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Committee on Trade and Environment
Committee on Technical Barriers to Trade

NEGOTIATING HISTORY OF THE COVERAGE OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE WITH REGARD TO LABELLING REQUIREMENTS, VOLUNTARY STANDARDS, AND PROCESSES AND PRODUCTION METHODS UNRELATED TO PRODUCT CHARACTERISTICS

Note by the Secretariat

1. This note has been prepared in response to requests at the meeting of the Committee on Trade and Environment on 21 June 1995 for the negotiating history, covering both the Tokyo and the Uruguay Round negotiations, of the provisions of the WTO Agreement on Technical Barriers to Trade relating to its coverage of labelling requirements, processes and production methods unrelated to product characteristics, and voluntary standards.¹ Thus, the note focuses on a select number of issues and does not attempt to provide a comprehensive review of the negotiating history of all disciplines in the Tokyo Round and WTO Agreements on Technical Barriers to Trade ("the TBT Agreements").

2. Section I summarizes the discussions on various issues that were considered to be relevant with regard to labelling requirements, including the coverage of these requirements under the TBT Agreements. Section II addresses three different aspects: (i) developments over time regarding the definitions of the terms "standard" and "standardizing body" in the TBT Agreements, in order to provide a basis for considering the coverage of these terms under the Agreements; (ii) disciplines under the TBT Agreements pertaining to preparation, adoption and application of standards by different types of standardizing bodies, i.e. by central government, local government, regional, and non-governmental bodies; and, (iii) disciplines under the TBT Agreements on different types of bodies dealing with conformity assessment. Section III summarizes the discussion on the coverage of processes and production methods under the TBT Agreements.

¹This note has been prepared by the Secretariat on its own responsibility. It is based on the Secretariat's record of the discussions during the negotiations and the documents that were circulated to the negotiating groups or to the Committee on Technical Barriers to Trade.

3. In the context of the discussions of the Committee on Trade and Environment on voluntary ecolabelling standards, the findings of this note can be summarized as follows:

- (a) Following the Decisions of the Tokyo Round and the WTO Committees on Technical Barriers to Trade, mandatory labelling requirements are subject to the notification provisions of Article 2.9 of the TBT Agreement regardless of the kind of information that is provided on the label. By implication, voluntary labelling standards are subject to the notification provisions of Article 4 and Annex 3 (Code of Good Practice for the Preparation, Adoption and Application of Standards) of the TBT Agreement regardless of the kind of information that is provided on the label;
- (b) Article 4 and Annex 3 of the TBT Agreement contain provisions on the preparation, adoption and application of voluntary standards for common and repeated use. Central Government standardizing bodies must comply with these provisions, which include the non-discriminatory application of standards, the avoidance of unnecessary obstacles to trade, the periodic notification of standards under preparation with allowance for the submission of and taking account of comments made on draft standards by interested parties in other WTO Members. Other standardizing bodies, including non-governmental bodies, involved in the preparation of standards for common and repeated use are invited to accept and comply with the Code of Good Practice in Annex 3 of the TBT Agreement. Whether or not a standardizing body does accept the Code of Good Practice, WTO Members are required under Article 4 of the TBT Agreement to take such reasonable measures as maybe available to them to ensure that it complies with the provisions of the Code of Good Practice. In addition, members must not take measures which have the affect of, directly or indirectly, requiring or encouraging the standardizing body to act in a manner inconsistent with the Code of Good Practice. Parallel provisions on procedures for the assessment of a product's conformity with a standard by central, local and non-governmental bodies are contained in Articles 5-9 of the TBT Agreement;
- (c) Standards that are based on processes and production methods (PPMs) related to the characteristics of a product are clearly accepted under the TBT Agreement, subject to them being applied in conformity with its substantive disciplines. The negotiating history suggests that many participants were of the view that standards based *inter alia* on PPMs unrelated to a product's characteristics should not be considered eligible for being treated as being in conformity with the TBT Agreement.

Towards the end of the negotiations, some delegations proposed changing the language contained in the "definitions" in Annex 1 of the Agreement to make it unambiguous that only PPMs related to product characteristics were to be covered by the Agreement, but although no participant is on record as having opposed that objective, at that late stage of the negotiations it did not prove possible to find a consensus on the proposal.

I. LABELLING REQUIREMENTS

(i) The Tokyo Round Negotiations

4. Initial work in the field of labelling requirements was carried out by Working Group 3, established by the Committee on Trade in Industrial Products in December 1969 to examine, among other subjects, "the unreasonable application of standards, packaging, labelling and marking

requirements" (L/3298). On the basis of information contained in an Inventory of non-tariff measures and para-tariff measures² and any information that might be subsequently furnished, the task of this group was to explore possibilities for concrete action with regard to standards acting as barriers to trade (L/3496, page 53).

5. The Group's examination of the notifications in the Inventory indicated that the problems in the area of labelling were arising because regulations were often too detailed or unnecessarily stringent and different practices were adopted in different countries. Other relevant aspects noted by the Group were that the type of information required, modalities of presentation, and languages to be used varied across countries, and by increasing production costs, labelling requirements could constitute obstacles to the development of international trade.

6. With regard to GATT disciplines, it was considered that while GATT did not explicitly refer to questions of packaging and labelling, "national treatment" accorded to imported goods under Article III of GATT, in particular under Article III:4, would apply to laws and regulations adopted by countries in the area of labelling.³ However, several delegations also expressed concerns regarding possible adverse trade effects of these requirements; for example, in February 1971, the Committee on Trade in Industrial Products in its second report to the Council concluded that "labelling ... requirements, many of which were designed to protect consumers, could also have adverse trade effects" (L/3496). Thus, a need for appropriate disciplines for labelling requirements within the GATT framework was emphasised. It was proposed that packaging and labelling be covered by the relevant provisions that were being discussed with regard to standards (L/3496, page 61). Working Group 3 provided its report in document COM.IND/W/108 (dated 25 June 1973)⁴, which included in its annex a "Proposed GATT Code of Conduct for Preventing Technical Barriers to Trade" ("Draft Standards Code").

7. Discussion on the issues related to labelling requirements continued and in this context, attention was also drawn to the work carried out in this area by the OECD's Committee on Consumer Policy, which had produced a report in 1972 on compulsory and voluntary labelling, with particular reference to textiles. The OECD paper called for compulsory labelling to protect the health or safety of the consumers (i.e. dangerous goods) or to provide information on the characteristics of the product (weight, volume, etc.). In addition, it distinguished between different types of voluntary labelling.⁵

8. At its meeting in February 1974, the Trade Negotiations Committee established Group 3(b) which was instructed to deal with, among other items, the issue of labelling. In particular, the task was to examine the work of other organizations in this area and then consider whether labelling requirements could be covered by the Draft Standards Code for preventing technical barriers to trade or by a separate legal instrument. In July 1974, the Group presented a report to the Trade Negotiations Committee (MTN/3), which showed a wide measure of agreement in the Group for international harmonization of packaging and labelling requirements, use of appropriate international

²In November 1967, the CONTRACTING PARTIES decided, as part of their future work, to set up an Inventory of non-tariff and para-tariff barriers affecting international trade. The Inventory was based on notifications received from contracting parties and consolidated by the Secretariat (see document L/3298).

³See COM.IND/W/114, page 1. This view was later reproduced, for instance, in MTN/3B/23, page 15.

⁴A corrigendum to this was circulated later in COM.IND/W/108/Corr.1, dated 30 October 1973.

⁵According to the OECD, there were four main types of voluntary labelling: (i) information labelling schemes applied by specialized organizations, mainly designed to give information on the composition and performance of products; (ii) labelling schemes applied by various private organizations such as standardization organizations; (iii) recommendations issued by standardization organizations or by governments; and (iv) application of complementary schemes by professional associations or other industrial groups. For further details see document COM.IND/W/114.

organizations for this purpose⁶, and for the GATT to support this work. Wide support was also expressed for other suggestions such as a need for procedures for prior consultations on mandatory packaging and labelling requirements, allowance for a grace period before introducing new requirements (except if urgent reasons including safety and health made this impossible), publicity to be provided to new packaging and labelling requirements under consideration and comments of affected parties be taken into account, notification to the GATT secretariat of changes in requirements, and a need to distinguish between consumer goods and other goods. Another suggestion was to consider the usefulness of developing an inventory of references to national practices, provisions and legislation in the field of labelling, setting out a summary description of products or areas covered by the provisions and whether the existing provisions conformed to international standards or to provisions of other countries, and the services responsible for the preparation and administration of such provisions. Discussions in the Group also considered a suggestion for establishment of enquiry points for providing information on packaging and labelling regulations and the establishment of procedures for consultations in cases of difficulty (MTN/3B/23, page 17).

9. Developing countries pointed out that labelling requirements were more onerous to their products than to others and thus represented a disproportionate burden to their trade. Therefore, they would accept any solution ensuring the simplification and harmonization of labelling requirements, and strongly supported the establishment of enquiry points and technical assistance. However, it was considered premature at that stage to decide which approach should be adopted.

10. Group 3(b) also reported a widely held view that potential problems were likely to be more important than those contained in the Inventory, since a trend towards more requirements was likely to continue. Several delegations were of the view that the proposed Draft Standards Code contained provisions to deal with most of the issues that had been raised. Some others, however, questioned whether the draft Code dealt with all the problems in this field.

11. In March 1975, the negotiating group on Non-Tariff Measures agreed to create a "Technical Barriers to Trade" Sub-Group ("TBT Sub-Group") to continue the work on labelling with the scope to draw up general rules in the area of standards (MTN/NTM/1). It was also agreed that "the applicability of these rules to health and sanitary regulations concerning agriculture and tropical products should be examined by the Groups 'Agriculture' and 'Tropical Products'" (MTN/NTM/1, paragraph 2).

