2.1 of the TBT Agreement.

37. Regarding the creation of a list of named substances, he recalled that the EC representative had explained that this would be inconsistent with the principle of industry responsibility and that it would be difficult to identify the substances in advance. However, the representative of Japan noted that if the provision for the scope of substances was too obscure, industries might not be able to identify substances that they had to register and this could entail an excessive burden. He reiterated that it was preferable to enhance effectiveness and transparency of the regulation through making a positive list of substances or products subject to the registration. With regard to the requirement for every manufacturer and importer to register a substance, he suggested that duplication of registration should be avoided for hazard data and data of risk assessment for the same use of the same substances.

38. The representative of Japan understood the importance of the objectives of REACH, namely, safeguarding human health and environment and recognized that the regulation could not work effectively without the cooperation of third countries and their industries. He hoped that the European Communities would continue to take into consideration the concerns of their trade partners and, in this sense, welcomed the EC's proposal to have bilateral dialogues with the countries concerned for further detailed discussions.

39. The representative of <u>Mexico</u> recalled that his delegation had made comments in the context of the EC trade policy review and in the consultations in May 2003. He regretted that Mexico had not received any response to these comments made in May 2003 and noted that, while the Communities had replied to other Members, the Mexican questions had still not been answered. He thought that the

presentation was useful, but that it was not a replacement for the consultations at the bilateral level between the European Communities and Mexico on the matters previously raised. He stressed that it was fundamental to be able to determine whether the REACH initiative had really been the object of an evaluation from the regulatory side beforehand, and which elements had been taken into account. He sought clarification on how the European Communities were considering granting special and differential treatment to the developing countries. He believed that the guidelines on how to use the system which were under preparation would not be enough for industries and firms to comply with REACH.

40. The representative of <u>Colombia</u> thanked the European Communities for the information provided. He noted that developing countries had just started to assimilate this regulation, and hoped that there could be greater communication of information, technical assistance and capacity building. He shared the concerns raised by Malaysia on the handling of confidentiality and intellectual property aspects of products which were to be registered, evaluated and authorized. This involved the designation of an agent for the handling of this information. He believed that this represented an additional cost because a special agent had to be designated only to handle this specific matter. He supported the comments made by Mexico to study the possibility of implementing the TBT Agreement as it referred to special and differential treatment for developing countries. He also sought clarification on granting authorization on the basis of socio-economic considerations, if the risk involved in the product could not be adequately managed.

41. The representative of <u>Egypt</u> noted that the comments made in the TBT Committee had come from either developed or advanced developing country Members. He feared that developing countries might not have understood nor evaluated the impact that the regulation might have on them. He asked whether the European Communities had made an evaluation of the impact of REACH on the market in general, and on developing countries in particular. He wondered if information on the sharing of developing countries' exports to the European Communities of substances, either in quantity or in value, was available on the EC website. He suggested that this information should be made available to help assess the impact of REACH on developing countries. He feared that the capacity of developing countries to make an evaluation of some substances would not be considered adequate by the European Communities, and asked what kind of recognition and assistance was being considered on the specific issue of evaluation.

42. The representative of <u>China</u> appreciated the transparency that the European Communities had provided on the REACH proposal, and the responses made to the Chinese enquiry point. He welcomed the fact that Members would be informed on major amendments to the proposal as commented in the EC response. He appreciated the expressed readiness to continue efforts to explain the REACH proposal to WTO Members and to continue to pursue bi-lateral and multilateral dialogue with their trading partners. His country was studying the response received and further concerns on REACH had arisen. Therefore, he reserved the right to provide further comments to the European Communities.

43. The representative of <u>Australia</u> shared a number of the questions raised by previous speakers. Her delegation had submitted comments both directly and through the Trade Policy Review process and she thanked the European Communities for the replies received. However, her delegation remained concerned about the WTO implications of the proposal.

44. The representative of <u>Thailand</u> thanked the European Communities for their responses to the comments and noted that more time was needed to study them. She was not sure whether her country's concerns and comments had been answered and taken into account, in particular with reference to the proposal made by Thailand to examine the registration of the substance in articles. She noted that the European Communities had stated that the proposal had given rise to a number of misunderstandings and wondered whether the European Communities could point out all of the misunderstandings wherever possible.

45. The representative of <u>Chinese Taipei</u> shared the concerns expressed by the previous speakers. His delegation also needed more time to discuss the response provided by the European Commission with the local industry. She noted that in the EC's presentation, it was mentioned that the requirements for the registration of substances and articles would come into force only 11 years and 3 months after the entry into force of the REACH Regulation. She wondered whether it could be presumed that until that time most of the substances would have been registered, and if it would be possible for manufacturers to get information on what substances were being registered and for what uses, instead of asking for this information to be provided from the supply chain.

46. The representative of <u>Chile</u> thanked the European Communities for the replies to the comments received, which were being reviewed. She sought clarification about whether the study on environmental impact was available, so that the variables which were used to calculate the cost of the system could be analysed. She was doubtful whether the REACH system was a risk-based one, since it was an obligation for the producer to demonstrate whether there was a risk, in order for a substance to be authorized. She thought it was still unclear which substances would reach that stage, and what the costs to demonstrate the existence of a risk would be. She was worried that until a guide would be made available, which could be by the end of 2005, it would not be possible to evaluate the impact of the cost and how the system would affect the exports of different countries. With respect to the obligation under Article 11.3 of the TBT Agreement to provide technical assistance, she noted that funding was not always available and the needs were different for different countries. Her delegation would continue bilateral discussions in order to have a better understanding, especially about the costs associated with the application of the regulation.

47. The representative of <u>Korea</u> noted that more time was needed to study in depth the information provided by the European Communities. As a general point, he raised a concern regarding the fact that importers of chemical substances would be likely to request from exporters the data necessary for registration. The exporters' proper understanding of the regulations was then critical for its successful implementation. He noted that according to the current draft of the regulation, exporters were not able to register. However, Korea was of the view that exporters should also be permitted to register, either directly or through importers. He sought clarification about the non-GLP data mentioned in the EC presentation. He noted that following 1.3 SAL (Structure Activity Relationship) over QSAL in Annex 4 of the REACH draft, SAL data could be accepted. However, it had not been mentioned how SAL programs having different systems or logic would be verified and accepted. This problem needed to be clarified.

48. The representative of <u>Cuba</u> raised four specific questions. First, on the compatibility of the REACH system with other international efforts to control chemical products, such as GHS and ICA, he asked whether compatibility with other international treaties and conventions such as the Basel Convention would be valid too. Second, he asked whether the requirements of REACH for specific substances, and the consequences and risks for human health associated with some of these requirements, were in all cases demonstrated scientifically. Third, he noted that, with respect to the difficulties of implementing REACH for developing countries, the European Communities had argued that on the basis of Article 11.3 of the TBT Agreement, capacity building and technical assistance would be provided and that this could be done through the Agency. He asked how the European Communities intended to implement this action. Fourth, he wondered if there was any substantive reason that had led the European Communities to set the specific limit of 11 years and 3 months with respect to Article 6 of REACH.

49. The representative of <u>El Salvador</u> reiterated the concerns that her delegation had expressed in the trade policy review of the European Communities. She stressed that the measures applied by the European Communities should not be more stringent than those applied in other international agencies.

50. The representative of the <u>Dominican Republic</u> recognized the right of all WTO Members to implement measures based on legitimate objectives, such as the objectives of REACH to provide a high level of protection for the environment, and human health. However, she stressed that the REACH system constituted a complex and costly initiative which might have a negative impact on the EC's trading partners. She urged the European Communities to incorporate special and differential treatment measures in their draft regulation and to establish a structured system of technical cooperation and assistance for developing countries and their small and medium-sized enterprises.

51. The representative of Canada shared the goals of REACH to protect human health and the environment, to promote competiveness of the chemical industry, and to increase transparency and integration within international efforts. She believed that international co-operation was essential to achieve these goals and wished to continue the on-going dialogue on chemical policy with the European Communities, including through regulatory co-operation. She recalled that her delegation had submitted comments in writing at each step in the process and had a number of additional questions to pose to the EC experts. She sought clarification on the following issues: (i) if forest products such as pulp, cellulose, and recovered paper were exempt from the proposed legislation; (ii) if waste would be included under the registration process of REACH, except in the case of unintentional release, and what was the definition of the phrase "unintentional release"; (iii) if the European Communities intended to allow an applicant to use pre-existing animal test data in its registration package, even though it might not be the first to register the substance. She believed that the proposed phase-in process in REACH would require much duplicative and repetitive testing and sought information on the steps that the European Communities were taking to encourage the submission of all available data regardless of the volume threshold reached by potential registrants when the substance was first registered; (iv) if criteria had been set out for the recognition of foreign testing bodies; and (v) if the European Communities intended to provide procedures for the recognition of data which were already available. She raised concerns on the process to be put in place to ensure the consistent application of REACH across the member States and asked if the data recognized by one member State would automatically be recognized by all member States.

52. The representative of <u>Uruguay</u> stated that it would be important to have access to the study about the impact of this regulatory initiative carried out by the European Communities. She raised concerns about the impact on market access for developing countries, in view of the complexity and cost of the system and encouraged the European Commission to provide concrete shape to any form of assistance which would help to clarify and to implement the REACH system before it came into effect.

53. The representative of <u>Brazil</u> supported the comments made by Mexico and by the Dominican Republic on the special and differential treatment for developing countries. She noted that the REACH system foresaw that the required tests would be undertaken by laboratories accredited according to OECD standards. Brazil, as other developing countries, had based its accreditation system on ISO standards. She noted that some kind of communicability between those systems should be ensured and asked the EC representative to address this issue.

54. The representative of the <u>European Communities</u>, in relation to the concern raised by Mexico on the non-response to comments made in May 2003, explained that the European Communities had not replied formally to any of the 6000 comments that had been made in response to its internet consultation. The response to these comments was the change to the proposal that had been made. The way in which those comments had been taken into account was set out in the explanatory memorandum accompanying the proposal. Nevertheless, the European Communities was willing to continue the dialogue in case there were outstanding questions from Mexico, or from other Members.

55. It was noted that a number of questions referred to the issue of the impact assessment and the extent to which REACH had been subject to an evaluation beforehand. It was explained that an impact assessment had been completed, and it was available on the EC website above. It had taken

into account both the direct costs to manufacturers and importers of complying with REACH as well as indirect costs to other industries. However, in relation to the question raised by Egypt, the impact assessment had not been carried out country by country. It had been conducted as an overall impact, bearing in mind that the overall phasing in of the substances to be registered was spread over an 11 year period.

56. On the question raised by Malaysia concerning problems that might be associated with intellectual property rights in connection with the formation of consortia, it was noted that the purpose of the creation of these consortia was for companies to benefit from the sharing of information and expertise. This was particularly important for small companies and companies from developing countries, which would be able to share and pool expertise when putting together a registration. However, the concern raised by Malaysia was a valid one, and this was why REACH proposed that consortia formation should be voluntary. If, in the development of a joint submission, concerns would arise about sharing information which an individual company would prefer to keep confidential, the proposal did not force that sharing of information, unless it was animal test data. In contrast, the "one substance one registration" proposal would force companies to form consortia, and this was one of the reasons the European Commission does not think such a proposal would work.

57. On the definition of "adequate control", it was recalled that, for the substances that had to be authorized for use, an authorization would be granted if the company, or the group of companies could demonstrate that the risks from exposure to those substances could be adequately controlled. The term "adequate control" meant that the company had identified a DNEL (derived no effect limit) below which there was no risk, and risk management measures were in place in order to ensure that exposures were kept below that level. On the authorization granted for socio-economic reasons, guidance might be needed in order to improve the understanding of these principles and provisions.

58. It was explained that some non-confidential information (e.g. on the hazardous properties of the substance) would be made available to the public via the Agency's website. The particular type of information was set out in Article 116 of the proposal. This was limited to information that was required for health, safety and environmental reasons.

59. The Agency would ensure a harmonized enforcement among the EC member States, particularly in the evaluation stage, and would ensure the decisions taken as a result of an evaluation in one member State were consistent with those that had been taken in another member State.

60. On the timing of the next notification to the TBT Committee, it was stated that the first major amendment to the proposal would be made following the first reading of the European Parliament, whose completion was tentatively expected in the Autumn of 2005. The Commission would then need some additional time to finalize an amendment, and it would at that point update the current notification to the TBT Committee.

61. It was stressed that it was difficult to draw up a list of substances to be subject to controls on the basis of existing knowledge. Only by requiring information on the properties of the substances which were not fully known, or on uses which were not fully known, would it be possible to understand whether the substances could pose any problem. The risk of drawing a list on the basis of the existing knowledge might be that the substances for which more information was available might be penalized, whereas substances for which less information was available could be considered safer. One purpose of the project was rather to raise the level of information on all substances.

62. In reply to several comments on the possibility to grant special and differential treatment to developing countries, it was stated that it was not yet possible for the European Communities to be specific about exactly how this would be done, since the legislation was still at a discussion stage. The agency, which would play a major role in the management of the legislation and a major role in capacity building exercises, had not been established yet, and it would not be established until some

months after the entry into force of the legislation. They stressed that the European Communities would fully abide with all of the obligations under the TBT Agreement, would take all possible measures in order to be able to ensure sufficient technical assistance, capacity building and training.

63. On the issue of prioritization in registration and on why the proposal had not been formulated on a more risk-based approach, it was explained that the proposal was based on volume, which was an approximation of exposure, and hazard. Nevertheless, a lot of other prioritization was foreseen in the proposal: it included the lower requirements for intermediates, the exemption of polymers and the requirements for substances in articles not coming into force until 11 years and 3 months after the entry of force of REACH. An advantage of a volume based system was that it provided legal certainty for companies to know when they had to register their substance. The period of 11 years and 3 months for the provisions on substances in articles had been chosen on the basis of the need to have these requirements come in after the last registration date for substances themselves, so that the information that was gained during the registration of those substances could be used, and allowing 3 additional months for importers and manufacturers to assess that information.

64. Some Members had been concerned about the nomination by third country exporters of a single representative who would take over the duties of registration, and about the additional costs that this might imply. In this respect it was noted that this was a voluntary requirement and was offered in order to help third country manufacturers, who could chose to appoint a single representative, in order to avoid giving confidential information to importers. The choice was theirs.

65. On the questions raised by Canada as to whether pulp cellulose and paper or waste paper were covered by REACH, it was stated that cellulose fiber would be a chemical substance, and as such would be covered, except in the cases foreseen in Annex III whereby they would be taken out if they were not chemically modified. This meant that cellulose would not normally be required to be registered, unless it had been chemically modified. Paper would be considered to be an article. As far as waste was concerned, it was neither a substance, a preparation nor an article, so it would not have to be registered and was outside the scope of REACH. However, in the assessment that was done of chemical substances, the consequences for the waste stage of their life-cycle would need to be taken into account.