12. During the general discussions regarding the Draft Standards Code, delegations were still uncertain whether labelling problems should be solved via general rules or by product groups, and whether such rules should be included in the Standards Code or elaborated as separate rules. However, the definition of the term "standard" in Annex 1 to the Draft Standards Code included labelling to the extent that it affected products rather than processes (MTN/NTM/W/5; see paragraph 28 below for the definition).

13. In May 1975, the TBT Sub-Group agreed that the "Draft Standards Code" would be a basis for further work and that it could take the form of a binding code. It was recognized that the Draft Code dealt generically with many of the problems in the area of labelling and thus labelling could be covered by the provisions of the Code, but delegations were free to suggest amendments to the text (including definitions) in order to ensure that all aspects related to labelling were adequately considered (MTN/NTM/3).

14. The TBT Sub-Group met several times between the end of 1975 and 1979 and many changes

⁶The Group had examined the work of other organizations in this area with the help of a secretariat note on this subject in MTN/3B/17.

were made to the text and to the substance of the Code. However, the issue of the coverage of labelling by the new Code was not questioned.

15. The final text of the Tokyo Round Agreement on Technical Barriers to Trade ("TBT Agreement") was circulated on 29 March 1979 (MTN/NTM/W/192/Rev.5). Annex 1 (Terms and Definitions for the Specific Purposes of the Agreement), defines "technical specification" as:

"a specification contained in a document which lays down characteristics of a product such as levels of quality, performance, safety or dimensions. It may include or deal exclusively with terminology, symbols, testing and test methods, packaging, marking or labelling requirements as they apply to a product".

(ii) The Uruguay Round Negotiations

16. During the Uruguay Round negotiations there was no recorded discussion of the coverage of labelling requirements by the TBT Agreement. However, the definitions contained in Annex 1 of the Agreement were modified and in the light of subsequent discussion in the Committee on Technical Barriers to Trade ("TBT Committee") it is important to note the inclusion of the word "also" in the second sentence of the definitions of both technical regulations and standards. This change was taken from a Nordic proposal in June 1990 (TBT/W/145) which is described in paragraph 21 below, but there was no recorded discussion at that time of the intent behind the inclusion of this word.

(iii) Discussions in the Tokyo Round TBT Committee

17. The need to clarify the relationship between labelling requirements and the provisions of the TBT Agreement was expressed by some delegations during the meeting of the TBT Committee of 31 May 1991 (TBT/M/40). One Member reported the entry into force of a Mexican regulation introducing changes in the labelling of textiles which had not been notified under the Agreement. According to Mexico, that regulation required that certain textile products bear "commercial information, whether the products were of domestic origin or imported, but it did not establish quality standards and his authorities therefore did not believe that it was a technical regulation within the meaning of Annex 1 of the Agreement." Mexico asked for further clarification of the coverage of the Agreement with respect to "labelling requirements", in particular the obligations to notify labelling requirements that did not contain "technical specifications".

18. Mexico's view of the definitions in Annex 1.1 of the Agreement was that "the first and second sentences of paragraph 1 needed to be read together so that only labelling requirements containing technical specifications relating to products were covered by the Agreement" (TBT/M/40).

19. The TBT Committee met informally at the end of June 1991 to discuss the issue further on the basis of a Secretariat note listing more than 250 labelling notifications that had been made under the TBT Agreement, of which fourteen concerned labelling requirements on textile and textile products. The Secretariat also gave the following informal comment (TBT/Spec/23):

"Article 2.5 of the Agreement addresses "technical regulations or standards" which "may have a significant effect on trade of other Parties". Article 2.5.2 of the Agreement requires that all such technical regulations be notified. Technical regulations are defined in Annex 1 of the Agreement as mandatory technical specifications, and labelling requirements are recognized explicitly as one possible type of technical specification. It would therefore appear that as long as it is mandatory for a product to bear a label if it is to enter the domestic market, and that the labelling requirement may have a significant effect on trade, then the labelling

requirement should be notified. That conclusion would appear to stand regardless of what is printed on the label. In some circumstances it may be that technical specifications have to be printed on the label; but even if the label contains nothing more than consumer information (e.g. on cleaning or washing guidelines), it would seem that it should be notified as long as the label is mandatory and it may have a significant effect on trade."

20. During the discussion on this issue, Mexico expressed the view that the second sentence of Annex 1.1 was "illustrative of the first". Therefore, a labelling requirement was subject to the notification obligation only if it contained product specifications.

21. A contrasting view was provided by Finland that the second sentence of Annex 1.1 was to be seen "as additional to the first and not merely illustrative" so that all mandatory labelling requirements had to be notified regardless of the information printed on the label. According to Finland, this was supported by the inclusion of "test methods" in the second sentence of Annex 1.1; a test method could not include technical specifications which laid down "characteristics of a product", yet it was clear that it was covered by the term "technical specifications". Furthermore, the new draft text of the Agreement which had been negotiated in the Uruguay Round included the word "*also*" at the beginning of the second sentence in Annex 1.1, and this supported the view that the second sentence was additional to the first. Labelling requirements which were not mandatory were instead covered by the meaning of "standards" given in Annex 1.3, and were notifiable upon request to other interested Parties under Article 2.5.3 of the Agreement. The United States and the European Community shared Finland's view.

22. Mexico proposed that a formal understanding be reached on whether all labelling requirements were covered by Annex 1.1 of the TBT Agreement and on whether all signatories had the right under Article 2.5.3 of the Agreement to request information on labelling standards.⁷

23. Following consultations, the Chairman of the Committee recommended the adoption of a formal decision in order to avoid further problems regarding the coverage of labelling requirements by the TBT Agreement. A draft text of the decision was circulated to all parties on 17 July 1992 (TBT/W/159), and at the Committee's meeting in October 1992 the decision was formally adopted. It read as follows:

"In conformity with Article 2.5 of the Agreement, Parties are obliged to notify all mandatory labelling requirements that are not based substantially on a relevant international standard and that may have a significant effect on the trade of other Parties. That obligation is not dependent upon the kind of information which is provided on the label, whether it is in the nature of a technical specification or not" (TBT/16/Rev.5).

24. At its meeting of 14 July 1995, the WTO TBT Committee formally adopted the same decision, the only change being to replace the word "Parties" by "Members" (G/TBT/1/Rev.1 and G/TBT/M/2).

II. VOLUNTARY STANDARDS

25. This section addresses three aspects of the disciplines pertaining to voluntary standards in the Tokyo Round TBT Agreement and the WTO TBT Agreement. The section begins with a summary of the developments regarding definitions of "standard" and "standardizing body" in the TBT Agreements. This would provide a basis for assessing the coverage of these terms under the Agreements. The second part of this section first addresses preparation, adoption and application of

⁷A label may represent a mark of conformity to a given standard or technical regulation. See Section II below for a discussion of the coverage of the TBT Agreements with regard to conformity assessment.

standards, and then summarizes the relevant aspects with regard to conformity assessment. With regard to voluntary standards, it summarizes the main aspects of the negotiations on disciplines imposed on different types of standardizing bodies and conformity assessment bodies. An important focus in this context is the differences in disciplines imposed on central government bodies and on other bodies, in particular on non-governmental bodies.

1. Definitions of "standard" and "standardizing body"

(i) The Tokyo Round Negotiations

26. Since 1969 delegations had emphasized that in order to regulate the application of standards, it was important to draw a clear distinction between mandatory regulations and voluntary standards. While mandatory regulations were issued by the governments, voluntary standards were usually issued by private organizations on a regional, national or international basis. The distinction was important because of the different possibilities and limits it implied for government action (L/3496).

27. In June 1974, the Government Officials Responsible for Standardization within the UN Economic Commission for Europe (ECE) adopted a set of definitions concerning standardization aimed at partly solving the problem of the lack of harmonization of international standards. According to these definitions⁸, a "standard" was:

"a technical specification or other document available to the public, drawn up with the co-operation and consensus or general approval of all interests affected by it based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and approved by a body recognized on the national, regional or international level."

Note 1: A technical specification which does satisfy all the conditions given in the definition may sometimes be called by other names, for example: "recommendation".

Note 2: In some languages the word "standard" is often used with another meaning than in this definition, and in such cases it may refer to a technical specification which does not satisfy all the condition given in the definition, for example "company standard".

"Standardizing body" was defined as:

"a body, governmental or non-governmental, one of whose recognized activities is in the field of standardization".

28. Following a request presented by the TBT Sub-Group at its meeting of March 1975, the Secretariat prepared a background note on standards (MTN/NTM/W/5) which contained, *inter alia*, a "Proposed GATT Code for Preventing Technical Barriers to Trade". Annex 1 to the proposed Code defined "standard" as:

"any specification which lays down some or all of the properties of a product in terms of quality, purity, nutritional value, performance, dimensions, or other characteristics. It includes, where applicable, test methods, and specifications concerning testing, packaging, marking or labelling to the extent that they affect products rather than processes. It excludes standards that are prepared for use by a single enterprise, whether governmental, semi-

⁸ See MTN/NTM/W/5, Appendix 2. For a comparison of GATT and ECE definitions conducted in 1975, see MTN/NTM/W/14.

*governmental or non-governmental, either for its own production or purchasing purposes."*⁹

29. The Annex distinguished between "mandatory standard" and "voluntary standard", the latter defined as *"a standard with which there is no legal obligation to comply"*. With respect to standardizing bodies, the Annex distinguished between:

voluntary standards body: *"any non-governmental organization which prepares voluntary standards for public use. Some of these are national standards bodies as defined below"*;
national standards body: *"a nationally recognized standards body which is, or is eligible to become, a member of non-governmental international standards bodies"*;

regional standards body: *"any international organization, whether governmental or non-governmental, which prepares standards, and which does not admit the relevant bodies in all adherents to participate in the preparation of such standards"* and;

international standards body: *"any international organization of recognized standing, whether governmental or non-governmental, which prepares standards, and which admits the relevant bodies in all adherents to participate in the preparation of such standards"*.

30. In May 1975, some suggestions regarding definitions were presented to the Sub-Group (MTN/NTM/W/12 and Add.1) and it was noted that the GATT meaning of "standard" was more limited than the corresponding ECE definition since it excluded company standards, standards relating to services and codes of practice. In September 1975, the representative of Finland presented a study on the applicability of the ECE/ISO definitions for the Draft Standards Code (MTN/NTM/W/18). He recommended that the terms "technical specification" and "voluntary technical specification" be used instead of the terms "mandatory standards" and "voluntary standard"; the term "voluntary standards body" be deleted from the set of definitions¹⁰; and that the concept of "standards body" was not needed because the concept of "standardizing body" was sufficient for the purposes of the Code.

31. The Nordic countries suggested adoption of ECE/ISO definitions without modifications and to include any qualification through separate notes (MTN/NTM/W/19, emphasis added). The Sub-Group decided to compare two hypothetical situations: hypothesis A was the Nordic proposal, and hypothesis B was to modify the text of the definitions instead of relying on separate notes (MTN/NTM/W/25). A discussion of these showed that there were diverse opinions regarding the two approaches.¹¹

32. The representative of Finland presented a proposal with a view to give a possible solution to the problem (MTN/NTM/W/35). Regarding the definition of "standard" he noted that "the scope of the ECE/ISO is partly too wide, partly too narrow for the purposes of the Code" and that the ECE and the ISO were not willing to make any amendments to the definitions. Therefore, he suggested that the ECE/ISO definition be accompanied by the following note which in fact gave a new definition for the term: *"Note: For the purposes of the Code a standard means a technical specification approved by a recognized body for continued application"* (emphasis added). For the definition of standardizing body he recommended the adoption of the ECE/ISO definition mentioned in paragraph 27 above.

⁹A footnote stated that "the term *standard* as used in this Code has a wider meaning than in customary usage".

¹⁰ The suggestions included replacing "voluntary standards bodies" by "non-governmental standardizing bodies" and "local government bodies, regulatory bodies other than central government bodies, and voluntary standards bodies" by "standardizing bodies other than central government bodies within their territories to do likewise".

¹¹ See for example documents MTN/NTM/W/25/Add.1, MTN/NTM/W/25/Add.2.

33. Comments on the Finnish proposal and additional suggestions were made to the Sub-Group at its meeting of January/February 1976 (MTN/NTM/W/37). In general, it was recommended to clarify the meaning of "recognized body". One suggestion was that the expression "recognized national standardizing body" should be used. It was pointed out that the word "body" covered also a national standardizing system and that "standardizing body" included a body of organization whose principal function was in the field of standardization. With respect to the coverage of "standard", the EC suggested that company standards be excluded, and the United States proposed to "exclude standards which were prepared for use by a single enterprise, whether governmental or non-governmental either for its own production or purchasing for its own consumption". According to another suggestion a "standard" could be defined as "a technical specification approved by a recognized standardizing body for continued and general application."

34. At the Sub-Group's request, the Secretariat circulated in March 1976 a Proposed Code with alternatives texts of the definitions based on the two hypotheses mentioned above (MTN/NTM/W/38). "Standard" was defined as:

Hypothesis A :

A technical specification or other document available to the public, drawn up with the cooperation and consensus or general approval of all interests affected by it, based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and approved by a body recognized on the national, regional or international level.

ECE notes

(1) A technical specification which does satisfy all the conditions given in the definition may sometimes be called by other names, for example: "recommendation".

(2) In some languages the word "standard" is often used with another meaning than in this definition, and in such cases it may refer to a technical specification which does not satisfy all the conditions given in the definition, for example "company standard".

Additional notes

(1) For the purposes of this Code the standard covers any technical specification approved by a recognized body for continued application.

(2) For the purposes of this Code the words "or other document" shall be deleted.

Hypothesis B:

Any technical specification approved by a recognized body for continued application and with which there is no legal obligation to comply.

For "standardizing body", only one definition was provided:

"A body, governmental or non-governmental, one of whose recognized activities is in the field of standardization."

35. In May 1976, the United States suggested that the term "standardizing body" be deleted and Japan proposed to insert the following text in the definition of standard: "any technical regulation approved by a body, either central governmental body, local governmental body, regulatory body, a

body other than a central or local governmental body, a non-governmental organization or any other standardizing body, for continued application and with which there is no legal obligation to comply" (MTN/NTM/W/50). The Sub-Group requested the representative of Finland to prepare two papers on the subject of definitions. The first identified the reasons for the differences between the ECE/ISO definitions and the definitions under Hypothesis B (MTN/NTM/W/70), and proposed deletion of the term "standardizing body". The second paper suggested a combination of the two hypotheses as a solution to the problem (MTN/NTM/W/86). The suggested definition of standardizing body remained the same as the definition provided by the ECE/ISO (see paragraph 27 above), while "standard" was defined as:

"A technical specification approved by a recognized body for continued application and with which compliance has not been made mandatory by a regulation".

Note: The corresponding ECE/ISO definition contains several normative elements which are not included in the above definition. For the purposes of the Code other documents than technical specifications are excluded. On the other hand also technical specifications which are not based on consensus are covered by the Code".

To avoid duplication of work between the GATT and ECE/ISO, the paper suggested that the definitions have "the meaning given to them by the ECE and ISO taking into account their context and in the light of the object and purpose of the Agreement. However, for the specific purposes of the Code the definitions given in Annex 1 apply."

36. The definition of "standard" was later amended to read:¹²

*"a technical specification approved by a recognized ~~body for continued application~~ **standardizing body for repeated or continuous application** with which compliance ~~has not been made mandatory by a regulation~~ is not mandatory.*

Explanatory Note:

*The corresponding ECE/ISO definition contains several normative elements which are not included in the above definition. ~~For the purposes of the Code other documents than technical specifications are excluded. On the other hand also~~ **Accordingly**, technical specifications which are not based on consensus are covered by the Code" "*
(MTN/NTM/W/93).

37. The unchanged definition of "standardizing body" and the revised definition of "standard" were incorporated in Annex 1 of the draft Code of Conduct for Preventing Technical Barriers to Trade (MTN/NTM/W/94). Subsequently an additional sentence (given in bold type below) was included in the explanatory note to "standard":

Explanatory note:

*The corresponding ECE/ISO definition contains several normative elements which are not included in the above definition. Accordingly, technical specifications which are not based on consensus are covered by the Code. **This definition does not cover technical***

¹² Bold print shows the new text added in the definitions, and the deleted text is indicated by striking out the relevant text.

specifications prepared by an individual company for its own production or consumption requirements.

38. In March 1979, an explanation of the term "body" was added to the explanatory note (MTN/NTM/W/192/Rev.4). Therefore, in the final text of the Tokyo Round TBT Agreement, Annex 1 (Terms and their Definitions for the Specific Purposes of the Agreement) contained the following definitions:

Standard

"A technical specification approved by a recognized body for repeated or continuous application with which compliance is not mandatory".

Explanatory Note:

The corresponding ECE/ISO definition contains several normative elements which are not included in the above definition. Accordingly, technical specifications which are not based on consensus are covered by the Code. This definition does not cover technical specifications prepared by an individual company for its own production or consumption requirements. The word "body" covers also a national standardizing system."

Standardizing body

"A governmental or non-governmental body, one of whose recognized activities is in the field of standardization."

(ii) ECE/ISO Definitions after the Tokyo Round

39. The definitions under the Tokyo Round TBT Agreement differed from those used by the ECE/ISO. The ECE government officials responsible for standardization policies met in September 1981 with the view, *inter alia*, to achieve the harmonization of the ECE/ISO definitions with the GATT definitions (United Nations Economic Commission for Europe - STAND/GE.1/R.54). Revised definitions of standard and standardizing body were provided in the fourth edition of the ISO/IEC Guide 2 (1983). The revised definition of standard included the term "standardizing body." The new definition of "standard" was:

"a technical specification or other document available to the public, drawn up with the cooperation and the consensus or general approval of all interests affected by it, based on the consolidated results of science, technology and experience, aimed at the promotion of optimum community benefits and adopted by a standardizing body".

NOTES:

1. *A document which satisfies all the conditions given in the definition may sometimes be called by other names, for example "recommendation".*
2. *In some languages the word "standard" is often used with another meaning than in this definition, and in such cases, it may refer to a technical specification which does not satisfy all the conditions given in the definition, for example: "company standard".*

"Standardizing body" was defined as "a body with recognized activities in the field of standardization".

40. Subsequently, at the suggestion of ECE, further work was done to alter the definitions. The following revised definitions of "standard" and "standardizing body" were provided in the fifth edition of ISO/IEC Guide 2 in November 1986:

Standard:

"Document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Note: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits".

Standardizing body:

"Body that has recognized activities in standardization".

(iii) Uruguay Round Negotiations

41. In the Uruguay Round, the Negotiating Group on MTN Agreements and Arrangements (NG8) was an umbrella for several sub-groups dealing with issues relating to Tokyo Round Agreements, including the Agreement on Technical Barriers to Trade. NG8 was the formal forum for negotiating changes to the TBT Agreement in the Uruguay Round, but the bulk of the discussions on changes in the TBT Agreement were conducted under the auspices of the TBT Committee in a process that was parallel to the negotiations under the Round. Though there was no formal link between the TBT Committee and NG8, information on the relevant discussions in the TBT Committee was provided to NG8. All proposals made to the NG8 relating to the renegotiation of the Agreement were issued concurrently as TBT documents. Several of the proposals had previously been discussed in the TBT Committee in the context of reviews under Article 15 of the Tokyo Round TBT Agreement, which provided the Committee with a mandate to review its operations and with the ability to amend the Agreement.