66. In response to Canada's questions about recognition of existing test data and accreditation of foreign test bodies, the representative of the European Communities noted that all existing data and other information that was not necessarily test data should be used to provide the information requirements and only as a last resort should new test data be generated. Such test data could be generated anywhere in the world, so there was no need for any accreditation of any foreign test bodies. To be used, data had to be fit for purpose, and that all available data should be registered along with the precise requirement.

67. It was stated that REACH was designed in such a way to be compatible with international conventions, such as the Stockholm Convention on Persistent Organic Pollutants (POPs). Finally, on the evaluation stage of REACH, it was stressed that the proposal made sure that certain parts of the evaluation were subject to strict deadlines. This was also valid in cases when member States were evaluating individual dossiers: they would be requested to notify the start and the finish of their evaluation process to the Agency.

# (ii) Argentina: MERCOSUR Regulation on Definitions Relating to Alcoholic Beverages Other than Fermented (G/TBT/N/ARG/159)

68. The representative of <u>Mexico</u> raised concerns on the MERCOSUR technical regulation on definitions relating to alcoholic beverages, that had been notified by Argentina in G/TBT/N/ARG/159, dated 16 April 2004. His delegation had sent comments to the Argentina enquiry point, but he was unaware of whether these comments had been taken up in the MERCOSUR

Technical Sub-group 3, which was the body competent to analyze them. Mexico wished to continue the dialogue with Argentina and the other MERCOSUR members. It was noted that being MERCOSUR Members as well as WTO Members, the measure should have been notified also by Brazil, Paraguay and Uruguay.

69. The representative of the <u>Dominican Republic, speaking also on behalf of Barbados, Trinidad</u> <u>and Tobago and Jamaica</u>, was concerned by the negative impact which this draft technical regulation of MERCOSUR could have on trade in wine and spirits of Caribbean countries. Her concerns were related, in particular, to the characterization of sugar cane based alcohols as well as simple alcohols, and to the reference in the regulation to rum as a totally or partially fermented beverage. Comments had been submitted to Argentina both through the Permanent Mission in Geneva, and to capital officials. Her authorities would continue studying the issue and she hoped that MERCOSUR would address the concerns raised.

70. The representative of the <u>European Communities</u> reiterated comments submitted to Argentina on 18 June 2004. He considered that the reply provided by Argentina, on 29 June 2004, had not been satisfactory and invited the Argentinian delegation to take the concerns into account and to provide a full written response.

71. The representative of <u>Barbados</u> endorsed the intervention made by the representative of the Dominican Republic. She recalled that at the previous TBT meeting, on 1 July 2004 the delegations of the Dominican Republic, Jamaica, Trinidad and Tobago and Barbados had elaborated their concerns, relating, *inter alia*, to the definition of alcoholic beverages as contained in the technical regulation notified by Argentina. These had also been submitted in writing. She reiterated her delegation's willingness to continue the dialogue between the respective technical experts.

72. The representative of <u>Argentina</u> recalled that at the last meeting of the Committee, his delegation had stated that the competent authorities were open to consider any comments and concerns expressed. On that occasion, it had also been pointed out that these comments were going to be addressed at the MERCOSUR level, in the Technical Sub-group 3. He highlighted that this was a *draft* regulation, and that any comments would be taken into account. His country notified MERCOSUR regulations once they were incorporated in the national legislation. He asked the EC representative to clarify what they had meant when stating that the responses received were not satisfactory.

73. The representative of <u>Brazil</u>, in reply to the concern expressed by Mexico, explained that Brazil had not notified the MERCOSUR draft resolution because it had not yet been incorporated into its national legislation. It was necessary to amend the Brazilian Decree 4851 before this could be done. Both the MERCOSUR draft regulation and the Brazilian Decree 4851 were being reviewed, and a notification would be submitted to the TBT Committee at the end of this process.

74. The representative of <u>Paraguay</u>, as a Member of MERCOSUR, had taken due note of all the concerns raised, which would be conveyed to national authorities. He pointed out that all WTO Members had the right to adopt regulations or measures to protect health, security, safety and environment, and supported the statement made by the representative of Argentina.

75. The representative of <u>Guatemala</u> stated that his authorities were studying the draft regulation and might make comments in the future.

(iii) Argentina: Legal Appellation System for Wine Products (G/TBT/N/ARG/107)

76. The representative of the <u>European Communities</u> reminded the Argentinean delegation of the comments sent on 27 August 2004 on the legal designation system for wine notified by Argentina in G/TBT/N/ARG/107. He raised concerns on the labelling requirements, which would create

unnecessary barriers to trade, and on the misuse by Argentina of the geographical indications for Champagne and Cognac. He invited Argentina to provide written answers to these concerns.

77. The representative of <u>Argentina</u> recalled that a preliminary response to some of the comments made had been provided to the European Communities; a copy of the replies sent on 4 October 2004 had been given to the EC delegation. His delegation remained open to discuss the issue further and to provide additional information.

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

78. The representative of the <u>United States</u> recalled that the Committee had been discussing the issue of the EC wine labelling regulations for some years. On 23 August 2003, the United States had submitted extensive comments and questions to which the European Commission had promised a written response, which had yet to be fulfilled. Some plurilateral meetings, hosted by relevant Commission officials, had been held in October 2002 and in July 2003, prior to the submission of her country's written comments. She expressed frustration with the Commission's continued assertion that questions and concerns had been addressed at those meetings. Her delegation was given the same response for the 24 questions that it had raised in the recent EC trade policy review. If that was the case, why could the European Communities not provide an explanation in writing? Outstanding questions and ambiguities remained, which made it difficult for suppliers to know how to comply. She believed that an explanation would seem to be in the Commission's interest if, as it had been stated, the purpose of the regulation was "to ensure that quality wine sector products are truthfully labelled".

79. It was the understanding of the United States that two wine industry associations in two EC member States had developed publications in an attempt to give guidance to their industries on how to comply with the regulations, and that the information contained in these publications was conflicting. It seemed that even European wine industries were experiencing difficulties with compliance. She also understood that additional amendments to the regulations might have been made, but that these had not been notified. She urged the European Commission to provide a clarification and written explanation in response to the questions and concerns raised.

80 The representative of <u>New Zealand</u> joined the United States in raising concerns about the Wine Labelling Regulations 753/2002 and 316/2004. She recalled that these concerns, both of a substantive and procedural nature, had been raised on a number of occasions. On substance, she considered that the limitation on the use of terms relating to vine varieties, production methods, and vintage to wines carrying a GI seemed to disregard fundamental TBT requirements as they could prevent accurate information from being conveyed to consumers. On procedure, she recalled that her delegation had raised concerns that the notification and consultations (of 753/2002) had to be in line with TBT requirements. New Zealand had welcomed the delays in implementation of the Regulation. However, she was surprised at the short time period between the publication and the notification of the amending Regulation (316/2004), on 24 February 2004, and its implementation on 15 March 2004. This had not provided sufficient time for Members to make comments and for those comments to be taken into account, as per the obligation in Article 2.9 of the TBT Agreement. The representative of New Zealand remained disappointed that the amendments by the Regulation 316/2004 had not adequately addressed all the concerns expressed. Nevertheless, she commended the European Communities for providing written responses to recent questions raised in relation to the REACH Regulation and reiterated her request that a written response in relation to the Wine Labelling Regulations be provided to help to understand justification for the Regulations.

81. The representative of <u>Mexico</u> supported the comments made by previous speakers. He believed that the Wine Regulations should be treated by the European Communities with the same open attitude shown in relation to the REACH Regulation. Written responses to comments made, and

detailed explanation of these Regulations would be useful to be able to understand what the objective pursued was, and to determine that the Regulations did not create unnecessary barriers to international trade.

82. The representative of <u>Australia</u> associated herself with the comments made by previous speakers. She noticed the difference in approach between the explanation that the European Communities had provided on REACH and the lack of responses with regard to the wine regulation. She sought written responses to questions posed by her delegation.

83. The representative of <u>Uruguay</u> shared the concerns stated by previous speakers and stated that the amendment made to Regulation 753/2002 did not cover all the concerns expressed by his delegation. He remained concerned about the impact that this regulation might have on trade.

84. The representative of <u>Argentina</u> was disappointed that the scope and coverage of Regulation 753/2002 had not been clarified.

85. The representative of the <u>European Communities</u> noted that legislation pursued a number of legitimate objectives, *inter alia*, the promotion of quality wines, and the protection of consumers' interests. He pointed out that, where appropriate, the European Communities had demonstrated, through amendments to wine labelling legislation adopted earlier in the year, its willingness to respond substantively to third countries' concerns. A number of informal consultations had also been held with interested Members to clarify the legislation in question. His delegation had taken note of the comments made, and would continue to reflect on these points.

### (v) Brazil: Decree on Beverages and Spirits (G/TBT/N/BRA/135 and G/TBT/N/BRA/160)

86. The representative of <u>Barbados</u> recalled that, at the TBT Committee Meeting of 7 November 2003, her delegation as well as the delegations of the Dominica Republic, Jamaica, and Trinidad and Tobago had raised their concerns in relation to the Brazilian Decree 4851, which contained amended definitions of rum, *cachaza, aguardiente*, and other spirit drinks. They believed that the amendments proposed in Decree 4851 would have a significant adverse affect on the trade of the Caribbean WTO Members involved in the production and trade of rum.

87. In subsequent written communications to the Brazilian authorities in November 2003 and February 2004, as well as at the TBT meetings of March and July of 2004, Barbados and the other Caribbean delegations had raised the issue of Decree 4851 again, and had outlined in detail their queries and proposed amendments. She thanked the Brazilian authorities for a communication, sent on 22 October 2004, in which they had sought to respond to the concerns raised. She sought additional clarification from Brazil, in particular with regards to the relationship between Decree 4851 and a pending Decree which, in her understanding, would revoke and replace Decree 4851.

88. Furthermore, the representative of Barbados drew the Committee's attention to Brazil's new draft technical regulation outlining minimum quality requirements for spirituous beverages, notified in G/TBT/N/BRA/160, on 3 September 2004. Her delegation, in conjunction with the governments of the Dominican Republic, Jamaica, and Trinidad and Tobago on 13 October 2004 had submitted written comments to the Brazilian authorities on this new draft. They had also requested that Brazil suspended the implementation of the new draft technical regulation for a reasonable interval, so that amendments accommodating the concerns raised could be made. She believed that this new regulation in its current form would have significant adverse affects on trade in distilled spirits on Caribbean rum producers. Generally, her delegation's concerns were similar to those raised in relation to G/TBT/N/BRA/135. More specifically on G/TBT/N/BRA/160, she sought clarification on: (i) why a definition for rum and other distilled spirits had not been included in the new draft technical regulation; (ii) the technical aspects in the new draft regulation concerning the distillation processes,

and the absence of language on fermentation; and, (iii) the content outlined in the new draft regulation on aged sugar cane.

89. In the joint letter dated 13 October 2004, the four delegations had also requested clarification on the relationship between Brazil's different technical regulations concerning definitions and quality requirements of spirituous beverages. These different regulations on spirituous beverages would include Decree 4851, the new draft regulation notified in G/TBT/N/BRA/160, and the pending decree which might or might not replace Decree 4851. In addition, she mentioned the MERCOSUR's regulation on definitions relating to alcoholic beverages which had been notified by Argentina in G/TBT/N/ARG/159. She reiterated her delegation's appreciation for Brazil's initial response to some of the concerns with regard to Decree 4851, and noted that further clarification would be requested. Her delegation remained interested in continuing dialogue in all competent fora on the full range of regulations which concerned trade in distilled spirits.

90. The representative of the <u>Dominican Republic</u> thanked Brazil for the replies to comments made in relation to G/TBT/N/BRA/135. She shared the concerns expressed by Barbados and reiterated her delegation's readiness to continue discussions on this matter at a technical level.

91. The representative of the <u>United States</u> recalled that she had raised concerns on the Brazilian Decree 4851 at past Committee meetings, and shared the comments made by Barbados, the Dominican Republic, Jamaica and Trinidad and Tobago. Her delegation would appreciate any updated information from Brazil.

92. The representative of the <u>European Communities</u> thanked Brazil for the reply to the comments made on both notifications G/TBT/N/BRA/135 and G/TBT/N/BRA/160. However, there was no reply concerning the issue of definitions, and the differences between products as defined in Articles 91, 92 and 93 were not clear. He reiterated his delegation's concerns on compliance with the TRIPS Agreement, and invited Brazil to take these concerns into account and to provide answers. He expressed his delegation's readiness to pursue dialogue at a technical level.

The representative of Brazil thanked the delegations of Barbados, the Dominican Republic, 93. Trinidad and Tobago, and Jamaica for the written comments received on G/TBT/BRA/160. These comments, along with those of the European Communities, had been replied to in writing. A response to the US comments would be given in due time. She recalled that Members, in several interventions, had emphasized technical differences between their definition for spirits and the Brazilian one, arguing that they might impede trade. She stressed that Article 34 of the Brazilian Decree 2314 of 1997 foresaw the possibility to import rum, and other alcoholic beverages, even though its composition differed from the Brazilian requirements if a certificate was presented, stating that the product: (i) had typical, regional and peculiar characteristics from a country; (ii) was in conformity with that country's legislation; or (iii) was consumed regularly and its name and composition were known in the region or country of origin. Hence, the aim of this Decree was not to impede trade. Moreover, she specified that G/TBT/N/BRA/160 had notified Ministerial Act number 59, whose objective was to lay down minimum quality requirements for *cachaza* and *aguardiente de cana*. Therefore, while Decree 4851 was a comprehensive document containing beverage definitions and set out the general requirements, the Ministerial Act number 59 detailed those requirements. She reiterated that any technical differences between the dispositions laid down by Ministerial Act No. 59 and those of other countries would not impede trade to Brazil.

### (vi) Korea: Import of Fish Heads

94. The representative of <u>New Zealand</u> once again raised concerns on the issue of edible fish head imports by Korea. She was concerned that during recent bilateral discussions, Korea had informed New Zealand of its intention to continue to prohibit imports of fish heads from New Zealand, but that it would allow imports of fish heads from certain other exporting countries. She understood from

discussions with the Korean authorities that they were concerned that opening the market to New Zealand hake heads would lead to requests from other hake-exporting nations for market access, which would in turn impact on Korea's domestic industry. Her delegation did not regard these concerns as a legitimate justification for the ban on hake head imports, whether considered in terms of GATT Article XI or under the relevant provisions of the TBT Agreement. While Korea allowed the importation of fish heads from certain species, it argued that these products and New Zealand hake head were not like-products, because the two species were biologically different. New Zealand did not accept that this was a legitimate distinction, particularly as a variety of edible fish heads, including hake heads, sourced from Korean fishing boats or from imported whole fish were consumed in Korean restaurants and homes on a daily basis.