42. At the TBT Committee meeting of October 1987, the Nordic countries proposed to update the definitions contained in Annex 1 of the TBT Agreement on the basis of the above-mentioned revision of ISO/IEC Guide 2 (TBT/W/103). Also, the amended Guide contained new terms, and it was suggested that the Committee assess the possible implications for the Agreement of the adoption of such terms; consider amendment and updating of the definitions and their explanatory notes; and consider the inclusion of additional terms and their definitions. A proposal was to delete "several normative" from the explanatory note to the definition of "standard", and to replace the GATT definition of "standardizing body" by the corresponding definition in ISO/IEC Guide 2, i.e. *"body that has recognized activities in standardization"*.

43. Many delegations supported the Nordic proposal, though they felt that it was premature to determine whether the issue of changes in the definitions should be addressed by the Committee or in the Uruguay Round negotiations. Following a request by the Committee, the Secretariat prepared a document comparing the definitions in the fifth edition of Guide 2: 1986 with those of the second edition of the Guide 2: 1978 (TBT/W/106).

44. The discussions on the Nordic proposal continued in the meetings of March and July 1988 (TBT/M/27 and TBT/M/28). Although an amendment to the definition of one term was agreed

upon¹³, no decision was taken regarding the change in the definitions of "standard" and "standardizing body".

45. In June 1990, following the presentation by the ISO representative of a draft amendment sheet to Guide 2: 1986 (ISO/STACO 151), the Nordic countries suggested that the definitions contained in Annex 1 to the Agreement be amended on the basis of the new ISO proposal (MTN.GNG/NG8/W/79). The proposed new definition of "standard" read as follows:

"a document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products, (processes and production methods) with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product."

46. In July 1990, a draft text of the Uruguay Round Agreement on Technical Barriers to Trade was presented by the Chairman of the negotiating Group (MTN.GNG/NG8/W/83/Add.3), which incorporated the definition of "standard" suggested by the Nordic countries but added the following explanatory note:

Explanatory note:

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This agreement deals only with technical regulations, standards and conformity assessment procedures related to products (processes and production methods). Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purposes of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This agreement covers also documents that are not based on consensus.

This explanatory note did not contain the following sentence from the explanatory note in the Tokyo Round TBT Agreement: *"This definition does not cover technical specifications prepared by an individual company for its own production or consumption requirements"*. Both the main text and the explanatory note in the definition of standard included "process and production methods" within brackets (for more detail on this aspect, see Section III below).

47. The definition of "standard" that appeared in the final text of the WTO TBT Agreement removed the brackets from the previous version (MTN.GNG/NG8/W/83/Add.3/Rev.1). It read:

Standard

"Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

Explanatory note:

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined

¹³The Committee decided to replace the term "self-certification" by the term "declaration of conformity".

by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This agreement covers also documents that are not based on consensus".

48. No specific definition of "standardizing body" was given in the revised Annex 1 of the WTO TBT Agreement. However, Annex 1 contains a statement that "[t]he terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, *General Terms and their Definitions Concerning Standardization and Related Activities*, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement". The definition of "standardizing body" in the ISO/IEC Guide 2: 1991 remains unchanged from the previous version of the Guide i.e. from the fifth edition of the Guide (see paragraph 38 above).

2. Disciplines for preparation, adoption and applications of standards, and for conformity assessment

49. This section summarizes the main aspects of the negotiating history of the disciplines under the TBT Agreements on standardizing bodies and conformity assessment bodies (in particular local government and non-governmental bodies), with regard to their work relating to standards.

(a) Preparation, adoption and application of standards

(i) Tokyo Round Negotiations

50. Initially, the term "standard" was used to denote both mandatory and voluntary standards, and different obligations regarding preparation, adoption and use of standards were considered for three categories: mandatory central government standards, mandatory local government standards, and voluntary standards (COM.IND/W/108). For mandatory central government standards, the Draft Standards Code specified first level of obligations on the signatories, i.e. mandatory obligations. Second level of obligations were specified for the other two categories of standards, i.e. signatories were to use all reasonable means within their power to ensure that the relevant obligations were met. One of the main concerns during the negotiations was the question of balance of rights and obligations amongst the signatories, for instance, the alleged inequality of obligations which would apply between countries with a large proportion of standardization work carried out by private sector bodies producing voluntary standards and those where all standards were mandatory.

51. Section 4 of the Draft Standards Code contained disciplines with regard to preparation, adoption and use of voluntary standards (MTN/NTM/W/5).¹⁴ The focus was on preventing voluntary standards from becoming obstacles to international trade, cooperation in preparation of international standards, use of international standards, providing notice and taking account of comments when voluntary standards are not substantially same as international standards, exceptions to certain disciplines in case of urgent problems, and compliance of regional standards bodies with the relevant disciplines. These disciplines were specified in terms of "best efforts" or second level of obligations. For example, the first paragraph of Section 4 stated that:

"Adherents shall use all reasonable means within their power to ensure that voluntary

¹⁴Disciplines regarding "information about mandatory and voluntary standards and quality assurance systems and arrangements" were given in Section 16 of the Draft Standards Code. These disciplines were similar to those contained in Article 10 of the Tokyo Round TBT Agreement.

standards are not prepared, adopted or applied with a view to creating obstacles to international trade. They shall likewise use all reasonable means within their power to ensure that neither the voluntary standards themselves, nor their application have the effect of creating an unjustifiable obstacle to international trade."

52. At the meeting of the TBT Sub-Group in May 1975, it was suggested that voluntary standards prepared by central government bodies should be dealt with separately from those prepared by other bodies, such as local government bodies and non-governmental bodies (MTN/NTM/W/12). A similar change was proposed also for the sections on "conformity with voluntary standards" and on "systems operated by quality assurance bodies other than central government bodies for assuring conformity with voluntary standards". Subsequent proposals suggested that the "best efforts" provision should apply only to developing country adherents and not to developed country adherents, that voluntary standards should be notified to GATT secretariat, and that a reasonable transition period be allowed (MTN/NTM/W/12/Add.1).

53. At the meeting of the Sub-Group in September/October 1975, the EC suggested that in Section 4 of the proposed Code, the two sub-items dealing with regional bodies be deleted (MTN/NTM/W/25). In 1976, Japan suggested that the first level of obligation ("shall ensure") should apply to mandatory standards, including test methods and quality assurance systems, of central as well as local government bodies, and that second level of obligations should apply to voluntary standards including quality assurance systems, regardless of bodies which prepare and apply them (MTN/NTM/W/25/Add.2). The EC proposed that preparation, adoption, and use of voluntary standards be subject to first level, and not second level, of obligations (MTN/NTM/W/37).

54. The draft Code presented in March 1976 replaced the terms "mandatory standards" and "voluntary standards" by "technical regulations" and "standards", respectively (MTN/NTM/W/38). In 1977, the EC proposed that first level of obligations be imposed for standards prepared, adopted or applied by central government, its ministries and departments or by any body subject to the control of the central government bodies, with the exception of disciplines pertaining to cooperation in developing international standards and disciplines on regional standardizing bodies (MTN/NTM/W/72). Canada proposed that throughout the draft Code the phrase "use all reasonable means within their power" should be replaced by "take such reasonable measures as may be available to them" since the latter phrase was contained in GATT Article XXIV:12 (MTN/NTM/W/120).

55. Noting the two different levels of obligations for central government bodies and other bodies, the EC emphasised that there was a need to seek a balanced level of commitment and advantages for all adherents to the TBT Agreement, whether or not they had a centralized structure. In 1978, the EC submitted a proposal which suggested a possibility to bring a dispute if a signatory was unable to achieve "results identical to those imposed under the first level obligations" (MTN/NTM/W/135). The text of the EC proposal was:

"Signatories would be responsible to other signatories in regard to the preparation, adoption and use of all technical regulations, standards, certification systems and other standardizing activity subject to the Code within their territory:

- (a) They would be under an obligation to ensure that the preparation, adoption and use of technical regulations, standards, certification systems etc., of central government bodies are in conformity with the obligations of the Code;*
- (b) They would be responsible to other signatories in regard to failure to achieve results identical to those imposed under the first level obligations, under the "best endeavours" provisions where technical*

regulations, standards, certification systems etc. are prepared by bodies within their territories;

- (c) *In the event that a signatory is unable to discharge its obligations in regard to the first level obligation, or to achieve results identical to the first level obligation under the "best endeavours" obligations, the matter could be raised by any other signatory, which feels that the obligations of the Code are not being fulfilled, under the provisions of the Code on dispute settlement (to be agreed)."¹⁵*

56. After discussions of the various proposals, a revised draft TBT Agreement was presented in October 1978 (MTN/NTM/W/192). This draft combined under a single section the disciplines on preparation, adoption and use of technical regulations and standards by central government bodies, and first level of obligations were imposed on these bodies. Preparation, adoption and use of technical regulations and standards by local government bodies were addressed separately, and another Section dealt with preparation, adoption and use of standards by non-governmental bodies. Second level of obligations were specified for bodies other than central government bodies.¹⁶ Also, though the section dealing with "standards by local government bodies and regulatory bodies other than central government bodies" stated that information on certain technical regulations (and comments on them) to be provided through adherents to the Code, it did not mention that these aspects relating to standards had to be provided. The section dealing with preparation, adoption and use of standards by non-governmental bodies did not include any reference to such information or comments being provided; the draft Code presented in December 1978 (MTN/NTM/W/192/Rev.1) included the possibility of "comment and discussions referred to in Sections 2.5.4 and 2.5.8 may also be through interested parties in other adherents".¹⁷

57. In the draft Code presented in December 1978 (MTN/NTM/W/192/Rev.1), the different levels of obligations were also taken into account in the Section dealing with dispute settlement. Section 14.21 of that draft stated that: *"The dispute settlement provisions set out above can be invoked in cases where an adherent considers that another adherent has not achieved satisfactory results under Sections 3, 4, 6, 8 and 9 and its trade interests are significantly affected. In this respect, such results shall be equivalent to those envisaged in Sections 2, 5, and 7 as if the body in question were an adherent."*

58. In MTN/NTM/W/192/Rev.4, there was an agreed text for Article 2 and the phrase "regulatory bodies other than central government bodies" was deleted from the Article on preparation, adoption and use of technical regulations and standards by non-governmental bodies. The Canadian suggestion for denoting best endeavours was adopted, i.e. the phrase "shall take such reasonable measures as may be available to them to ensure" replaced "shall use all reasonable means within their power to ensure". Also, in the Article on preparation, adoption and use of technical regulations and standards by local government bodies, the revised text included additional references regarding

¹⁵For an outline of institutions and dispute settlement and some detail on these issues, see MTN/NTM/W/144 and 192 and its addenda.

¹⁶In Section 2, the draft included a provision on non-discriminatory treatment which is contained in Article 2.1 of the Tokyo Round TBT Agreement. The text of Section 2 in this draft Code showed lack of agreement on the conditions under which standards had to be notified, and on certain disciplines regarding regional standardization bodies and preparation, adoption and use of standards by non-governmental bodies (see MTN/NTM/W/192, pages 3 to 8). Two subsequent texts of the draft Code (MTN/NTM/W/192/Rev.2 and 3) contained proposals for changes in the text of Article 2 which, *inter alia*, dealt with non-discriminatory treatment in providing copies of standards, with conditions under which international standards might not be appropriate, and with the exceptions provided in situation with urgent problems.

¹⁷Section 2.5.4 pertained only to technical standards. The text of Section 2.5.8 stated: "allow other adherents with respect to technical regulations, and interested parties in other adherents with respect to standards, to present their comments in writing, discuss these comments upon request and take the written comments and the results of any such discussion into account."

information that had to be provided through the Parties.¹⁸ Furthermore, the following sentence was added in the Articles dealing with preparation, adoption and use of technical regulations and standards by local government bodies and by non-governmental bodies, i.e. in Articles 3 and 4: "*In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such non-governmental bodies to act in a manner inconsistent with any of the provisions of Article 2.*"

59. These provisions were included without further change in the final text of the Tokyo Round TBT Agreement.

(ii) Uruguay Round Negotiations

60. In the Uruguay Round, several delegations wanted enhancement of the disciplines on preparation, adoption and application of standards in the Tokyo Round TBT Agreement. A number of proposals addressed increased transparency and participation in the standards-related activities of different types of standardizing bodies, i.e. central government, local, regional or non-governmental standardizing bodies.¹⁹

61. India proposed notification of voluntary draft (or proposed) standards, including those draft standards which were not national standards, but whose wide adoption by local industry gave them a status similar to national standards (MTN.GNG/NG8/W/9, 45); notification of voluntary standards that were made mandatory by legislation or by statutory orders (MTN.GNG/NG8/W/9); and information to be provided on, and ensuring compatibility among, standards issued by recognized national bodies and other standardization bodies within the territory of a party (MTN.GNG/NG8/W/9). India explained that many parties to the Agreement were not notifying voluntary draft standards even though they were national standards, or were being widely applied by the local industry which gave them a status similar to that of national standards. Also, it was difficult to obtain information on standards that had been made mandatory by legislation or on standards being formulated by different bodies in the country. India suggested that the standards prepared by local bodies be notified and that a national body be made responsible for providing information on, and ensuring compatibility of, standards issued by other recognized bodies in the country.

62. The United States proposed enhanced transparency of standards-related agreements (MTN.GNG/NG8/W/1, 34, Rev.1 and Rev.3), and of the activities of regional standardization bodies (MTN.GNG/NG8/W/1, 35). Improved information on standards-related agreements was emphasised because such information could be of immediate interest and use to parties, and would facilitate trade by making it easier to deal with the new technical requirements and standards. Regarding regional standards, the United States noted that many parties belonged to a variety of governmental and non-governmental regional standards development organizations, and these organizations frequently did not allow non-members to fully participate in their standards-related activities. In MTN.GNG/NG8/W/35, the United States proposed a draft Code of Conduct relating to regional standardization and certification activities which addressed, *inter alia*, aspects related to transparency of preparation, adoption and application of standards by regional bodies or systems, provision of comments on proposed standards, enquiry points, and opportunity for consultation to help achieve the objectives of the Code.

63. Japan addressed increased transparency of the operation of certification systems

¹⁸ In relevant part, the text stated that " ... noting that the provision of information regarding technical regulations referred to in Articles 2.5.3 and 2.6.2 and comment and discussion referred to in Articles 2.5.4 and 2.6.3 had to be through Parties".

¹⁹ For a complete list of the initial proposals, see MTN.GNG/NG8/W/13.

(MTN.GNG/NG8/W/6, 36, 36/Rev.1), and of the drafting process of standards and certification systems (MTN.GNG/NG8/W/6, 37). It considered that in addition to notification/comments on rules of the certification systems, it was necessary to ensure transparency of the operation of the system in order to prevent the system from becoming an undue obstacle to international trade. Regarding standards and certification systems, Japan noted that these were notified to the parties after their drafting was complete. Japan said that it was desirable to allow representatives of foreign interests to have an opportunity to participate in the drafting process or to state their opinion during that process.

64. On behalf of the Nordic countries, Finland made certain proposals to improve transparency (MTN.GNG/NG8/W/43/Rev.1, and 75). These proposals, which overlapped with some of the aspects mentioned above, were based on a number of recommendations of the TBT Committee and addressed improvements in timing of notifications, functions of the enquiry points and responsibility for the notification procedures.²⁰

65. The EC proposed that the Agreement's disciplines pertaining to non-governmental standards bodies be enhanced, both at the national level and at the local level. For this purpose, it proposed a Code of Good Practice for Non-Governmental Standardizing Bodies as an annex to the Agreement (MTN.GNG/NG8/W/8).²¹ According to the EC, the aim of this proposal included making "*the obligations already laid down in Articles 4, 6 and 8 of the Agreement more concrete, and to provide some yardstick by which the performance of both Parties and private bodies could be measured*". The disciplines in the EC's initial proposal for the Agreement covered transparency, non-discriminatory treatment, possibility to comment in writing, efforts to rely on international standards for adopting technical regulations and standards, determining conformity, and operating certification systems (MTN.GNG/NG8/W/8). Subsequently, the EC provided a more detailed proposal on the Code in MTN.GNG/NG8/W/31, and clarified that acceptance of the Code by non-governmental bodies would be voluntary, subject to the Parties taking all practicable measures to ensure acceptance of and adherence to the Code by non-governmental standardization and certification bodies within their territory. It also suggested that the following aspects of transparency to be included in the Code of Good of Good Practice for Non-Governmental Standardizing Bodies:

"(1) Annual information would have to be available on a body's programme for the adoption of standards or technical regulations in the coming year, and on its adoption of international standards during the previous year;

(2) at least sixty days in advance, information would have to be available on any particular standard or technical regulation to be adopted, unless substantially the same as an international standard, as well as on a certification system to be introduced;

(3) whether this information should be made available at a national enquiry point, obtainable for interested Parties on request, or should be notified to other Parties via an international central point (such as ISONET) is to be investigated further;

(4) the full text of a proposed technical regulation, standard or certification system should be available upon request;

²⁰Complementarity was noted between the Nordic proposal on transparency and the proposal by the United States on improving transparency of standards-related agreements (MTN.GNG/NG8/W/34), and Japan's proposals on improving certain provisions of the Agreement on transparency (MTN.GNG/NG8/W/36 and 37).

²¹See also, MTN.GNG/NG8/W/31, 49 and 71. The EC suggested that the Code of Good Practice should cover standards as well as technical regulations and pre-standards.

(5) Technical regulations and standards which have been adopted should be published promptly in such a manner as to enable interested Parties to become acquainted with them. They should be made available upon request subject to the usual commercial terms and conditions."

66. The EC also made a proposal for extending the major obligations under the Agreement to local government bodies (MTN.GNG/NG8/W/8, 32). The EC proposed that there should be an increase in the level of responsibility of Parties for ensuring the adherence of local government bodies in their territory to the obligations of the Agreement, "*by obliging Parties to ensure that local government bodies do not violate these obligations One element the EEC considers especially important to include is a procedure by which a draft technical regulation of a local government body has to be notified through the Party concerned to other Parties, whenever its technical content is not substantially the same as the technical content of relevant international standards or a previously notified national technical regulation, and the draft technical regulation may have a significant effect on trade of other Parties. Comments in writing and discussion on such notified draft technical regulations should be possible through the Party concerned*" (MTN.GNG/NG8/W/32).

67. A number of these proposals covered aspects related to standards as well as certification systems, and addressed disciplines pertaining to different types of bodies, i.e. central government, local government and non-governmental bodies. Thus, the proposals by Japan, the United States and Nordic countries addressed certifications procedures also (MTN.GNG/NG8/W/1, 34, 34/Rev.3, and 35). The United States' proposal on transparency of standards-related Agreements suggested that in addition to arrangements on testing and inspection and laboratory accreditation, agreements on the harmonization or concordance of standards and regulations and the general issues of standards policy should be covered, including those concluded by the Parties with "*private bodies or systems or regional bodies or systems*" (MTN.GNG/NG8/W/34 and 34/Rev.3). The United States' proposal on regional standardization bodies addressed Articles 2, 9 and 10 of the Tokyo Round TBT Agreement, and suggested certain mandatory obligations for these bodies (MTN.GNG/NG8/W/35). Similarly, the proposals on increased transparency by Nordic countries included enhanced transparency of certification systems, of participation in international and regional standardizing bodies and certification systems, and of activities of relevant central government, local government or non-governmental bodies (MTN.GNG/NG8/W/43/Rev.1, and 75). Similarly, as mentioned above, the proposals by the EC covered standards-related aspects as well as determination of conformity and operating certification systems.