95. The representative of <u>New Zealand</u> recalled that Korea had previously stated that it did not allow the importation of hake heads for human consumption because it regarded it as a waste product, and this despite the popularity of the product as a food item in Korea's domestic market. She reiterated her assurance that hake heads for export to Korea could be prepared to an edible standard, and that her government could provide the appropriate sanitary assurances. Her country considered that, provided the product was accompanied by official certification giving assurance that the product was fit for human consumption, Korea ought to allow the importation of edible fish heads. This was the practice with most other seafood products exported to Korea and would seem to be the least-trade restrictive measure available to address all legitimate concerns. She encouraged Korea to move quickly to meet its WTO obligations in this regard.

96. The representative of the <u>European Communities</u> shared the concerns expressed by New Zealand and thanked Korea for the bilateral discussions underway. He hoped that market access would be granted soon for these products.

97. The representative of <u>Norway</u> shared the concerns expressed by New Zealand, and recalled that his delegation had also raised the same issue at previous meetings. His country was holding a constructive dialogue with the Korean authorities and was of the view that a solution should be based on the MFN principle, in line with the provisions of the WTO Agreements.

98. The representative of <u>Korea</u> was fully aware of New Zealand's concerns and remained open to seeking a possible solution through bilateral consultations. It was his understanding that the two parties had undertaken several consultations on this matter since the last meeting of the TBT Committee, and that there was still a different point of view on how to solve this issue in a mutually satisfactory manner. He noted that this issue would also be dealt with at the meeting between Korea and the Joint Committee on Economic Co-operation, which would be held on 10 November. He appreciated New Zealand's willingness to provide appropriate sanitary assurance for Hake head. In this regard, his country was hoping that New Zealand would provide relevant information and data to the Korean authorities as soon as possible, as it would facilitate the bi-lateral discussion. He believed that the issue could be resolved in a mutually satisfactory manner through consultations, and noted that fruitful consultation were also taking place with the European Communities and Norway.

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

99. The representative of the <u>European Communities</u> recalled that on 3 June 2004 it had submitted comments on G/TBT/N/CHE/39 regarding the determination of the particle number emission level of passenger cars with compression ignition engines. She reiterated the request to Switzerland to provide an answer to the comments sent.

100. The representative of <u>Switzerland</u> noted that her delegation had been hoping to be in a position to reply to comments made by the European Communities and the United States for the

current meeting. However, the process of internal decision concerning this draft was complicated, as it was the fruit of the work of an environmental group in the Parliament. She explained that the proposal was being re-discussed on the basis of comments received and that a decision would probably not be taken before the spring of 2005; she would inform the Committee of the result.

# (viii) United States: Measure on Refillable Lighters

101. The representative of the People's Republic of China reiterated her concerns regarding the US safety standard on lighters. She recalled that the concerns expressed were related to the rationale for maintaining a relationship between product, price and safety. China had requested the United States to make a notification to the WTO in accordance with Article 1.6 and 2.9 of the TBT Agreement. Her delegation had also questioned why the international standard ISO 9994 for lighters could not meet the objectives of the United States. She stressed that Article 2.4 of the TBT Agreement requested Members to use the relevant international standard as a basis for technical regulations and recalled that in the EC-Trade Description of Sardines<sup>6</sup>, the Appellate Body had upheld the Panel's finding to the effect that Article 2.4 of the TBT Agreement applied to measures that had been adopted before 1 January 1995, but which had not ceased to exist, and that Article 2.4 of the TBT Agreement applied to existing technical regulations. She considered that, although bilateral discussion had taken place, China's concern had not been adequately addressed and therefore sought further clarification from the US delegation regarding the link between price and safety for lighters. She also reiterated the request to the United States that it notify the measure to the WTO, providing a comment period for Members.

102. The representative of the <u>United States</u> believed that the record from the discussions at the last meeting was clear on her delegation's views on whether this proposal should have been notified. She recalled that it had been published for comments some time ago, and that there had not been a change to the regulation. Substantial information had been provided to China in this regard. She was not yet in a position to respond to the question of whether the regulation could change in light of the recent adoption of an international standard and would come back to that in due course.

### *(ix)* New Zealand: Ban on the Importation of Trout

103. The representative of <u>Canada</u> reverted to the issue of New Zealand's ban on trout imports. She recalled that, on 7 December 1998, New Zealand had passed an order in Council entitled *Customs and Import Prohibition (Trout) Order 1998*, which had passed a temporary ban on the commercial importation of trout. In the meantime Canada had raised concerns on the trout ban with the New Zealand authorities, including at the Ministerial level, and also at previous meetings of the TBT Committee, including at the October 2001, March 2002 and July 2004 meetings. Her country did not consider the ban to be scientifically justified and had never received, nor had been made aware, of any science-based evidence from New Zealand. As such, she considered the ban to place New Zealand in a position of being inconsistent with its trade obligations under the TBT Agreement. Her delegation was disappointed to learn that New Zealand had recently extended the ban for the fifth time, for another three years, until November 2007. The representative of Canada urged New Zealand to immediately restore trade in trout.

104. The representative of <u>New Zealand</u> reminded the Canadian delegation of the background of this measure. Trout fishing was an important recreational sport in New Zealand, and the conservation of trout continued to be a subject of particular concern. For this reason, the Conservation Act of 1997, prohibited the purchase or sale of trout in New Zealand. To ensure the effectiveness of the domestic sales ban, imports of trout in commercial quantities had been prohibited by successive customs orders. The New Zealand Government had decided to extend the import ban through a new order in Council to ensure that the integrity of the domestic sale prohibition was not undermined. Moreover, the new

<sup>&</sup>lt;sup>6</sup> WT/DS/231/AB/R.

order did not prohibit the importation of all trout into New Zealand, but specifically provided for the importation of non-commercial quantities for personal consumption. In this way, it ensured that both domestic and imported trout were subject to the same treatment.

105. The representative of <u>New Zealand</u> further stated that in extending the customs order, the Government had tasked officials to report back on alternative measures to retain the unique status of trout well before the expiry of the temporary measure in 2007. This approach had been adopted as an indication of willingness to work together with trading partners to address this issue of mutual concern. Her delegation did not agree with Canada's suggestion that the measure raised questions in relation to New Zealand's obligations under the TBT Agreement. The order was not discriminatory, nor protectionist; it addressed legitimate objectives and was fully in accordance with trade obligations. There were significant concerns that the sale of trout, whether domestic or imported, would foster the poaching of the stock in New Zealand. This would undermine conservation of the stock and frustrate the legitimate objective that underpinned New Zealand's domestic conservation regime for trout.

### (x) Netherlands: "Vos" Bill on Wood Products (G/TBT/N/NLD/62)

106. The representative of the <u>United States</u> appreciated the Netherlands's early notification of the Vos Bill on the sustainable production of wood products (G/TBT/N/NLD/62). She noted that this proposal addressed a number of the US concerns, which had been raised in response to a previously notified amendment to the Environment Management Act, in 1998.<sup>7</sup> However, she believed that additional changes might still be warranted to eliminate certain ambiguities and elements that could inappropriately restrict trade. She recalled that, in response to the concerns raised at the last Committee meeting by Canada, the European Communities had informed the Committee that the Dutch notification was under examination to assess its compatibility with Community law, and at that time no comments had been received from third countries. She noted that both the US Government and industry comments had since been submitted and looked forward to the European Communities' written response.

107. The representative of the <u>European Communities</u> informed the Committee that the draft Dutch regulation was still under examination by the European Commission and the member States to assess its compatibility with Community law. The need to avoid the creation of unnecessary obstacles to trade was taken into account and, once this evaluation was concluded, the European Communities would reply to the comments.

### (xi) United Arab Emirates: Conformity Assessment System and Halal Certification

108. The representative of the <u>United States</u> recalled that, at the previous meeting of the Committee, she had raised concerns on the functioning of the United Arab Emirates enquiry point and notification authority, and on the lack of notifications. At the time, her delegation had been seeking information about a proposed conformity assessment programme known as the Emirates Conformity Assessment System (ECAS), whose status was not known, nor the reasons why it had not been notified. She informed the Committee that her delegation had since held bilateral discussions and that it was her understanding that the programme would be a voluntary one, and as such there would be no reason to make a notification.

# (xii) Mexico: Standard for Glazed Pottery Ware, Glazed Ceramic Ware and Porcelain Ware (G/TBT/N/MEX/69)

109. The representative of the <u>European Communities</u> reminded the Mexican delegation that on 10 November 2003 comments had been submitted on G/TBT/N/MEX/69 regarding glazed pottery

<sup>&</sup>lt;sup>7</sup> See discussions on notification G/TBT/Notif.98.448 in G/TBT/M/13, para. 5 (November 1998).

ware, glazed ceramic ware and porcelain ware. She reiterated the request to Mexico to provide answers. The concerns expressed were related, in particular, to the lead and cadmium limits introduced by the notified draft measure regarding flat ware, which were more stringent than those laid down in relevant ISO international standards. She sought clarification on whether the Mexican authorities would accept the result of conformity assessment procedures of ceramic table wear produced in the European Communities in compliance with ISO standards.

The representative of Mexico recalled that the European Communities had informed his 110. delegation of their comments regarding the official draft standard PROY-NOM-231-SSA1-2002. When the comments had been submitted, the comment period had already expired by one month. The Health Secretariat had received these comments and analysed them carefully. However, since they had not been presented within the deadline for public consultation under the Mexican legislation, there was no obligation to publish the responses in the Official Gazette. The draft standard in question had taken into account, with some deviations, the international standard to which the European delegation had referred. These deviations had been based on the special circumstances of Mexico, as allowed under the TBT Agreement. He invited the European Communities to consult the statement of regulatory impact, available on the website of the Economy Secretariat, to analyze the reasons for which Mexico required a greater level of protection than those offered by the international standards. He highlighted that, with regard to the possibility of accepting the conformity assessment results for ceramic produces in the European Union, Article 6 of the TBT Agreement promoted the recognition of conformity assessment by central government bodies and set out the procedure for such recognition. He invited the European Communities to follow this procedure to obtain such recognition.

# (xiii) European Communities: Traceability and Labelling of Biotech Food and Feed Products (G/TBT/N/EEC/6-7 and Add.1-3; G/TBT/N/EEC/53 and Add.1)

111. The representative of <u>Canada</u> recalled that at the July 2004 meeting, Canada had raised concerns regarding the European Communities traceability and labelling of biotech food and feed products (G/TBT/N/EEC/6-7 and Add.1-3; G/TBT/N/EEC/53 and Add.1). With respect to the GMO moratorium and authorizations, she remained sceptical that the authorization process was functioning as intended. In fact, despite positive scientific assessment, the decision to approve had not been made at the regulatory committee level, nor at the level of Council of Ministers, thereby forcing the Commission to authorize a product after 30 days. Canada continued to monitor the pending canola applications, which were currently at various stages in the authorization process. Canada considered that one authorization did not afford sufficient evidence to imply that the European Communities was acting in full compliance with its obligations under the WTO Agreements.

112. The representative of Canada believed that the adopted regulations dealing with traceability and labelling were burdensome, and might create unnecessary barriers to trade. Canada would continue to monitor their implementation, with the objective that exported goods did not experience undue delays when imported into the European Communities. She pointed out that the labelling and traceability measures were creating uncertainty for Canadian exporters, since the European Communities had failed to clarify how the regulations would be applied. She wondered how it could be possible for foreign suppliers, especially smaller manufacturers of value added products, to know when they were in compliance with the measures in the absence of clear guidance. Canada noted the notifications of the Commission's recommendation regarding sampling and detection (G/TBT/N/EEC/53 and Add.1). However, it remained unclear how the traceability and labelling requirements could be implemented effectively in the absence of segregation systems and of internationally accepted testing methodologies to validate the presence of GMOs.

113. The representative of the <u>United States</u> supported the comments made by Canada.

114. The representative of the European Communities recalled that the measures on traceability and labelling of GMOs were notified in G/TBT/N/EEC/6 and 7. Addenda to these notifications had been provided in order to keep Members fully briefed. In addition, the European Commission had recently adopted a non-binding recommendation providing guidance on sampling and detection of GMOs that would be published shortly. The Commission's proposal for this recommendation had been notified in G/TBT/N/EEC/53 and Add.1. He stressed that the European Communities had, at every stage in the process, followed the highly transparent approach in-line with its international obligations. The legitimate objectives of the measures, as explained on other occasions, were related, *inter alia* to the protection of human, animal and plant health or safety, and environmental and consumer protection. These objectives had been pursued in the least trade restrictive manner. He informed the Committee that, while the traceability and labelling regulation had been in force for over six months, no reports of major difficulties concerning the imports of GMOs and derived products had been brought to the EC's attention.

### C. OTHER MATTERS

### 1. Special Meeting on Procedures for Information Exchange (held on 2-3 November 2004)

115. The <u>Chairman</u> recalled that the Special Meeting on Procedures for Information Exchange was held pursuant to the Committee's decision to convene, on a biennial basis, regular meetings of persons responsible for information exchange, including persons responsible for enquiry points and notifications.<sup>8</sup> At the meeting, Members had had an opportunity to discuss, at a technical level, the activities and concerns relating to information exchange in the context of the TBT Agreement, and to review the functioning of notification procedures and enquiry points. The discussions had taken place in panel sessions and had focused on four key issues: the notification process, the handling of comments, the transparency obligations under the Code of Good Practice, and the functioning of enquiry points. He highlighted three key cross-cutting aspects of transparency brought up by participants: (i) the importance of internal coordination; (ii) the increased and better use of electronic tools; and (iii) the dissemination of information.

116. *Internal coordination* had been deemed as essential at all stages of transparency procedures. The Chairman recalled that participants had emphasized the need to establish mechanisms and procedures to ensure lasting institutions which could help a better implementation of the TBT Agreement. One example of such a mechanism was the creation of a "national TBT Committee" to oversee and coordinate the implementation of the TBT Agreement by various agencies. The importance of good regulatory practice had also been linked to this discussion.