68. The discussion in the Committee showed diverse opinions on the proposals (see MTN.GNG/NG8/4, 6, 8, 10, 12, 16, 17 and 18). Based on the discussions, revised proposals were submitted by India with regard to voluntary draft standards (MTN.GNG/NG8/W/45), by Norway with regard to Article 10 (MTN.GNG/NG8/W/75), and by the EC with regard to the Code of Good Practice (MTN.GNG/NG8/W/49 and 71).²²

69. In its first revision of the proposal for a Code of Good Practice for Non-Governmental Standardizing Bodies (MTN.GNG/NG8/W/49), the EC covered non-governmental bodies at the regional, national and local levels, and suggested an amendment to Article 4 of the Agreement, to read as follows:

"Preparation, adoption and application of standards by non-governmental bodies

²²The Nordic delegations submitted a proposal on "terms and definitions for the specific purposes of the Agreement" (MTN.GNG/NG8/W/79), in which they provided definitions of, *inter alia*, international body or system, regional body or system, central government body, local government body, and non-governmental body.

4.1 *Parties shall take such reasonable measures as may be available to them to ensure that non-governmental standardizing bodies within their territory as well as non-governmental regional standardizing bodies of which one or more of their non-governmental standardizing bodies are member, accept and comply with the code of good practice for non-governmental standardizing bodies in Annex 4 to this Agreement. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging non-governmental standardizing bodies to act in a manner inconsistent with the code of good practice in Annex 4.*

4.2 *As soon as possible after a non-governmental standardizing body within their territory or a non-governmental regional standardizing body of which one or more of their non-governmental standardizing bodies are member, has accepted or withdrawn from the code of good practice in Annex 4, Parties shall notify other Parties through the GATT secretariat of this fact, except to the extent that the non-governmental regional standardizing body has fulfilled this obligation. The notification shall include the name and address of the body concerned and the products covered by its current and expected standardization activities."*

70. In addition, the EC suggested that the Committee take a Decision that "*... at least once a year [it would] review a list, drawn up by the GATT secretariat and sub-divided into separate sections for each Party, of the non-governmental standardizing bodies that have accepted the code of good practice in Annex 4, for the purpose of affording Parties the opportunity of consulting on any matters relating to the operation of that code.*" Further, the EC suggested that a recommendation to the Committee be made to establish under ISONET, a system through which all ISONET member bodies must transmit to the ISO Information Centre in Geneva the relevant information, and through which the ISO Information Centre in Geneva shall in turn promptly transmit the information received from one of its member bodies to all other member bodies.

71. Following further discussion of the various aspects regarding transparency and disciplines relating to standards, the EC again revised its proposal on the Code of Good Practice, but did not limit it to only non-governmental bodies (MTN.GNG/NG8/W/71). The proposal was for a Code of Good Conduct for the Preparation, Adoption and Application of Standards in the Agreement on Technical Barriers to Trade, covering central government bodies, local government bodies and regional governmental bodies producing standards, as well as the non-governmental bodies that were already covered in the EC's previous proposal. The disciplines on preparation, adoption and application of standards were to be separated from those relating to technical regulations, and all standardizing bodies, whether governmental or non-governmental, local, national or regional, were to be covered by the Code of Good Practice which, along with a proposed Article 4, provided the main disciplines for preparation, adoption and application of standards.²³ Under Article 4, first level of obligations, i.e. mandatory obligations, were proposed for central government bodies and second level of obligations, i.e. Parties taking "such reasonable measures as may be available to them to ensure", were proposed for local government, non-governmental and regional standardizing bodies.

72. In July 1990, the Chairman of the Negotiating Group presented a draft text of the Agreement, with his assessment of the sections of the Agreement on which there was broad convergence of views (MTN.GNG/NG8/W/83/Add.3). In his introductory note to the draft text, the Chairman stated that "... text in **bold** type represents areas of broad convergence without prejudging its final acceptance by any participant. However, it is necessary to note that, while there is a large majority supporting these issues, sometimes with different views, at least one delegation has opposed the inclusion of a Code of Good Practice for the preparation, adoption and application of standards ... The text appearing in

²³This also implied making accommodating changes to Articles 2 and 3 of the Tokyo Round TBT Agreement. See MTN.GNG/NG8/W/71.

normal type represents areas where there are divergences, sometimes fundamental, or where further work is needed." The relevant sections from that document are reproduced below.

"

Article 4

Preparation, adoption and application of standards

With respect to their central government bodies

4.1.1 Parties shall ensure that products imported from the territory of any other Party shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country in relation to such standards.

4.1.2 Parties shall ensure that standards are not prepared, adopted or applied with a view to creating obstacles to international trade. Parties shall likewise ensure that neither standards themselves nor their application have the effect of creating unnecessary obstacles to international trade. In so doing, Parties shall comply with the provisions of Article 2, sub-paragraphs 1.2.1 to 1.2.6.

4.2 Parties shall ensure that their central government standardizing bodies accept and comply with the code of good practice for the preparation, adoption and application of standards in Annex 4 to this Agreement. They shall take such reasonable measures as may be available to them to ensure that local government or non-governmental standardizing bodies within their territory as well as regional standardizing bodies of which they or one or more bodies within their territory are member, accept and comply with this code of good practice. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such standardizing bodies to act in a manner inconsistent with the code of good practice in Annex 4.

4.3 As soon as possible after a body mentioned in Article 4.2 has accepted or withdrawn from the code of good practice in Annex 4, Parties shall notify other Parties through the GATT secretariat of this fact, except, in the case of a regional body, to the extent that the regional body has itself fulfilled this obligation. The notification shall include the name and address of the body concerned and the products covered by its current and expected standardization activities.

Article 4bis

Whenever a Party has reached an agreement with any other party on issues related to standards and technical regulations (including processes and production methods) which may have a significant effect on trade, at least one Party to the agreement shall notify other Parties through the GATT secretariat of the products to be covered by the agreement and a brief description of the agreement. Parties concerned are encouraged to enter, upon request, into consultations with other Parties for the purpose of concluding similar agreements or of arranging for the participation in such agreements.

...

ANNEX 4

**CODE OF GOOD PRACTICE FOR THE PREPARATION,
ADOPTION AND APPLICATION OF STANDARDS**

GENERAL PROVISIONS

A. For the purposes of this code the definitions in Annex 1 of this Agreement shall apply.

B. This code is open to acceptance by any standardizing body within the territory of a Party to the GATT Agreement on Technical Barriers to Trade, whether a central government body, a local government body, or a non-governmental body; to any governmental regional standardizing body one or more members of which are Party to the above Agreement; and to any non-governmental regional standardizing body one or more members of which are situated within the territory of a Party to the above Agreement (hereafter collectively or individually called standardizing bodies).

C. Standardizing bodies shall notify their relevant central government authorities or, in the case of a regional body, those of their members, of the fact that they have accepted or withdrawn from this code. The notification shall include the name and address of the body concerned and the subject matter covered by its current and expected standardization activities. Regional standardizing bodies may alternatively make this notification directly to the GATT secretariat.

Standardizing bodies shall simultaneously make the same notification to the ISO Information Centre in Geneva. Standardizing bodies within the territory of a Party shall do this through the national member of ISONET, or in the absence thereof, directly. Regional standardizing bodies shall do this through an international affiliate of ISONET or through one or more national members of ISONET or, in the absence of both, directly.

SUBSTANTIVE PROVISIONS

D. Where international standards exist or their completion is imminent, standardizing bodies shall use them, or the relevant parts of them, as a basis for the standards they develop, except where such international standards or relevant parts are inappropriate for inter alia such reasons as the prevention of deceptive practices*; protection for human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological problems; and, in the case of developing countries, development, financial or trade needs.

***protection of competition**

E. With a view to harmonizing standards on as wide a basis as possible, standardizing bodies shall, in an appropriate way, play a full part within the limits of their resources in the preparation by relevant international standardizing bodies of international standards regarding subject matter for which they either have adopted, or expect to adopt, standards. For standardizing bodies within the territory of a Party, participation in a particular international standardization activity shall, whenever possible, take place through one delegation representing all standardizing

bodies in the national territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates.

F. Standardizing bodies shall make every effort towards the establishment of, and their association with, a member of ISONET on the national territory or the regional level and towards the acquisition by this member of the most advanced membership type possible.

G. Standardizing bodies within the territory of a Party shall make every effort to avoid duplication of or overlap with the work of other standardizing bodies on the national territory or with the work of regional standardizing bodies which covers the national territory. They shall also make every effort to achieve a national consensus on the standards they develop and on the comments they make under paragraph L.

H. Wherever appropriate, standardizing bodies shall specify standards in terms of performance rather than design or descriptive characteristics.

I. At least once every six months, standardizing bodies shall publish in a national or, as the case may be, regional publication of standardization activities a work programme containing their name and address, the standards they are currently preparing and the standards which they have adopted in the preceding period. A standard is under preparation from the moment a decision has been taken to develop a standard until that standard has been adopted.

The work programme shall for each standard indicate, in accordance with any ISONET rules, the classification relevant to the subject matter, the stage attained in the standard's development, and the references of any international standards taken as a basis. No later than at the time of publication of their work programmes, standardizing bodies shall notify the existence thereof to the ISO Information Centre in Geneva. Standardizing bodies within the territory of a Party shall do this through the national member of ISONET or, in the absence thereof, directly. Regional standardizing bodies shall make this notification through an international affiliate of ISONET or through one or more national members of ISONET or, in the absence of either, directly. The notification shall contain the name and address of the standardizing body, the period to which the work programme applies, its price (if any), and how and where it can be obtained.

J. Before adopting a standard, standardizing bodies shall hold a public enquiry of at least 60 days on the full text of the draft standard. No later than the start of this public enquiry, standardizing bodies shall publish a notice announcing the period of the public enquiry on the draft standard concerned in a national or, as the case may be, regional publication of standardization activities.

K. On the request of any interested party in a Party to the GATT Agreement on Technical Barriers to Trade, standardizing bodies shall provide a copy of a draft standard which they submitted to public enquiry. Standardizing bodies shall either send such copies themselves or have them sent by another body with which they have a contractual arrangement for this purpose. Such copies shall be sent by speedy means of delivery at the start of the public enquiry. If the request has been received during the public enquiry, as promptly as possible. For this service a reasonable fee may be charged, which shall, apart from the real costs of delivery, be the same for

domestic and foreign parties.

L. *Standardizing bodies shall take comments on their draft standards into account whenever those comments have been received during the period of public enquiry from standardizing bodies that have accepted this code of good practice*. Such comments shall be replied to as promptly as possible. Standardizing bodies shall make an objective effort to resolve dissenting viewpoints. Where such a comment contests a proposed deviation from an international standard, it is up to the standardizing body that has prepared the draft standard to explain why that deviation is necessary for a legitimate objective such as mentioned in paragraph D.*

**Standardizing bodies shall allow all interested parties in other Parties to make comments in writing, discuss these comments upon request, and take these written comments and results of the discussions into account.*

M. *Once the standard has been adopted, it shall be promptly published.*

N. *On the request of any interested party in a Party to the GATT Agreement on Technical Barriers to Trade, standardizing bodies shall promptly provide a copy of their most recent work programme or of a standard which they produced. Standardizing bodies shall either send copies themselves or have them sent by another body with which they have a contractual arrangement for this purpose. For this service a reasonable fee may be charged, which shall, apart from the real costs of delivery, be the same for foreign and domestic parties.*

O. *Standardizing bodies shall afford sympathetic consideration to and adequate opportunity for prompt consultation regarding complaints with respect to any of the good practices in this code whenever those complaints are made by standardizing bodies that have accepted this code of good practice. They shall make an objective effort to resolve such complaints.*

* * *

Companies established or incorporated in the territories of Parties shall be accorded the right of participation in regional bodies or systems in the same manner as it is accorded to any other companies participating in those bodies or systems."

73. By October 1990, the discussions resulted in agreement on the text of Article 4 and the Code of Good Practice, which was reflected in a draft of the Agreement circulated in MTN.GNG/NG8/W/83/Add.3/Rev.1. This text of Article 4 and the Code of Good Practice was the same as that in the Final Text of the WTO TBT Agreement.

74. The proposals on transparency by the Nordic countries, especially those contained in MTN.GNG/NG8/W/75, formed the basis for Article 10 in the Agreement.²⁴ Certain aspects of the United States' proposal on transparency of activities of regional standardizing bodies were incorporated in Article 10.7 of the Agreement.

(b) Testing, certification and conformity assessment

²⁴ See in particular the last part of the chapeau which states "as well as to provide the relevant documents", and Articles 10.1.4, 10.2, 10.3.3, 10.4, 10.10 and 10.11.

75. The issue of coverage with regard to conformity assessment includes the types of activities covered by "conformity assessment" and the nature of disciplines for different types of conformity assessment organizations (i.e. central or local government, or regional or non-governmental). This section summarizes the negotiating history of the disciplines regarding conformity assessment.²⁵

(i) Tokyo Round Negotiations

76. The Draft Standards Code (COM.IND/W/108; MTN/NTM/W/5) contained a number of provisions dealing with "conformity with standards" and "quality assurance systems". Section 8 of the proposed Code addressed conformity with voluntary standards (covering governmental and non-governmental bodies), section 10 dealt with quality assurance systems of central government bodies for assuring conformity with voluntary standards, section 12 dealt with systems operated by quality assurance bodies other than central government bodies for assuring conformity with voluntary standards, and section 15 dealt with international and regional quality assurance systems or arrangements for assuring conformity with voluntary standards. Of these, only Section 10 contained disciplines in terms of first level of obligations, while all the other sections had disciplines in terms of "adherents shall use all reasonable means within their power to ensure that". The Draft Standards Code defined quality assurance body as "an organization or person, governmental or non-governmental, independent of the producer or supplier, which provides assurances that products conform to the standards in question or information on which a decision as to conformity with the standards can be taken"; quality assurance system was defined as "a formal arrangement having its own rules of procedure and management under which one or more quality assurance bodies provide an assurance that products approved or certified under the system conform to the requirements of the standards in question".²⁶

77. In 1976 (MTN/NTM/W/37, page 9), the EC proposed an alternative text for Section 8, i.e.²⁷:

"(a) Adherents shall ensure that quality assurance bodies under the direct jurisdiction of central government shall comply with the provisions of Sections 5 and 6 as regard:

(i) their test methods and administrative procedures for determining conformity with voluntary standards, and;

(ii) the provision of assurances of conformity with voluntary standards, substituting the word 'voluntary' for 'mandatory' throughout and substituting 'Section 4' for 'Section 2' in Section 5(b).

(b) Adherents shall use all reasonable means within their power to ensure that other quality assurance bodies within their territories comply with the provisions of paragraph (a) above".

²⁵The previous section has already mentioned the proposals for enhanced transparency of different activities, including those related to conformity assessment. Among the proposals for enhanced transparency of certification systems were Japan's proposals for increased transparency of the operation of certification systems (MTN.GNG/NG8/W/6, 36, 36/Rev.1), and for increased transparency regarding the drafting process of standards and certification systems (MTN.GNG/NG8/W/6, 37).

²⁶The texts of the proposed Code that were circulated after MTN/NTM/W/71, did not include definitions of quality assurance or certification system or body.

²⁷A similar proposal for first level of obligations on central government certification bodies was made by the EC in 1977 (MTN/NTM/W/72, page 12).

78. In March 1976, the term "quality assurance" was changed to "certification" (MTN/NTM/W/38). A number of proposals were considered over time (see for example, MTN/NTM/W/37, 50, 72, 95, 120 and 151), and in 1978 a wide-ranging proposal was made for redrafting Sections 5 to 15 (MTN/NTM/W/176). This redraft combined technical regulations and standards in Section 5, which dealt with determination by central government bodies of conformity with technical regulations or standards. The proposed Section 6 dealt with determination by local government bodies and non-governmental bodies of conformity with technical regulations or standards. Certification systems operated by central government bodies were the subject of Section 7, Section 8 addressed certification systems operated by local government bodies and non-governmental bodies, and Section 9 covered international and regional certification systems.

79. First level of obligations were specified in Section 5, while Section 6 contained second level of obligations: the obligations in Section 5 were similar to those contained in Article 5 in the Tokyo Round TBT Agreement; the obligations in Section 6 were in terms of "shall use all reasonable means within their power to ensure". As mentioned above, the phrase in Section 6 that denoted best efforts was subsequently altered to "shall take such reasonable measures as may be available to them to ensure" (see paragraph 58 above). Also, similar to the changes made to Articles 3 and 4, a statement was added to Article 6 later that "Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with any of the provisions of Article 5" (MTN/NTM/W/192/Rev.4; see paragraph 58 above).

80. In MTN/NTM/W/176, the revised text of Section 7 (which addressed certification systems operated by central governmental bodies), contained first level of obligations for these bodies, and the nature of the obligations were similar to those contained in Article 7 of the Tokyo Round TBT Agreement. The main difference in comparison to the final text of the TBT Agreement was that the term "without discrimination" was not included in provisions that corresponded to the Tokyo Round Articles 7.3.3, 7.3.4, 7.4.2 and 7.4.3, and the meaning of access for suppliers was not provided. In December 1978, the meaning of "access for suppliers" was added in Article 7.2 and the term "without discrimination" was added in the provisions mentioned above (MTN/NTM/W/192/Rev.1 and Rev.2).

81. The text of Section 8 in MTN/NTM/W/176 had two paragraphs of which the second contained the same obligations as in Article 8.2 of the Tokyo Round TBT Agreement. Section 8 stated:

- "(a) Adherents shall use all reasonable means within their power to ensure that local government and non-governmental bodies within their territories when operating certification systems comply with the provisions of Section 7.*
- (b) Adherents shall ensure that their central government bodies rely on certification systems operated by local government or non-governmental bodies only to the extent that these bodies and systems comply with the relevant provisions of Section 7".*

In Article 8.1, the obligations with regard to information to be provided through the Parties was included in the text presented in March 1979 (MTN/NTM/W/192/Rev.4)²⁸.

²⁸The relevant part of the text stated that " ... noting that the provision of information referred to in Articles 7.3.3 and 7.4.2, the notification referred to in Article 7.4.1, and the comment and discussion referred to in Article 7.4.3, shall be through Parties."

82. Section 9 in MTN/NTM/W/176 contained two paragraphs, the first being similar to Article 9.1 of the Tokyo Round Code. The second paragraph stated that:

"Adherents shall use all reasonable means within their power to ensure that international and regional certification systems and bodies, in which relevant bodies within their territories are members or participants comply with the provisions of Section 7".

Discussions continued on the sections dealing with certification systems operated by central government bodies, and international and regional certification systems, and Articles 9.3 and 9.4 were added to the Article on international and regional certification systems in December 1978 (MTN/NTM/W/192/Rev.1).

(ii) Uruguay Round Negotiations

83. Disciplines on conformity assessment of standards are provided mainly in Articles 5-9 of the Uruguay Round TBT Agreement. This section first summarizes the developments regarding the different types of conformity assessment activities for which disciplines were proposed in the Uruguay Round. Then, the nature of the disciplines on different types of organizations will be addressed.

Types of activities covered by conformity assessment

84. In the area of conformity assessment of standards, the Tokyo Round TBT Agreement covered disciplines mainly with respect to testing and certification. Negotiators in the Uruguay Round extended the coverage of the activities to also include inspection and product approval. In the early phase of the negotiations, the United States submitted proposals on "testing, inspection and type approval" and on procedures for issuing product approval (MTN.GNG/NG8/W/1 and 23). The discussion of these proposals focused, *inter alia*, on types of activities and bodies subject to disciplines, the nature of disciplines imposed on different bodies, practicality of relying on impartial technical experts for each approval, relevant time limits, and the importance of dealing with testing and inspection along with product approval. It was also emphasized that there should be reference to internationally accepted criteria for the operation of approval bodies and that progress in this area in other fora should be taken into account (see MTN.GNG/NG8/4, 6, 8, 10, 12, 16, 17 and 18).