117. The Chairman stressed that the use of *electronic tools* was growing, also in developing countries. However, resource constraints and technological disparities between countries remained and capacity building in this regard needed to be improved. He recalled that, in line with a recommendation of the Third Triennial Review<sup>9</sup>, a proposal to develop a facility to fill in notifications on-line had been reiterated, in order to simplify and accelerate the notification procedure. This would be complementary to other approaches currently in use. Moreover, the use of websites to share information related to specific notifications had been encouraged, for instance with regard to comments formulated on a particular notification. Also, following presentations on existing databases on notifications (such as the "Documents Online" facility of the WTO Secretariat), the importance of using them to their full extent had been highlighted.

118. The Chairman recalled the need for improving the *dissemination of information*. One way of doing this was to filter and sort the information contained in the notifications in order to better target it to the interests of the relevant national stakeholders. In this context, various web-enabled

<sup>&</sup>lt;sup>8</sup> The programme of the meeting is contained in document G/TBT/GEN/13. See also "Transparency Requirements and Procedures", Note by the Secretariat, to be issued.

<sup>&</sup>lt;sup>9</sup>G/TBT/13, paragraph 27.

applications put in place by national enquiry points had been presented.<sup>10</sup> Other alternative means of disseminating information, such as bulletins and publications, had also been mentioned. The language barrier had again been seen as a major impediment to the circulation and dissemination of information and, in this respect, some examples had been given of how translations were handled. For example, it had been suggested that resources be focused on the translation of essential information only and that enquiry points speaking the same language be encouraged to share the burden of translation.

In conclusion, he believed that the work of enquiry points was essential to a better 119. implementation not only of all transparency provisions, but also of the principles enshrined in the TBT Agreement in general. He noted that enquiry points enjoyed a unique position to act as focal points on trade barrier issues for all relevant stakeholders; this went beyond the simple role of information providers as foreseen in the TBT Agreement. He stressed that this Special Meeting had particularly highlighted the close link between transparency and the avoidance of unnecessary obstacles to trade. The dissemination of TBT notifications and other TBT-related information by enquiry points to national stakeholders was a first step towards the identification and formulation of national positions and policies on TBT-related trade issues, including the identification of specific trade concerns. The need for technical assistance and capacity building to assist Members in implementing their obligations under the TBT Agreement, as well as the importance of cooperation between various enquiry points in different countries, had been recognized in this context. He recalled that a proposal had been made to create a webpage on the WTO website containing information on, and contact details of, all TBT enquiry points. A summary report would be included in the minutes of the present meeting.<sup>11</sup>

120. The representative of <u>Canada</u> drew the Committee's attention to the Third Triennial Review Recommendation contained in paragraph 27 of G/TBT/13 (first tiret) and recalled that Canada had made this proposal. 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. The representative of Canada proposed that the Secretariat could look into the feasibility of setting up such a facility. The Committee so <u>agreed</u>.

### III. TRIENNIAL REVIEW

A. ISSUES ARISING FROM THE THIRD TRIENNIAL REVIEW

### 1. Good Regulatory Practice

121. The <u>Chairman</u> said that the discussion in the TBT Committee at its last meeting had provided a good starting-point to the identification of elements of good regulatory practice at the domestic level, which was the subject of the first of the three relevant recommendations contained in paragraph 14 of the Third Triennial Review (G/TBT/13). He recalled that several Members, including Colombia and Mexico, had shared their national experience in this area. The representative of Chile had also informed the Committee about a Seminar on Good Regulatory Practice held by APEC and OECD. A number of elements of good regulatory practice had been mentioned during this discussion, such as transparency, harmonization, equivalence, regulatory impact assessment, consensus, representation and non-duplication.

<sup>&</sup>lt;sup>10</sup> These included "Export Alert!" in Canada, "Alerta Exportador" in Brazil, "Notificanorm" in Mexico.

<sup>&</sup>lt;sup>11</sup> See Annex 2 on page 38.

122. The representative of <u>Mexico</u> drew attention to the submission in document G/TBT/W/248 which identified some of the elements involved in good practices used in his country. In particular, the document set out seven disciplines of good practices that had been identified and three examples of measures which had helped towards better regulation in Mexico.

123. The representative of <u>Chile</u> recalled that her country had hosted the APEC Workshop in 2004, and, in that context, seminars on competition policy and regulation had been held. She explained that this was part of an APEC-OECD initiative which was initiated in 2000. She drew the Committee's attention to Job(04)/163 in which Chile had summarized the main aspects of the APEC OECD cooperation. A checklist of regulatory reform had also been distributed (circulated as a Room Document). In September 2004, a conference on good practice, standards and conformity assessment had been held in the framework of APEC. It had dealt, among other things, with issues related to coordination and infrastructure.

124. The representative of <u>OECD</u> introduced relevant work on good regulatory practice and market openness in the OECD.<sup>12</sup> He recalled that the OECD had been working on trade-related regulatory reform since the mid 1990s. The starting point of the work had been the recognition of the importance of good regulatory practice at the national level, and the objective had become to develop a conceptual framework for reviewing national experiences with good regulatory practice. To refine the understanding of good regulatory practice, country peer reviews of regulatory reform had been undertaken. Some 20 OECD countries had been reviewed and some non-Member countries, such as Russia, were being reviewed as well.

125. He noted that the OECD had been cooperating with APEC in a series of discussions focusing on country experiences, and had participated in the development of an integrated checklist, which was designed for self assessment of good regulatory practice. The checklist would be adopted formally by OECD and APEC in 2005. The OECD conceptual framework was based on six principles of efficient regulation, considered as key for assessing market openness implications of regulatory practice. He explained that these were similar to the principles that APEC and other bodies had identified and that, conceptually, they underpinned WTO principles, especially those of the TBT Agreement. These were: transparency, non-discrimination, avoidance of unnecessary trade-restrictiveness, use of internationally harmonized measures, streamlining conformity assessment procedures and integration of competition principles into regulatory approaches.

126. In his view, five interrelated issues seemed to be particularly relevant to the field of standards, technical regulations and conformity assessment. The first was the choice of instruments for achieving regulatory objectives in a trade-friendly environment, which had been discussed to some extent in the TBT Committee as mandatory versus voluntary measures. He pointed out that there had been a general move away from mandatory measures towards voluntary, industry-led standards and related conformity assessment procedures. This tendency was based on the realization that voluntary standards, being market driven, were more economically efficient, took less time to elaborate and offered more flexibility in implementation. He noted that an exception to this trend could be seen for certain consumer products which presented health and safety risks, or which might be characterized by information asymmetries.

127. The second issue was related to transparency mechanisms. He stressed the importance of having the necessary information readily available, and of ensuring the predictability of the procedures used for elaborating and implementing standards, technical regulations and conformity assessment procedures. The effective use of public consultation in the development of standards and technical regulations, and the existence of codified procedures, open to all stakeholders, with well timed opportunities for public comment, were particularly important is this regard. He also stressed

<sup>&</sup>lt;sup>12</sup> Reference was made to the OECD document "Integrating Market Openness into the Regulatory Process: Emerging Patterns in OECD Countries", TD/TC/WP(2002)25/FINAL, 17 February 2003.

the need for regulatory coordination between central and sub-central authorities, and with nongovernmental parties, in order to strengthen the regulatory quality by involving technical expertise.

128. The third issue was related to the use of regulatory impact assessment mechanisms (RIAs). He noted that many countries relied on RIAs to improve regulatory quality, although often these were not formulated specifically in terms of market access or market openness considerations. Some countries, however, explicitly subjected proposed technical measures to transparent RIAs, involving analysis of the problems, identification of alternative solutions, analysis of costs and benefits of these solutions including with respect to trade, and assessment of feasibility of enforcement mechanisms.

129. The fourth issue was related to equivalency. He emphasized that there were often significant difficulties in accepting equivalency and that a high level of regulatory confidence underlying systemic compatibility was needed. The most common approaches for recognizing equivalence included unilateral recognition, when regulatory systems were already broadly complementary, and regional recognition in cases where there was regulatory confidence and systemic compatibility. Cross-border regulatory co-operation had been used in a number of cases where work had been undertaken to enhance understanding of national systems in various areas. Finally, he stressed that government-business dialogue could promote greater understanding and acceptance of equivalence.

130. In relation to streamlining conformity assessment procedures, he stressed that duplicative or unduly restrictive procedures should be avoided. Attempts to do this had come through unilateral recognition or through mutual recognition, of which several forms existed, such as government to government agreements. He noted that these were often resource intensive and seemed to work best in sectors that were already closely integrated. Agreements among private certification bodies could also be useful, entailing recognition of accreditation of private bodies in other countries. He pointed out that supplier's declaration of conformity (SDoC) was sometimes viewed as promising due to the flexibility that it entailed, but it required professional integrity and an operative system of product liability and market surveillance. He emphasized that these emerging findings were still to be considered as work in progress, and hoped to continue sharing experience and further findings with the TBT Committee in this area.

131. In summing up, the <u>Chairman</u> noted that the discussion on good regulatory practice had concentrated on the first of the three recommendations from the Third Triennial Review, which was the exchange of national experiences. He recalled that paragraph 14 contained two further recommendations. The first was to continue the exchanges on Members' experiences and to hold focused discussions on (i) the choice of policy instruments and the decision as to whether to use mandatory versus voluntary measures; and (ii) the use of regulatory impact assessments to facilitate good regulatory practice. Second, the Committee was to initiate a process of sharing experiences on equivalency, and particularly with regard to how the concept was implemented in practice. He encouraged Members to come forward at the next meeting with submissions on these elements or on any additional elements of good regulatory practice.

### 2. Transparency Procedures

132. The <u>Chairman</u> noted that wide-ranging discussions had been held on the issues covered by the recommendations of the Third Triennial Review. For instance, recommendations relating to the handling of comments or concerning the electronic transmission of information had been at the centre of the discussion in the Special Meeting on Procedures for Information Exchange held on 2-3 November 2004 (Annex 2). He drew attention to the proposal made by Canada on the creation of an electronic notification form (paragraph 120, above). He invited Members to share their views on any additional issue the Committee might discuss in respect of transparency procedures in the follow-up to the Third Triennial Review.

### 3. Conformity Assessment

133. The <u>Chairman</u> 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

134. The <u>Chairman</u> drew the attention of the Committee to the recommendation agreed at the Third Triennial Review "to exchange information and experiences and hold a workshop on SDoC covering issues such as: the regulatory authorities, sectors and suppliers which use SDoC; the surveillance mechanism, liability law and penalties used to ensure that products comply with requirements; the incentives for suppliers to comply with requirements; and the legislation that underpins the relationship between buyers and sellers" (G/TBT/13, paragraph 40).

135. He noted that, with respect to the exchange of information and experiences on SDoC, Brazil, Chinese Taipei, the European Communities, New Zealand and Australia had shared their experiences in implementing SDoC programmes. Members had discussed issues such as the appropriateness of SDoC in view of the nature of the risks involved; the importance of market surveillance and product liability laws; and the reduction of compliance costs. He also recalled that the Committee had decided to hold the SDoC Workshop on 21 March 2005, back-to-back with its regular meeting.<sup>13</sup> He informed the Committee that the activity had been included in the 2005 Technical Assistance and Training Plan to secure funding for the participation of capital-based officials from developing country Members. The programme for the workshop would be issued in early 2005. He encouraged Members, especially developing countries Members, to come forward with proposals for case studies to be presented at this event.

### (b) Accreditation Fora

136. The <u>Chairman</u> drew the Committee's attention to the recommendations agreed in the Third Triennial Review to "exchange information and experiences on the participation of Members in national, regional and international accreditation schemes" and to "invite representatives from relevant international and regional accreditation fora to provide information on their operation and the participation of Members, in particular, developing country Members, in their systems" (G/TBT/13, paragraph 40).

137. He recalled that at the previous meeting, the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), the European Co-operation for Accreditation (EA) had made presentations on the operation of these fora, and on the participation of Members, in particular, developing country Members, in their activities. The Committee had also heard a presentation on the new ISO Standard for accreditation (ISO/IEC 17011). The Chairman noted that the recommendation of the Third Triennial Review stated that "users, such as certification bodies, should also be invited to share their experiences in this respect". He suggested that a number of "users" could be called upon to give input in this respect, for instance in the context of the future workshop on approaches to conformity assessment (see paragraph 139 below).

### (c) Other Issues related to Conformity Assessment

138. The <u>Chairman</u> recalled that the Committee had also agreed "to exchange information and experiences on existing conformity assessment procedures and practices, the use of relevant international standards, guides and recommendations". He noted that valuable information had been

<sup>13</sup> G/TBT/M/32, paragraph 86.

provided to the Committee at the previous meeting by the presentations of Jordan and the European Communities, and by reports on the work of the BIPM, the IEC, the OECD, and the OIML.

139. At the Third Triennial Review, Members had also agreed to hold a workshop on the different approaches to conformity assessment, including the acceptance of conformity assessment results (G/TBT/13, paragraph 40). He informed the Committee that the Secretariat would suggest the inclusion of this workshop in the 2006 TA Plan at the time of its preparation. Finally, in accordance with Paragraph 41 of the Review, progress made on the Work Programme on conformity assessment was reflected in the Committee's Annual (2004) Report to the Council for Trade in Goods.<sup>14</sup>

### 4. Technical assistance

140. The <u>Chairman</u> recalled that at the Third Triennial Review the Committee had agreed to consider the creation of an information coordination mechanism, including the possible development of voluntary notification procedures (G/TBT/13, paragraph 54). Key to such a mechanism would be the communication of current and forward looking information. Members had also noted that aside from the five specific proposals<sup>15</sup> addressing the creation of such a mechanism (both with respect to the internet facility and the management approach) many other proposals made in the run-up to the Triennial Review remained on the table, including the numerous responses to the survey questionnaire.<sup>16</sup> At the July 2004 meetings, the Committee had also heard presentations on the WTO/OECD Trade and Capacity Building Database and the Standards and Trade Development Facility (STDF) in the SPS context. As a way of advancing the debate, he proposed to produce an "issues and options paper" which would seek to facilitate further discussions and to find possible ways forward for the Committee. This paper would take into account the discussion and submissions made to date on technical assistance to the TBT Committee.

141. The representative of <u>Switzerland</u> made two specific proposals. First, he suggested to add value to the OECD/WTO Database by including a more qualitative assessment of the information contained therein. He recalled that work had already been done by the Secretariat when doing the survey (referred to by the Chairman in the paragraph above) and that other agencies, such as UNIDO, had also analyzed this information. This work could be used in analyzing the data contained in the OECD database. Second, he proposed to build on the information contained in the survey; the information contained in the OECD database could be analyzed to match the needs expressed in the replies to the survey questionnaire and related to the areas that had been identified by the Secretariat in its analysis of the replies to the survey. That information could also be linked to the progress of implementation of the TBT Agreement. A website system with three components could be set up: (i) the needs reflected in the replies of the survey questionnaire; (ii) the technical assistance provided which was reported to the OECD/WTO database; and, (iii) information related to the implementation of the Agreement, taken from Trade Policy Reviews and the work done by the Committee.

142. The representative of <u>Brazil</u> stressed that his delegation attached great importance to the Committee's mandate in this area and was concerned that, in the last few meetings, not much progress had been made. His delegation was flexible with respect to their own proposal (G/TBT/W/232) and was willing to engage in an exchange of views with other Members to move the process forward. He believed that a mechanism could be set up at minimal cost and that any duplication with the work done in other international organizations had to be avoided. He noted that flexibility and predictability in the activities on technical cooperation and technical assistance was needed; these tended to be scattered and provided by many different organizations. This could be assembled in a

<sup>&</sup>lt;sup>14</sup> G/L/710, 8 November 2004, para. 3.

<sup>&</sup>lt;sup>15</sup> New Zealand (G/TBT/W/212 and 216, 27 and 30 June 2003), Egypt (G/TBT/W/225, 14 July 2003), Canada and New Zealand (G/TBT/W/233, 20 October 2003) and Brazil (G/TBT/W/232, 21 October 2003).

<sup>&</sup>lt;sup>16</sup> The questionnaire is contained in G/TBT/W/178; a compilation of responses in G/TBT/W/186 and Add.1; and, an analysis of the priorities identified is contained in G/TBT/W/193.

simple website and users could be provided with a mechanism so that they could find the best alternative to have their needs and specific concerns addressed.

143. The representative of Egypt supported the proposal to produce an "issues and options paper". He recalled that the recommendations in paragraph 54 of the Third Triennial Review were based on the proposals made by Canada and New Zealand on the establishment of an internet facility, and on a proposal to have a management tool, as suggested by Egypt (G/TBT/W/225) and Brazil. He noted that the discussions in the Committee had mainly focused on the internet facility. This should not duplicate activities from other relevant organizations, and the costs associated with the creation of such a mechanism needed to be taken into account. The product should be user friendly, especially for developing countries. He believed that the second component of the recommendation, relating to the management tool, had not had an equal degree of attention. He invited Members to provide their comments in a constructive manner on how to put in place such a management tool and make it operational.

### 5. Other Elements

144. No issues were raised under the item.

# B. PREPARATION OF THE FOURTH TRIENNIAL REVIEW

145. The <u>Chairman</u> recalled that at its March 2004 meeting, the Committee had agreed that, before the end of 2004, the Chairperson would develop a procedural work programme for the preparation of the Fourth Triennial Review.<sup>17</sup> In the Committee's subsequent discussions of the draft work programme it was stressed that: (i) the duration of the three stages set out in the work programme should be seen as flexible; (ii) it would be possible for the Committee to revert to issues and submissions discussed on previous occasions; and, (iii) at its first meeting in 2006, the Committee might need to continue its discussion of topics identified for review, and not only focus on the stocktaking exercise. Taking into account these points, the Committee <u>endorsed</u> the work programme contained in Annex 1 to this document (page 36).

# IV. TECHNICAL CO-OPERATION

146. The representative of the <u>European Communities</u> noted that its submission contained in G/TBT/W/244 was made in response to one of the recommendations from the Third Triennial Review, contained in paragraph 54, which invited Members to communicate to the Committee information regarding technical assistance activities. He noted that this was the fourth time that such information had been submitted; the information was not only related to projects from the Commission, but also to projects funded by member States. All projects listed were on-going, some were of a "framework type", and did not only cover TBT-related work.

147. The representative of <u>Switzerland</u> explained that its submission contained in G/TBT/W/247 described the overall approach of Switzerland in the field of standards, and went beyond purely TBT-related issues, to include, for instance, SPS measures. The paper was divided into five main chapters: the first dealt with the strategic orientations, the second with the general approach, the third described the main measures, the fourth was about lessons learned and the last chapter presented the projects which were on-going. These had been divided into four main categories: (i) strengthening institutional infrastructure; (ii) promoting better participation in international standard-setting organizations; (iii) facilitation and compliance of quality standards for market access; and, (iv) promoting organic production and fair trade in the Swiss market.

<sup>&</sup>lt;sup>17</sup> G/TBT/M/32, paras. 111-115.

148. The representative of <u>Mozambique</u> thanked the European Communities and Switzerland for the support given to Mozambique. She noted that some information contained in their respective papers regarding the assistance provided to her country in the past few years was not accurate. She stressed that assistance was much needed in order to implement a quality policy. The <u>Chairman</u> suggested that Mozambique clarify the issues with the European Communities and Switzerland bilaterally.

149 The representative of the ISO informed the Committee that the ISO Strategic Plan for the period 2005-2010 had been adopted at the General Assembly of the ISO in 2004 (G/TBT/GEN/14). He pointed out that the ISO had also completed its Code of Ethics, which put together a number of statutory rules and principles implemented in the development of standards and international standards. The action plan for developing countries was based on surveys and consultations with ISO members, and also on collaboration with WTO and other international organizations to identify the needs in this area. It was intended for ISO members and for regional and sub-regional organizations who were involved in standardization, and it was directed to international, regional and national funding agencies. He noted that the ISO itself was not a funding agency; funds received from ISO members were used to initiate some actions, such as workshops and assisting participation in international standardization activities. The plan was based on five major objectives: (i) to improve awareness; (ii) to build capacity of ISO members to take part and develop standardization activities and infrastructure; (iii) to increase regional and national co-operation; (iv) the use of IT tools; and (v) to involve developing countries in the technical activities, for instance through arrangements such as twinning.

150. The representative of the IEC reported to the Committee on the functioning of the IEC Affiliate Country Programme, launched in June 2001. He stressed that the Programme facilitated the participation of developing countries in the elaboration of international electrotechnical standards, and encouraged their use as a basis for national standards. It was unique in that it gave those individuals responsible for standardization activities the tools and abilities to get fully involved. He underlined that the Programme had a number of benefits, including: (i) access rights to technical work programs and working documents (including draft standards) selected according to the needs of the country concerned; (ii) a basic library of standards in electronic format; (iii) a facilitated adoption procedure; (iv) the potential for participation in one of the three IEC conformity assessment schemes. He noted that there was no participation fee. The leader of the Affiliate Country Programme, Mr. Mesai Girma, the Director General of the Quality and Standards Authority of Ethiopia, had been active in representing the collective voice of the Affiliates in the IEC management bodies, and had been able to secure the commitment for assistance from the IEC schemes to provide a dedicated guidance document aimed at helping the Affiliates understand better how to use and participate in the IEC's global conformity assessment schemes. Currently, 67 countries were participating in the Programme; an Affiliate country had become a full IEC Member (currently 63 members). Countries were starting to adopt IEC international standards, either using the catalogue notification processes as specified in the ISO/IEC Guide 21 or making use of the facilitating process established to support the Affiliate Country Programme, which facilitated republication of the IEC International Standards as National Standards. The IEC had also started to receive the first comments from Affiliates on standards under development.

151. The representative of the <u>OIML</u> informed the Committee that the OIML had held, in conjunction with its 12<sup>th</sup> International Legal Metrology Conference, a Forum called "Metrology - Trade Facilitator". The aim of the new event was to find out the needs of developing countries in terms of metrology and to analyse what was available from national, regional or international donors in this field. The event also emphasized the importance of metrology as a part of a package of measures which formed the technical structure to conformity assessment. The Forum was attended by both Members and non-Members of the OIML, and took the format of round table discussions. He noted that from the beginning of November 2004, all OIML publications were available free of charge

on the OIML website in electronic format, and that paper versions of these documents would no longer be produced.

152. The representative of the <u>ITC</u> drew the Committee's attention to two recent national workshops on the TBT Agreement, which had been conducted in Bishkek, Kyrgyz Republic, on 21-22 October 2004 and in Dushanbe, Tajikistan, on 25-26 October, respectively. He explained that these workshops were aimed at a better preparation by the business sector to trade successfully under the terms of the TBT Agreement and at a better understanding of the potential benefits associated with its implementation. The objective was to facilitate a more effective national strategy in the multilateral trading system, through a better private sector participation in the formulation of national trade policy, in particular in the field of standards, technical regulations and conformity assessment procedures. These workshops were funded by SECO (the State Secretariat for Economic Affairs of Switzerland).

153. The representative of Japan thanked the representatives from the ISO and the IEC for their update. He appreciated the five year action plan of the ISO and the existing IEC efforts for the participation of developing countries to ISO and IEC community. He believed that the Affiliate Country Progamme was helpful in enabling developing countries to take an active part in the development process of international standards, and also in encouraging them to use international standards in their technical regulation field. He stressed the importance of developing countries' active involvement in the international standard developing process, as it would also help them to implement the TBT Agreement.

154. The representative of the <u>Secretariat</u> reported on the five categories of TBT–related technical assistance activities that the Secretariat had been engaged in 2004, and foreseen for 2005.<sup>18</sup> She recalled that the purpose of the Secretariat's technical assistance activities was to assist beneficiary countries in their understanding of the main disciplines and rules of the TBT Agreement, and also to update capital-based officials on the issues currently taken up in the TBT Committee. The programs and presentations for these activities were constructed to meet and respond to national or regional interests including any specific trade concerns. They were adapted to take into account the level of awareness of the participants.

155. The Secretariat stressed communication of information from Members themselves was an invaluable input to workshops and efforts were made to ensure that participants discussed cases based on country experiences. In 2004, the substance of the workshop programs had been enhanced by the presentation made by TBT Members themselves. The representative of the Secretariat thanked Mrs. Danielle Shonte Avenel from Mexico, Mrs. Annalina Comboim from Brazil, Mr. George Opoyo from Uganda and Mr. N'dungu Evanson from Kenya – who had also served as panellists at the Special Meeting on Procedures for Information Exchange – for their inputs and presentations at the regional workshops for Central and Latin America, and for East Africa and other COMESA Members, respectively.

156. Looking ahead, in 2005 the intention was to give weight to some of the other issues arising from the Third Triennial Review, for instance on the work programme on conformity assessment procedures. As for the mode of delivery, in scheduling the workshops, coordination was sought with the SPS team in the Secretariat, to organize TBT events back-to-back with SPS ones, especially in national workshops. The Secretariat would organize, where possible, national workshops back to back with regional ones.<sup>19</sup> The 2005 technical assistance activities were still subject to formal approval by the Committee on Trade and Development of the 2005 Technical Assistance and Training Plan.<sup>20</sup>

<sup>&</sup>lt;sup>18</sup> This information will be included in the Annual Review to be issued ahead of the next TBT Committee meeting.

<sup>&</sup>lt;sup>19</sup> The TBT web page on technical assistance included information on the Secretariat's past and future TA activities.

<sup>&</sup>lt;sup>20</sup> Subsequently adopted and circulated as WT/COMTD/W/133/Rev.2 on 16 December 2004.

### V. OBSERVERS

### A. REQUESTS FOR OBSERVER STATUS

157. On the issue of requests for observer status, the <u>Chairman</u> drew the Committee's attention to document G/TBT/GEN/2, which set out the situation with respect to observership by intergovernmental organizations in the 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

158. The representative of <u>Codex</u> explained that, in addition to the summary of the recent Codex activities presented in G/TBT/GEN/12, more information, especially on the results on the  $27^{\text{th}}$  session of the Codex Alimentarius Commission could be obtained on the website of the Codex.<sup>21</sup>

The representative of UNCTAD informed the Committee that, in the context of the UK -159. DFID funded project on "Building Capacity for Improving Policy Making and Negotiations on Key Trade and Environment issues", UNCTAD had organized a technical meeting in Costa Rica on 17-18 August 2004, to discuss progress on draft case studies on environmental requirements and their impact on exports of selected agricultural products in 8 countries in Central America. Cuba and the Dominican Republic. These studies would be discussed in a regional workshop scheduled to take place at the beginning of 2005. A sub-regional workshop on environmental requirements, market access and export competiveness for the agricultural sector had been held in Thailand, from 29 September to 1 October 2004. The discussions had taken place in the form of case studies prepared by national experts from participating countries, and the EUROPGAP Secretariat was among the private sector representatives. The sub-regional workshop had then been followed by a national training workshop on the same subject for Bangladesh on 4-5 October 2004. These Workshops articulated concerns on the treatment of tropical fruit and vegetables in recent and upcoming pesticides regulations on maximum residue levels in various developed countries. Recommendations had been made that interested developing countries might develop national or sub-regional codes of good agricultural practice for agriculture exports that were benchmarked to key codes in export markets, such as EUROPEGAP.

160. On 28-29 October, the Foundation for International Environmental Law and Development (FIELD), in cooperation with the UNCTAD Secretariat, had held a workshop on consultative processes and impact assessment related to the proposed EC Regulation "REACH", involving experts from the European Commission, European industry, NGO's and the key chemical exporting developing countries, including Brazil, China, Costa Rica, India, the Philippines, and Thailand. He explained that a large number of experts from various Directorates of the European Commission had provided clarification of actual or potential impact of REACH on developing country exports of chemicals and downstream products. The meeting had also provided an opportunity to exchange views on developing countries' concerns on the registration and evaluation requirements of REACH.

161. He informed the Committee that the first substantive meeting of UNCTAD's Consultative Task Force on Environmental Requirements and Market Access would take place on 5-6 November 2004. Finally, he informed Members that the third meeting of the joint UNCTAD/ FAO/IFOAM International Task Force on Harmonization and Equivalence in Organic Agriculture was scheduled to take place in Rome, from 17-19 November.

<sup>&</sup>lt;sup>21</sup> The report of this meeting is contained in the Codex document ALINORM 04/27/41.

162. The representative of the <u>United States</u> recalled that, at the last meeting, UNCTAD had circulated a paper on the meeting held in Rio de Janeiro, and since then a more detailed report had been obtained. She noticed that the meeting had also included private sector participation, and she thought that there seemed to be some confusion and potential misunderstanding with respect to the coverage of the TBT Agreement, for example on the definitions of standards and technical regulations, on the publication of drafts versus publication of work programs and on the role of enquiry points. She encouraged coordination between the participants in UNCTAD work and government representatives in the TBT Committee.

### VI. ANNUAL TRANSITIONAL REVIEW (TRM) MANDATED IN PARAGRAPH 18 OF THE PROTOCOL OF ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA

163. The <u>Chairman</u> recalled that Paragraph 18 of the Protocol of Accession of the People's Republic of China (WT/L/432) put in place a "Transitional Review Mechanism". Accordingly, he drew attention to documents by the European Communities (G/TBT/W/242), Japan (G/TBT/W/243) and the United States (G/TBT/W/245) containing questions put to China in this respect. He also noted that China had submitted a paper providing information relating to Annex 1A of its Protocol of Accession (G/TBT/W/246).

164. The representative of the <u>People's Republic of China</u> stressed that enormous efforts and substantial progress had been made by his country with respect to the notification of TBT measures and regulations. He pointed out that 18 TBT notifications had been made to the Committee in 2004. With regard to some of the notifications where it had been claimed that they did not provide enough time for public comments, he emphasized that these measures were notified as emergency measures. He stressed that with many WTO Members, including China, the regulation and administration of the TBT-related measures involved many different government authorities and that, in addition, TBT measures were highly technical. According to the statistics of TBT notifications collected by China, there was still much room for improvement in some developed country Members of WTO.

165. With regard to China's national standardization and regulatory system, he explained that foreign enterprises and joint ventures were increasingly participating in the standards-setting process. He noted that under the "CCC" Certification Scheme, after the issuance of a new or revised national standard, the Chinese government revised the relevant implementation rules of certification in a timely manner and allowed a certain transitional period for the products meeting the existing national standards. China's Law on Standardization stipulated the adoption of international standards. Besides the standards of ISO, IEC and ITU, China had preliminarily recognized standards developed by 40 international organizations as international standards. A large number of standards developed by regional standardization organizations and other developed countries had also been adopted.

166. He emphasized that, in terms of the "CCC" Certification Scheme, pursuant to paragraph 192 of the Working Party Report of China's accession, China would not maintain multiple or duplicative conformity assessment procedures, nor would it impose requirements exclusively on imported products. In this regard, the Chinese government had taken steps to eliminate the old double conformity assessment requirements, i.e. the CCIB Safety Mark and the "Great Wall" Mark, which were unified into the single "CCC" Certification Scheme. He added that, in accordance with paragraph 196(b) of the Working Party Report, China's current "CCC" certification procedures could be finished within 3 months. He noted that the list of products subject to the "CCC" Certification Scheme had been determined on the basis of risk assessment. With the upgrading of product technology and improvement of the industrial manufacturing capacity, there might be some adjustments in the products list in accordance to the risk situation.

167. He further recalled that the Provisions on the Environmental Administration of New Chemical Substances of China had been enforced on 15 October 2004, in compliance with paragraph 196(a) of the Working Party Report. China had issued administrative instructions thereafter. He

explained that the chemicals listed in the "inventory chemicals" annexed to the above new law were exempted from the registration obligation. Furthermore, a uniform application and registration procedure applied to both domestic and imported chemicals. The rules and procedures of the applications on the new chemical substances were available on the website of the Chemicals Registration Center of the State Environmental Protection Administration (SEPA).<sup>22</sup> He stressed that China was ready to pursue a bilateral dialogue with WTO Members.

168. The representative of the <u>United States</u> appreciated China's efforts to implement the TBT Agreement. She noted that her delegation's submission (G/TBT/W/245) contained a number of general and specific questions on the operation of the Chinese system. She believed that useful information had been obtained in China's presentation on the operation of its enquiry point and domestic coordination mechanisms, given at the Special Meeting on Procedures for Information Exchange, and welcomed the increased use of websites for the provision of information. She recalled that discussion had taken place on China's evolving conformity assessment procedures and clarification had been provided on some changes in the catalogue of products subject to compulsory certification. China had also provided detailed information in response to specific questions on scrap recycling regulations, distilled spirits, chemicals, radio frequency identification, and cosmetics.

169. The representative of the <u>European Communities</u> thanked China for their statement and recalled that there were five areas of priority for his delegation: the "CCC" system, automobiles, cosmetics, pharmaceuticals and foodstuff. On the CCC system, the main concerns related to the list of products subject to certification, fees and double certification. On automobiles, the main issues was related to the design, adoption and implementation of standards and the notification, adoption and implementation of technical regulations. In the cosmetic area, his concerns related to the registration and labelling of cosmetic products, and on BSE issues. On pharmaceuticals, the main concern was related to active pharmaceutical ingredients, requirements, registration and transparency. Finally, on foodstuffs, the European Communities was concerned about the labelling standards for wine and spirits. He noted that bilateral discussions were ongoing and looked forward to a continuing dialogue.

170. The representative of <u>Japan</u> appreciated China's efforts to make its regulatory system more transparent and efficient. His delegation still had concerns in some areas, for instance: in respect of the implementation of the CCC marking system; in the electric devices area; and in the areas of automobiles, digital camera and chemical products. He asked China to take these concerns into consideration.

171. The representative of <u>China</u> clarified that, regarding the concerns expressed on automobiles, China would fulfil its WTO obligations and publish a notice on the corresponding technical regulations, notify them and allow reasonable time for comments. On the "CCC" certification scheme for electrical products, he explained the procedure could be finished within the specified time of three months. He noted that, according to the international practice, mutual recognition of mandatory certification testing results, were based on bilateral or multilateral agreements, between governments or between bodies recognized by governments. China supported mutual recognition of certification testing results, on the basis of equivalence, in order to avoid technical barriers arising from redundant testing and certification. He recalled that China was a Member of the IECEE Scheme, therefore the CB certificates issued by the Members of the IECEE Scheme were recognized under the CCC system. Moreover, under the CCC scheme, after the insurance of the newly formulated or revised national standard, the Certification and Accreditation Administration of the People's Republic of China (CNCA) would revise the relevant implementation rules of certification in a timely manner, and make them known to the public allowing a certain transitional period for products to comply.

<sup>&</sup>lt;sup>22</sup> www.crc-sepa.org.cn.

172. The Committee <u>adopted</u> its 2004 Report to be submitted to the Council for Trade in Goods on the Transitional Review mandated in China's Protocol of Accession.<sup>23</sup>

# VII. REPORT (2004) OF THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE

173. The Committee <u>adopted</u> its 2004 Report to the Council for Trade in Goods.<sup>24</sup>

### VIII. DATE OF NEXT MEETING

174. The <u>Chairman</u> announced that the next regular meeting of the Committee would take place on 22 and 23 March 2005, and would be preceded, on 21 March, by the Workshop on Supplier's Declaration of Conformity (SDoC).

<sup>&</sup>lt;sup>23</sup> Subsequently circulated as G/TBT/W/249, 8 November 2004.

<sup>&</sup>lt;sup>24</sup> Subsequently circulated as G/L/710, 8 November 2004.

# ANNEX 1:

### 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.

Dates / Time Frame	Proposed Action
Identification phase	
mid-February 2005	Preliminary identification of topics for review by delegations
2-3 March 2005 Meeting	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
22-23 June 2005 Meeting	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
1-3 November 2005 Meeting	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

#### Work Programme for the Fourth Triennial Review

#### ANNEX 2:

#### SUMMARY REPORT OF THE FOURTH SPECIAL MEETING ON PROCEDURES FOR INFORMATION EXCHANGE

11. The "Fourth Special Meeting on Procedures for Information Exchange", held in Geneva on 2-3 November 2004, aimed at discussing at a technical level the activities and concerns of the TBT Agreement, in particular with regard to the functioning of notification procedures and enquiry points.<sup>25</sup> It provided a forum for Members to exchange experiences regarding the implementation of transparency provisions of the TBT Agreement.<sup>26</sup> Panel sessions addressed seven topics: (i) prior to notifications; (ii) preparation and submission of notifications; (iii) processing and circulation of notifications; (iv) handling of comments; (v) transparency obligations under the Code of Good Practice; (vi) the functioning of enquiry points; and (vii) benefiting from transparency provisions through dissemination of information. The following is a summary of the various experiences presented, including any additional information provided during the discussions.<sup>27</sup>

A. PRIOR TO NOTIFICATIONS

### 1. The Chilean National Commission on TBT<sup>28</sup>

12. The representative of <u>Chile</u> indicated that coordination among regulatory bodies was considered a determining factor to ensure that relevant protection levels were achieved by the standards set and that regulatory interventions did not distort market performance. For that purpose, Chile created in 1997 a National Commission on TBT. The Commission was comprised of representatives of the different ministries that developed, adopted and applied technical regulations, their respective agencies and officials from the Foreign Affairs Ministry and the National Standardization Institute. The task of the Commission was to coordinate and thus provide consistency to the work of the various institutions involved with the drafting of technical regulations and conformity assessment procedures.

13. Responsibilities of the National TBT Commission included: Reviewing and analyzing standardization, regulation and conformity assessment systems; providing periodic updates on WTO/TBT activities; analysing WTO-related issues that required a national position; taking measures to strengthen market surveillance; reviewing the public availability of national technical regulations; and identifying capacity building requirements. Examples of topics discussed by the Commission in order to come to a national position were: eco-labelling, the Cartagena Protocol and the REACH system.

14. The National TBT Commission worked on a Decree implementing Law 19.912. The scope of the Law, and therefore the Decree, related to the principles of the TBT Agreement and good regulatory practices. This included the use of international standards, non-discrimination, the avoidance of unnecessary barriers to trade and transparency. The Decree put in place a system of public consultations with a period of no less than 60 days for comment and required regulatory agencies to make relevant information available to the public. The Decree contributed to enhancing the various agencies' awareness of the benefits of having clear and uniform rules on how technical regulations and conformity assessment procedures should be developed, adopted and applied.

15. In order to improve public availability of technical regulations, a new website containing all Chilean technical regulations would be established under the coordination of the Ministry of Economy

<sup>&</sup>lt;sup>25</sup> The programme of the meeting is contained in document G/TBT/GEN/13.

<sup>&</sup>lt;sup>26</sup> See "Transparency Requirements and Procedures", Note by the Secretariat, to be issued.

<sup>&</sup>lt;sup>27</sup>All slideshows presented during the Special Meeting are available at

http://www.wto.org/english/tratop\_e/tbt\_e/meeting\_nov04\_e/info\_exchange\_nov04\_prog\_e.htm

<sup>&</sup>lt;sup>28</sup> Presentation made by Mrs. Ana María Vallina, Head of the Foreign Trade Department, Ministry of the Economy, Chile.

and with the participation of all agencies involved in the National TBT Commission (this website would be financed in the context of an EU cooperation programme). To improve the general understanding of the TBT Agreement, the Chilean National Commission planned to organize training of regulatory agencies and the business sector. The Commission also intended to increase the knowledge of consumers on technical regulations.

#### 2. The "Notice and Comment" Procedure in the United States<sup>29</sup>

16. The representative of <u>United States</u> noted that for the development of new technical regulations, US federal regulatory agencies worked together with interested parties. The Administrative Procedures Act was the key law governing the US regulatory process under which federal agencies created the regulations needed to implement governmental legislation. It ensured transparency in the establishment of new regulations, providing for the participation of interested parties in the process and ensuring that agencies met the same obligations for all regulations. As defined by the Administrative Procedures Act, the US process for developing regulations involved three steps, known as the "Notice and Comment" procedure.

17. First, a notice of the proposed regulation was published in the US *Federal Register* as a "notice of proposed rulemaking". This notice signalled to the public a new regulation, described the regulation in detail (including information on a cost-benefit analysis of alternative solutions, risk assessments and impact statements) and solicited public comments. Second, within a period of 60 days (maximum 90 days), all interested domestic and foreign parties could submit comments, which were all equally considered. Public comments enhanced the agency's knowledge of general and specific technical information on the proposed regulation and allowed it to take corrective action, if necessary. Decision-makers needed to take into consideration all the substantive views expressed before the issuance of a final regulation. In case of significant differences of opinion, the agency would allow a second opportunity for public comments. Third, after the consideration of all comments, the final rule was issued, including information on how comments had been addressed.

18. The "notice and comment" procedure for all new technical regulations could be tracked at the federal level in a daily publication, the US *Federal Register*. To be able to notify final rules to the WTO, the US enquiry point depended on regulatory agencies to alert it. To track regulations at the sub-federal level, the US enquiry point used an electronic tool, *RegAlert*, which allowed it to monitor all fifty States for changes in technical regulations and conformity assessment procedures. A new website<sup>30</sup> further contributed to the transparency and accountability of the US regulatory system. It was used as a portal where comments on regulations were submitted online.

#### B. PREPARATION AND SUBMISSION OF NOTIFICATIONS

#### 1. The Experience of Canada: the Standards Council and *Export Alert*!<sup>31</sup>

19. The representative of <u>Canada</u> said that International Trade Canada (ITCan) retained overall responsibility for the coordination and implementation of all the WTO Agreements. Since January 1980, ITCan contracted the operation of the national notification authority and the national enquiry point to the Standards Council of Canada (SCC).<sup>32</sup> Canada's experience showed that combining the two entities into one office allowed for a better and more rapid coordination. SCC was responsible for fulfilling the transparency obligations of the TBT, SPS and NAFTA Agreements, distributing WTO notifications, answering enquiries and providing information to foreign enquiry points on Canadian standards, technical regulations and conformity assessment procedures. While notification

<sup>&</sup>lt;sup>29</sup> Presentation made by Ms. Anne Meininger, U.S. Enquiry Point, National Institute for Standards and Technology.

<sup>&</sup>lt;sup>30</sup> See <u>http://www.regulations.gov</u>.

<sup>&</sup>lt;sup>31</sup>Presentation made by Ms. Andrea Spencer, Coordinator of the Canadian WTO/NAFTA Enquiry Point.

<sup>&</sup>lt;sup>32</sup> See <u>http://www.scc.ca</u>.

activities fell under the jurisdiction of the enquiry point, the response to technical enquiries was handled by the Information and Research Service.

20. At the federal level, proposed measures were published in the *Canada Gazette*. To ensure proper consultation among the Canadian public, regulators were required to provide, along with the proposed regulation, a Regulatory Impact Analysis Statement (RIAS), which included a description of the regulation as well as an analysis of alternatives, costs, and benefits. Regulators were also required to provide a comment period of at least 75 days for regulations that affected trade. The SCC reviewed the proposed regulations to determine whether they should be notified. Sub-national regulations were published on different schedules in their respective provincial gazettes, which were also reviewed regularly to identify the regulations that had to be notified. Sub-national notifications continued to be a challenge for Canada, because many provinces only published their regulations once adopted.

21. Canada notified technical regulations and conformity assessment procedures at the draft stage. Once completed, the notification format was sent to the WTO CRN (Central Registry of Notification), with copies to the Canadian authorities and NAFTA counterparts. Since Canada started to include, in July 2000, the URL to the regulation in the notification format, the number of requests for regulatory texts from foreign enquiry points had decreased. Canada believed that this type of instant coordination and cooperation ensured that all stakeholders had the same information and opportunity to provide comments. Every three years, Canada organized a workshop for regulators on the TBT Agreement during which an emphasis was put on the need to share comments with the enquiry point because often comments were sent directly to regulators without going through the enquiry point.

22. In order to filter the information contained in notifications received, the Standards Council of Canada developed a system known as *Export Alert*!.<sup>33</sup> *Export Alert*! was a web-based application free of charge to Canadians used to disseminate WTO notifications to a variety of stakeholders ranging from industry, regulatory agencies and standards development organizations to academia. The service helped companies keep abreast of regulatory changes in global markets before they became law and provided input on measures that might affect their trading activities. Canada had launched a second version of *Export Alert*!, which currently enabled users to: Track regulatory developments in selected countries, in addition to subject areas; request regulatory texts more easily; and receive HTML e-mail notifications. The SCC developed a Spanish version of *Export Alert*! to help Latin American countries disseminate WTO notifications to national stakeholders. Bolivia would be the first country to use the service.

# 2. The Notification Procedure of the Trinidad and Tobago Bureau of Standards<sup>34</sup>

23. The representative of <u>Trinidad and Tobago</u> noted that the Trinidad and Tobago Bureau of Standards (TTBS), the national enquiry point since 1996, complied with its notification obligations under the TBT Agreement by sending notifications on standards proposed for compulsory status to the WTO. Voluntary standards were adopted by the TTBS board and compulsory standards (equivalent to technical regulations) by the Ministry responsible for Trade and Industry after recommendation by the committee responsible for the development of the standard. The notification process at TTBS began when its Standardization Division sent a notice of a draft standard for public comment. Draft standards were advertised for public comment in local daily newspapers. The enquiry point checked whether the standard was compulsory and if so extracted the information necessary to complete the WTO notification format. The completed form was then forwarded by e-mail to the Ministry of Trade and Industry (notification authority).

<sup>&</sup>lt;sup>33</sup> To register at *Export Alert!*, a profile indicating areas and countries of interest must be filled in on <u>www.scc.ca</u>.

<sup>&</sup>lt;sup>34</sup> Presentation made by Mrs. Devitra Maharaj-Dash, Head of the Standards Information Centre of the Trinidad & Tobago Bureau of Standards (TTBS).

24. At the enquiry point, the notification procedure took between one and two days after the advertisement for public comment had been made. TTBS was developing a new website where draft standards would be available online with an open forum for comments. Due to the number of steps that were necessary before the notification reached the WTO, the enquiry point used a variety of available technological tools to speed up the process. Notifications were checked at the Ministry of Trade and Industry and then forwarded to the Trinidad and Tobago Mission in Geneva via e-mail, which sent it to the WTO CRN. The Ministry also sent to the mission the original documents for information.

25. Food, Drugs and Cosmetics Regulations were handled by the Chemistry, Food and Drugs Division. While there was a well established relationship between this Division and TTBS, different procedures existed in the two agencies with regard to how regulations were handled. After internal consultations, it had been agreed that regulations, before being sent to the Ministry of Legal Affairs, would be notified through the enquiry point for comment. Also, measures were being implemented to ensure that existing technical regulations would be made available on the new TTBS website.

### 3. The Notification Procedure of the Thai Industrial Standards Institute <sup>35</sup>

26. The representative of <u>Thailand</u> said that in 1995, the Thai Industrial Standards Institute (TISI) had been appointed as the single national enquiry point for both the TBT and SPS Agreements. Following reforms in 2002, two separate national enquiry points were established: TISI, for all industrial products; and the National Bureau of Agricultural Commodities and Food Standards, for food and agricultural products. To ensure the fulfilment of the notification obligations, coordination with relevant regulatory bodies was ensured through the establishment of national committees. These committees included representatives from relevant government organizations and the private sector. To ensure effective coordination, representatives from the two national enquiry points were represented in each other's TBT and SPS national committees.

27. TISI remained informed about new technical regulations by monitoring the cabinet website, receiving advice from regulatory bodies and checking information through the media. Regulatory bodies were reminded of their obligation to notify every three months. In case TISI had doubts on whether or not to notify, it would always notify. Once filled-in, the notification was sent to the WTO Permanent Mission which in turn submitted it to the WTO CRN.

28. Thailand's notification procedure had six steps: (i) check for new or proposed measures; (ii) assess if a notification was required; (iii) decide whether it had to be notified under the TBT Agreement and/or the SPS Agreement; (iv) decide whom to notify; (v) complete the notification form; and, (vi) submit it to the WTO. Thailand encountered certain specific difficulties: insufficient awareness of the notification obligations at the operational level; problems in distinguishing between TBT or SPS notifications; incomplete notification forms; delay in translating technical regulations into English, due to budgetary constraints; and occasionally late notification of regulations.

#### C. PROCESSING AND CIRCULATION OF NOTIFICATIONS

#### 1. The Processing of Notifications by the WTO Secretariat<sup>36</sup>

29. The representative of the <u>Secretariat</u> indicated that three instances were involved in the internal processing of a TBT notification once it had reached the WTO: (i) the Central Registry of Notifications (CRN); (ii) the Trade and Environment Division; and (iii) the Document Management System (DMS). The lifecycle of a TBT notification began when a Member sent a notification to the

<sup>&</sup>lt;sup>35</sup> Presentation made by Mrs. Rampaipan Nakasatis, Director of the Standards Bureau of the Thai Industrial Standards Institute (TISI). <sup>36</sup> Presentation made by Mrs. Stafanic Pernekà WTO Secretariet Trade and Environment Division

<sup>&</sup>lt;sup>36</sup> Presentation made by Mrs. Stefania Bernabè, WTO Secretariat, Trade and Environment Division.

CRN, by post, fax or e-mail. Then, the notification was put on a file, given a record number and forwarded to the Trade and Environment Division. It was important that notifications be sent via e-mail as otherwise they had to be retyped by the Secretariat.

30. Once the notification had reached the Trade and Environment Division, it was checked, and when necessary, clarification was requested. If a notification contained SPS elements, the Trade and Environment Division asked the Agriculture and Commodities Division to check whether it had received the same notification. If this was not the case, the Trade and Environment Division contacted the notifying Member to draw its attention to the fact that the notification contained SPS elements. It was then up to the Member to decide whether to notify the measure under TBT, SPS or both Agreements.

31. Once checked, the notification was transmitted to the DMS, which automatically sent it for translation. Once the notification was attributed a number, it was circulated to the permanent missions in Geneva (in paper copy) and posted on the WTO website. An automated weekly e-mail distribution had been set up to facilitate Members' access to notifications.<sup>37</sup> Normally, the internal processing of notifications by the Secretariat took two working days.

#### 2. How to Use the WTO Website and the CRN Database?<sup>38</sup>

32. The representative of the <u>Secretariat</u> said that there were two ways to access notifications on the WTO website: the traditional way through "Documents Online"; and through the CRN search interface. To begin a search in "Documents Online", one could go to the "Advanced Search"<sup>39</sup> interface of "Documents Online" and fill in some basic fields (e.g. "G/TBT/..." for TBT documents). The search could be restricted by type (e.g. "notification"), by date or by Member. If one searched by Member, both documents submitted by that Member or which included that Member's name would appear. The search could be also restricted by entering text in the "full text" field and only those notifications containing those words would be retrieved.

33. The CRN search interface permitted the retrieval of notifications using specific data fields of the CRN database. The search mechanism operated in the same way as the standard search interface of "Documents Online" on the public WTO website. The difference was that it included a search by trade coverage of notifications and a search by the requirement under which they were submitted.

34. In both systems, retrieved documents were presented in the standard display format of "Documents Online" and could be consulted directly on-screen or downloaded to a local computer. Documents could be downloaded and saved by clicking on the right mouse button. To download a series of documents, one could use the "download" feature which appeared at the top of the page.

#### D. HANDLING OF COMMENTS

# 1. The Experience of the TBT Enquiry Point of the European Communities and its TBT Website<sup>40</sup>

35. The representative of the <u>European Communities</u> noted that the role of the TBT enquiry point, managed by the European Commission, was, *inter alia*, to: (i) analyse, with the help of companies, the regulations notified; (ii) coordinate the issuing of comments; (iii) transmit EC notifications to the WTO Secretariat; (iv) ensure the follow-up of comments received by the European Communities; and (v) answer requests for information about notified projects. Once or twice a year, the

<sup>&</sup>lt;sup>37</sup> <u>http://www.wto.org/english/tratop\_e/tbt\_e/tbt\_mailing\_list\_e.htm</u>.

<sup>&</sup>lt;sup>38</sup> Presentation made by Mr. John Dickson, WTO Secretariat, Documents System Section.

<sup>&</sup>lt;sup>39</sup> http://docsonline.wto.org/gen\_search.asp?searchmode=advanced.

<sup>&</sup>lt;sup>40</sup> Presentation made by Mr. Cyril Hanquez, European Commission, Directorate General Enterprise.

European Commission held meetings of notification authorities of EC members States in order to discuss the implementation of the TBT Agreement.

36. To enhance the participation of economic operators and to ensure the highest level of transparency vis-à-vis WTO Members, the European Communities launched in June 2004 a TBT website.<sup>41</sup> Available in the three WTO languages, it provided: (i) information on the TBT Agreement and on the objective and scope of TBT notification procedures; (ii) a list of all national enquiry points and notification authorities (WTO Members were encouraged to send their respective websites); (iii) a compilation of notifications of WTO Members which had led to comments by the European Communities and EC notifications which had led to comments by WTO Members; and (iv) a search facility of the EC database for notifications. The EC/TBT website also offered a mailing list service for subscribers to be informed via e-mail of new notifications made.

37. Notifications coming from one of the 25 member States were available in all the 20 official languages. The European Communities hoped that the practice of making draft texts available and indicating in the notification a link to the PDF version would be followed by other Members. If the European Commission, a member State or an economic actor showed an interest in a particular notification by a WTO Member, the EC/TBT enquiry point verified the time delay for the submission of comments and, if necessary, requested an extension. If a service of the European Commission wished to comment, an internal procedure of consultation of the relevant services of the Commission and possibly the national member State authorities was put in place. Once finalized, the comments were sent to the WTO Member concerned and published on the EC/TBT website.

38. In case of comments on a notified EC text, the European Communities took the comments into account and made every effort not to adopt the text before having replied to the comments. The response, drafted by the relevant services of the Commission, was sent to the TBT enquiry point of the WTO Member concerned. With regard to notifications by one of the 25 member States, the Commission wrote the final answer together with the member State concerned and sent it in the name of the European Communities. As the European Communities had an exclusive competence in the area of common commercial policy, a member State notifying a draft regulation directly to the WTO Secretariat had to inform the European Commission of the comments received on its national draft.

E. TRANSPARENCY OBLIGATIONS UNDER THE CODE OF GOOD PRACTICE

#### 1. The Malaysian Standards Infrastructure<sup>42</sup>

39. The representative of <u>Malaysia</u> said that the Malaysian standards system was made up of two institutions: (i) the SIRIM Berhad, and (ii) the Department of Standards Malaysia (DSM). DSM appointed SIRIM Berhad as the sole standards development agency. DSM was responsible for all policy matters with regard to standardization and also operated the national accreditation program for operating laboratories and certification bodies. SIRIM Berhad had operational responsibility, organized Malaysian representation in regional and international standards bodies, published, printed, sold and distributed Malaysian Standards.

40. In 1996, DSM notified its acceptance of the TBT Code of Good Practice to the ISO/IEC Information Centre. As the officially recognized national standardizing body in Malaysia, DSM's role was to ensure that the national standards system was in compliance with the Code. The Standards Malaysia Act required the publication of all approvals and withdrawals of standards in the government gazette and included mandatory provisions for providing opportunities to comment

<sup>&</sup>lt;sup>41</sup> <u>http://europa.eu.int/comm/enterprise/tbt/</u>.

<sup>&</sup>lt;sup>42</sup> Presentation made by Ms. Salmah Mohd Nordin, Senior Standards Executive of the Standards Management Department of Malaysia.

before the adoption of standards. To ensure that the development of standards was in compliance with the Code of Good Practice, a "Quality Manual by Operating Procedures and Work Instructions" had been established describing the various processes, e.g.: Process for obtaining public comments; process for the publication of standards; and process of harmonization with international standards.

41. Public comment was one of the most important and critical stages in the development of Malaysian standards. All draft standards were issued for public comment by announcement in national newspapers and published on SIRIM Berhad's website for a comment period of sixty days, where they could be downloaded free of charge.<sup>43</sup> Draft Malaysian Standards which followed the exact content of international standards were, however, not placed on the website due to copyright restrictions, but available at a charge upon request.

42. All interested parties had the possibility of participating in the standards development process, through sectoral or technical committees, working groups, or through the public comment process. Procedures were in place to provide for balanced representation of all stakeholders in the various committees. The obligations contained in Paragraph J of the Code of Good Practice were fulfilled by publishing the work programme twice a year in the *Standards and Quality News*. Additionally, the approval of new projects and the withdrawal of standards was announced in national newspapers and on websites on a regular basis. Pursuant to Paragraph K of the Code of Good Practice, DSM was a national member of ISONET and SIRIM Berhad an Associate Member of ISONET.

43. With regard to the harmonization provisions contained in the Code of Good Practice, Malaysia had implemented a policy of adopting the most relevant parts of international standards as a basis for the development of Malaysian standards. Both at the national and regional level (e.g. APEC), there were initiatives to align standards with international standards. Malaysia had undertaken numerous actions to increase its participation in international standardization: Promotional and educational events on the benefits of participating in international standardization had been held, and international standards meetings hosted.

# 2. The Activities of the ISO/IEC Information Centre<sup>44</sup>

44. The representative of <u>ISO</u> noted that the objective of the Information Centre, jointly operated by the International Organization for Standardisation (ISO) and the International Electro-technical Commission (IEC), was to provide stakeholders with information on standards, standardization, and related matters. Linked to the ISO/IEC Information Centre, there were websites and activities related to the World Standards Services Network (WSSN)<sup>45</sup> and to international standards organizations. ISO also operated the information network ISONET, which was monitored by the ISO Central Secretariat. The ISO/IEC Information Centre also served as an information office on draft standards.

45. The ISO/IEC Information Centre provided four types of services: an ISO/IEC information website (opened in November 2004);<sup>46</sup> answers to enquiries; information to the WTO Secretariat; and maintenance of a library of ISO and IEC publications. The ISO/IEC website contained information on standardisation and conformity assessment, the TBT Agreement, the TBT Standards Code Directory, which was updated annually, other standards publications, general vocabulary on standardization and general classification of standards widely used. The website also contained an enquiry service where questions could be posted, which were, depending on the scope of the enquiry, directed to IEC, ISO or other standardizing bodies. The enquiry service was provided by the IEC customer information centre and ISO information services, in accordance with their respective areas of competence.

<sup>&</sup>lt;sup>43</sup> <u>http://www.sirim.my/std\_dev/public\_comment\_page.htm</u>.

<sup>&</sup>lt;sup>44</sup> Presentation made by Mr. Evgueni Patrikeev, Director of ISO information services.

<sup>45</sup> http://www.wssn.net/WSSN/index.html.

<sup>&</sup>lt;sup>46</sup> <u>http://www.standardsinfo.net</u>.

46. The information services provided to the WTO included the registration of notifications received from standardizing bodies, e.g. on the acceptance of the Code of Good Practice and the existence of work programs. ISO/IEC also published, once a year, the WTO TBT Standards Code Directory with updated information on the acceptance of the Code of Good Practice; it was normally circulated to all Members every year at the first meeting of the TBT Committee. The Information Centre's library, which was mainly used by students and experts from Small and Medium-Sized Enterprises (SMEs), was a useful resource containing the wide range of ISO and IEC publications.

#### F. THE FUNCTIONING OF ENQUIRY POINTS

# 1. The Functioning of the Brazilian Enquiry Point and the Services Developed to Assist Exporters<sup>47</sup>

47. The representative of <u>Brazil</u> said that to promote the implementation of the TBT Agreement, Brazil remodelled the activities of the enquiry point and notification authority under the responsibility of the National Institute of Metrology, Standardization and Industrial Quality (INMETRO). In order to help Brazilian exporters overcome technical barriers to trade, INMETRO launched in March 2002 a new online service. Brazilian exporters used this to contact the enquiry point directly and access all information on technical regulations, as provided by WTO Members, before they entered into force. This service was free of charge and could be accessed through the INMETRO website.<sup>48</sup>

48. INMETRO also carried out a series of workshops to promote exporters' awareness of the importance of participating in the notification process. In order to provide Brazilian exporters with a fast access to technical regulations and conformity assessment procedures in force, it was decided to launch one more service: a list of technical regulations in force by country and product available on INMETRO's website.

49. *AlertaExportador*, implemented with the assistance of the Canadian enquiry point SCC, set up an automatic early notice of proposed technical requirements to provide companies with the opportunity to adapt their products before the relevant requirements were in force and to thus prevent delays in the delivery of goods. Once registered online, exporters received an automated e-mail every time the database was updated with a new proposal by a WTO Member. A summary of the notification was available in Portuguese to provide exporters with the most relevant information on the possible impact on the market. After having received an early warning notice and deciding upon its relevance for access to a particular market, exporters could request the full text of any technical regulations and conformity assessment procedures notified. They were then able to present comments through the internet facility. Exporters could also send a complaint concerning a technical barrier to trade, which was then analyzed by the staff of INMETRO to launch the necessary procedures and possible consultations with other agencies of the Brazilian government. In August 2004, an agreement had been reached under the auspices of the standardization organizations of Brazil and of other MERCOSUR countries to provide these countries with an access to *AlertaExportador*.<sup>49</sup>

#### 2. The Chinese Experience in Enhancing the Role of the Enquiry Point<sup>50</sup>

50. The representative of the <u>People's Republic of China</u> noted that in 1997, in preparation for its WTO membership, a TBT enquiry point had been established, which was further strengthened after the country's accession in December 2001. Located at the State General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), the "WTO/TBT National Notification and Enquiry Center of the People's Republic of China" had 15 staff members which serviced three departments,

<sup>&</sup>lt;sup>47</sup> Presentation made by Ms. Annalina Camboim, Head of the Brazilian Enquiry Point.

<sup>&</sup>lt;sup>48</sup> http://www.inmetro.gov.br/barreirastecnicas.

<sup>&</sup>lt;sup>49</sup> During the discussion, Mozambique expressed its interest in taking part in the Brazil-MERCOSUR agreement to also benefit from access to AlertaExportador. In this context, it pointed to the problems of translation it encountered as a Portuguese speaking country and the necessity of sharing translations and information from different workshops and seminars among WTO Members.

<sup>&</sup>lt;sup>50</sup> Presentation made by Mrs. Guo LiSheng, Deputy Director of the Chinese enquiry point.

the Department of TBT Notifications and Enquiry, the Department of TBT Research, and the Department of Networks. The enquiry point recruited highly qualified personnel, and equipped its offices with an advanced IT infrastructure.

51. The TBT enquiry point was responsible for the technical check of Chinese TBT notifications filled out by various ministries. A system of three-level examination had been adopted to ensure the quality of notifications. To facilitate the strict adherence to the rules and procedures recommended by the TBT Committee, 85 resolutions and recommendations had been translated into Chinese, compiled into a brochure and published. Although, in China, some technical regulations were adopted by the local government bodies (i.e. provincial, municipal, autonomous and regional), so far, only national technical regulations had been notified.

52. Concerning notifications by other WTO Members, China translated all TBT notifications into Chinese within two to three working days, and distributed both the Chinese and English versions to government departments, industrial sectors and other related organizations. At the same time, notifications were submitted to the Chinese TBT/SPS website<sup>51</sup> and were made available to the public free of charge. The enquiry point compiled and published a number of reports on technical barriers to trade, such as a the "WTO/TBT Express", "Reports of the TBT-SPS Enquiry Points", "Understanding of the TBT Agreement" and a nationwide periodical containing information on technical trade barriers. Additionally, TBT information was disseminated via traditional media channels, weekly on China's central TV station. The TBT enquiry point carried out research on key issues in international trade and published reports which were used as reference material for selected industries.

53. The Chinese enquiry point replied to reasonable enquiries from governmental, import and export enterprises as well as domestic and foreign trade associations by providing interested parties with the full text of notifications from the WTO database and/or referring them to the relevant regulatory agencies and ensuring coordination among different agencies, when necessary.

54. When China received TBT notifications from other Members, the TBT enquiry point distributed them to government agencies, the industrial sector and related organizations for comment. To increase companies' knowledge of the TBT Agreement, the enquiry point carried out selected publishing and training activities. It also organized workshops on formulating effective comments on notifications. Comments received from other WTO Members concerning China's notifications were conveyed to competent departments and translated into Chinese, if necessary.

55. China's experience demonstrated that the following elements were of crucial importance for a successful operation of a national TBT enquiry point: the full attention of the central government, clear working procedures, highly qualified staff and advanced office equipment along with an active participation in meetings of the TBT Committee and other related activities.

# 3. The Kenyan Experience in Establishing and Running a National Enquiry Point<sup>52</sup>

56. The representative of <u>Kenya</u> recalled that in 1995, the Kenya Bureau of Standards (KEBS)<sup>53</sup> was officially designated as the TBT national enquiry point. However, its implementation and functioning was only realized in 1999, aided by technical assistance from WTO/UNCTAD/ITC under Phase I of a JITAP<sup>54</sup> project, which provided technical facilities, helped setting up a technical regulation database, and organized a study tour to European enquiry points. In the process of establishing the national enquiry point, it was realized that its functions and operations were closely related to those of the KEBS Standards Information Resource Centre (SIRC), which stored all

<sup>&</sup>lt;sup>51</sup> The TBT/SPS website included information on technical barriers to trade in China and abroad.

<sup>&</sup>lt;sup>52</sup> Presentation made by Mr. Evanson Ndung'u of the Kenya Bureau of Standards (KEBS).

<sup>&</sup>lt;sup>53</sup> The Kenya Bureau of Standards was established in 1974.

<sup>&</sup>lt;sup>54</sup> Joint Integrated Technical Assistance Programme.

standards and technical regulations for Kenya. To avoid a duplication of activities, the national enquiry point was integrated into the existing SIRC.

57. To speed up the process of receiving TBT notifications, one of the two staff of the national enquiry point downloaded TBT and SPS notifications directly from the WTO website and stored them on the local server. Then, the national enquiry point summarized each notification and compiled this information in a monthly publication, the "WTO/TBT Notification Update Bulletin" which was distributed electronically to over 400 organizations and individuals. As this bulletin was only compiled and circulated monthly, a selective dissemination of information had recently been introduced. Notifications on specific products were selected on a daily basis and then sent to specific clients. This service would gradually be offered (free of charge) to the industry in 2005.

58. The response time to enquiries received by the national enquiry point depended on the nature of the information required; an average of two days for information available in Kenya and up to one week for information from other countries. The national enquiry point had experienced some problems and challenges, which could be addressed through technical assistance: The limited awareness of industry on the trade benefits of the notification procedure; the lack of office technology to make Kenya's enquiry point a one-stop-information-service-point; the difficulties of translation and reception of full texts when requested from other national enquiry points; the lack of internet access for many SMEs; the limited server capacity of the enquiry point; and the need to create an interactive website, which could allow full text searches.

G. BENEFITING FROM TRANSPARENCY PROVISIONS: DISSEMINATION OF INFORMATION

# 1. The Experience of the Mexican TBT/SPS Enquiry Point <sup>55</sup>

59. The representative of <u>Mexico</u> said that the Mexican TBT/SPS enquiry point, located at the Under-Secretariat of the Foreign Affairs Ministry, had been operating since 1995. One problem was the difficulty to evaluate and assess the enquiry points' role, as the benefits provided to the business community were often indirect and not visible. Insufficient budgets resulting in the lack of material and human resources were issues of common concern which made it difficult to respect deadlines. The lack of continuity and follow-up, especially after a change of government, was an aspect which burdened the work of some Members' enquiry points. It was thus necessary to establish clear processes and procedures.

60. Several tools could help to satisfy users of the enquiry point and provide the relevant information in a timely manner: Internet portals were a means to ensure appropriate accessibility to the information and establish more effective communication amongst the stakeholders involved; knowledge exchange between Members could help to generate ideas; technical assistance could play an important role. Moreover, it was necessary to be in contact with stakeholders nationally, such as chambers of commerce, associations and businesses. As information providers, enquiry points needed to function as a link between private and public bodies nationally and internationally. In providing their services, enquiry points should construct the management of information strategically and stand ready to advertise the benefits of the services provided.

61. After a paper bulletin had been in place between 1995 and 1997, and later replaced by an online bulletin, the Mexican enquiry point developed, between 2001-2004, *Notificarnom-Alert*,<sup>56</sup> a service accessible online. *Notificarnom-Alert* functioned in the same way as the web Canadian and Brazilian facilities.

<sup>&</sup>lt;sup>55</sup> Presentation made by Mrs. Danielle Schont Avenel, representative of the Mexican enquiry point.

<sup>&</sup>lt;sup>56</sup> <u>http://www.economia.gob.mx/?P=85</u>.

# 2. The Experience of Chinese Taipei and the Product-Classified Notification Dissemination System <sup>57</sup>

62. The representative of <u>Chinese Taipei</u> noted that the Bureau of Standards, Metrology and Inspection (BSMI) was responsible for the implementation of notification procedures under the TBT Agreement. Electronic tools were used for checking and downloading notifications from the WTO website, translating and categorizing them and subsequently uploading and distributing them via e-mail to the public and the private sector concerned. A product-classified notification dissemination system introduced in early 2004 aided in distributing the right notifications to the relevant public and private sector entities, grouped notifications into 14 different categories and classified them by HS code. Translated notifications could be accessed at the BSMI website<sup>58</sup> and also in a monthly publication.

63. To handle feedback appropriately, BSMI assisted the public and the private sector in making requests for additional information from other WTO Members. The enquiry point accumulated and filed comments on Members' regulations, discussed those with authorities and associations before finalizing them and sending them to WTO Members. A survey undertaken among 20 companies and associations had indicated that most of them were satisfied with the dissemination of notifications and that their business operations benefited from these notifications. Chinese Taipei was dedicated to the transparency of notifications and had undertaken different activities in this regard. While the notification dissemination system was greeted positively by the private and public sectors, the awareness of the private sector, mainly SMEs, on TBT issues needed to be further increased.

# 3. The Uganda TBT/SPS Coordination Committee <sup>59</sup>

64. The representative of <u>Uganda</u> indicated that the infrastructure for implementing the TBT Agreement was threefold. First, the Ministry of Tourism, Trade and Industry was the WTO focal point and the national notification authority for TBT and SPS. It was responsible for the notification procedures and for bilateral and plurilateral trade negotiations. Second, the Uganda National Bureau of Standards (UNBS) was the national enquiry point for TBT and SPS as well as the national contact point for the Codex Alimentarius Commission. It was responsible for answering enquiries about technical regulations, standards, conformity assessment procedures and sanitary and phytosanitary measures.

65. Third, the TBT/SPS Coordination Committee (chaired by the UNBS) was an institutional and multi-sector committee consisting of regulatory and private sector organizations responsible for the implementation of the TBT and SPS Agreements at the national level. This Committee provided the backbone for the distribution of TBT notifications. Notifications that required comments were identified by the members of the Committee and then brought to the attention of the national notification authority, which requested their texts. When the notified draft regulations had been obtained, the national notification authority distributed them to members of the Committee for comments. Each member of the Committee submitted written comments to the national notification authority which then compiled, merged and circulated them for discussion during the Committee's coordination meeting. When the Committee met, the comments that were agreed upon were forwarded to the national notification authority of the notifying WTO Member. Subsequently, the Ugandan notification authority circulated feedback received from the notifying Member to the TBT/SPS Coordination Committee including information on how the comments were handled.

66. There were some gaps in the implementation of the transparency provisions of the TBT Agreement in Uganda: As the TBT/SPS Coordination Committee was only one year old, an efficient IT infrastructure still needed to be set up to facilitate the dissemination of information; the

<sup>&</sup>lt;sup>57</sup>Presentation made by Mr. M. S. Chen, Section Chief of the Bureau of Standards, Metrology and Inspection.

<sup>&</sup>lt;sup>58</sup> <u>http://www.bsmi.gov.tw</u>.

<sup>&</sup>lt;sup>59</sup> Presentation made by Mr. George Opiyo, Manager of the TBT and SPS notification point of Uganda.

Committee had yet to obtain legal status; the lack of personnel at the national enquiry point (only one staff member, the presenter himself); budgetary constraints which resulted in the inability of capitalbased officials to attend meetings of the TBT Committee; awareness among the private sector and regulatory bodies on the benefits of the SPS and TBT Agreements needed to be raised; and notifications were distributed through electronic means, but internet access, especially by the private sector, was still inadequate.