85. The Nordic countries proposed to develop and strengthen the provisions on testing and certification "by adding an obligation to use internationally agreed recommendations in national and regional testing, inspection and certification activities, as well as by clarifying some of the present provisions of the Agreement" (MTN.GNG/NG8/W/15/Add.1). Their proposals regarding testing procedures and inspection procedures incorporated these aspects (MTN.GNG/NG8/W/41 and 42), and the proposal on inspection procedures also addressed other issues such as definition and scope of certain terms²⁹, transparency, non-discriminatory treatment, simplified procedures and administrative mechanisms which would not cause undue delay or create obstacles to international trade, and reciprocal recognition of inspection results.³⁰ In addition, the Nordic proposal on inspection procedures included disciplines with regard to the activities of local government and non-governmental bodies (see below).

²⁹These were "inspection", "inspection body" and "inspection method".

³⁰In MTN.GNG/NG8/W/58, New Zealand stated that its proposal regarding PPMs was complementary to the Nordic countries' proposal on testing and inspection procedures. See Section III for more detail on the proposal by New Zealand.

86. The discussions resulted in revised and consolidated proposals on different aspects of conformity assessment. The United States made a revised proposal on product approval (MTN.GNG/NG8/W/52/Rev.1; see also paragraph 139 below), and presented a proposal on systems for the accreditation or approval of testing laboratories, inspection or quality systems registration bodies (MTN.GNG/NG8/W/60). It noted that the latter proposal was complementary to previous proposals on testing, inspection and approval procedures, paralleled the provisions on certification in the Tokyo Round TBT Agreement, and some of the proposed text had its origin in other proposals made during the negotiations.

87. The Nordic countries presented a revised, combined proposal on "Testing and Inspection Procedures" (MTN.GNG/NG8/W/50; see also paragraph 139 below). This proposal addressed Article 5, and defined certain relevant terms: "evaluation of conformity" was defined as "systematic examination of the capability of a product, process or service to meet specified requirements"; "testing" was defined as "evaluation of conformity by measurement or analysis of one or more characteristics of a given product, process or service according to a specified procedure"; and "inspection" was defined as "evaluation of conformity by other means than testing (e.g. by visual checks)".

88. Subsequently, Canada proposed disciplines on certification systems (MTN.GNG/NG8/W/69), focusing on improving the operation, transparency and mutual recognition of product certification systems under the Agreement. The proposal suggested amending the title of the Article to "Assurance of Conformity with Technical Regulations or Standards" and adding provisions on operation of certification systems in parallel with those applying to procedures for evaluating conformity with technical regulations and standards (e.g. testing) in Article 5 as appropriate; replacing references to "self certification" with "declaration of conformity" in Article 5.2; incorporating the principle of encouraging mutual recognition of certification through acceptance of products certified by bodies accredited under relevant international guidelines and standards; expanding provisions of the Agreement to ensure transparency of certification procedures; and integrating provisions on certification and other conformity assurance methods in the Agreement, e.g. by including Article 9 on regional and international certification systems under the Article suggested by Canada.

89. In view of the various aspects covered under the different proposals, the EC presented a proposal on conformity assessment procedures which was more comprehensive in its coverage of different activities (MTN.GNG/NG8/W/72). In that proposal, "conformity assessment procedure" was defined as:

"any technical procedure used, directly or indirectly, to give positive assurance that a product conforms with the applicable technical regulations or standards"

An explanatory note stated: *"For the purposes of this Agreement, possible conformity assessment procedures or elements thereof are, inter alia, a manufacturer's declaration of conformity regarding the product or the quality assurance system used; the submission or availability of information regarding the product or the quality assurance system used; testing or inspection of the product or the quality system used; certification of the product or registration of the quality assurance system used; application of a mark of conformity; accreditation of testing laboratories, inspection bodies, or certification bodies; type approval, lot approval or unit approval of the product or approval of the quality assurance system used; good manufacturing practices; good laboratory practices; good clinical practices"*.

90. For Article 5, the EC's proposal suggested revised disciplines similar to those which were included in the final text of the WTO TBT Agreement. The proposal also included suggestions

pertaining to conformity assessment procedures operated by local government bodies and non-governmental bodies, mutual recognition agreements concerning conformity assessment procedures, and certain amendments to Article 10.

91. The draft of the Agreement presented by the Chairman of the Negotiating Group in July 1990 (MTN.GNG/NG8/W/83/Add.3) showed that there was "broad convergence of views" on Article 5, except for the following provisions:

"5.1.3 any requirements for conformity assessment procedures of individual specimens of a product shall be limited to what is reasonable and necessary;

5.1.4 approval authorities shall make their approval decisions on the basis of sound technical evidence;

...

5.1.8 the confidentiality of information about imported products arising from or supplied in connection with such conformity assessment procedures shall be respected in the same way as for domestic products in such a way that legitimate commercial interests are protected".

However, convergence of views had not been reached for the definition of conformity assessment procedures, for provisions relating to recognition of conformity assessment (Article 6), or for procedures for assessment of conformity by local government and non-governmental bodies (Article 7). The draft provided two alternative definitions of conformity assessment procedures, one suggested by the Nordic delegations (based on the ISO/IEC definitions)³¹, and the other the definition provided in the EC's proposal on conformity assessment procedures. These were:

"Conformity assessment procedure

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Note: Conformity assessment procedures include inter alia procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

Conformity assessment procedure

Any technical procedure used, directly or indirectly, to give positive assurance that a product conforms with the applicable technical regulations or standards.

Explanatory note:

For the purposes of this Agreement, possible conformity assessment procedures or elements thereof are, inter alia, a manufacturer's declaration of conformity regarding the product or the quality assurance system used; the submission or availability of information regarding the product or the quality assurance system used; testing or inspection of the product or the quality system used; certification of the product or registration of the quality assurance system used; application of a mark of

³¹See MTN.GNG/NG8/W/79. The draft amendments made to the relevant definitions in the ISO/IEC Guide 2 were reproduced in the Appendix to MTN.GNG/NG8/W/79.

conformity; accreditation of testing laboratories, inspection bodies, or certification bodies; type approval, lot approval or unit approval of the product or approval of the quality assurance system used; good manufacturing practices; good laboratory practices; good clinical practices."

92. The former definition was adopted for the final text of the WTO TBT Agreement. Incorporating conformity assessment in the Agreement meant that the two separate sections on testing and certification in the Tokyo Round TBT Agreement were combined under conformity assessment. Hence, accommodating changes had to be made in other parts of the Agreement, for example in Article 9.

Disciplines on different types of bodies involved with conformity assessment

93. Some of the proposals mentioned above specifically addressed disciplines on conformity assessment by local, non-governmental or regional bodies. For example, the EC's proposals on Code of Good Practice for non-governmental bodies and for extending obligations to local governmental bodies addressed Articles 3, 6 and 8 of the Agreement and included conformity and operation of certification systems in their scope. The coverage of the Code of Good Practice was defined by the EC to include "*also the determination of conformity and the operation of certification systems*" (MTN.GNG/NG8/W/31, page 2), and the EC emphasized "*the link with the other two elements to follow, namely local government bodies and testing and certification activities. Any definitive evaluation should, therefore, be made on the basis of all three elements together*" (MTN.GNG/NG8/W/49, page 2). The previous section summarized the developments regarding the discussion on the EC's proposals on Code of Good Practice and on the United States' proposals on regional standards and certification systems and on transparency regarding standards-related agreements. This section focuses on the other proposals on conformity assessment activities which contained specific provisions relating to bodies other than central government bodies.

94. The Nordic proposal on inspection procedures included disciplines with regard to the inspection service performed by local government and non-governmental bodies, and stated that "*Parties shall take such reasonable measures as may be available to them to ensure that local government bodies and non-governmental bodies within their territories comply with the above provisions concerning inspection procedures. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with any of the above provisions concerning inspection procedures*" (MTN.GNG/NG8/W/42, page 3).

95. Similarly, the United States' proposal on systems for the accreditation or approval of testing laboratories, inspection or quality systems registration bodies (MTN.GNG/NG8/W/60), included the following provisions:

"8.1 Parties shall take such reasonable measures as may be available to them to ensure that local government bodies and non-governmental bodies within their territories when operating systems for the accreditation or approval of testing laboratories, inspection or quality system registration bodies comply with the provisions of Article 7, except paragraph 4, sub-paragraph 2, noting that the provision of information referred to in Article 7, paragraph 4, sub-paragraph 3 and paragraph 4, sub-paragraph 2, the notification referred to in Article 7, paragraph 5, sub-paragraph 1, and the comment and discussion referred to in Article 7, paragraph 5, sub-paragraph 3, shall be through Parties. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with any of the provisions of

Article 7.

8.2 *Parties shall ensure that their central government bodies rely on systems for the accreditation or approval of testing laboratories, inspection or quality system registration bodies operated by local government and non-governmental bodies only to the extent that these bodies and systems comply with the relevant provisions of Article 7".*

An accommodating change was suggested in Article 5.2, by replacing the text of that Article by the following text:

"Parties shall ensure, whenever possible, that their central government bodies accept testing and inspection results, certificates or marks of conformity issued by relevant bodies in the territories of other Parties; or rely upon declaration of conformity by producers in the territories of other Parties even when the testing and inspection methods differ from their own, provided that the relevant body has been accredited or approved under (New) Articles 7 or 8, or provided they are otherwise satisfied that the methods employed in the territory of the exporting Party provide a sufficient means of evaluating conformity with the relevant requirements. It is recognized that prior consultations may be necessary in order to arrive at a mutually satisfactory understanding regarding declaration of conformity, testing and inspection methods and results, and certificates or marks of conformity employed in the territory of the exporting Party, in particular in the case of perishable products or of other products which are liable to deteriorate in transit".

96. The EC's proposal on conformity assessment (MTN.GNG/NG8/W/72) contained the following Article on disciplines with regard to local government bodies and non-governmental bodies³²:

7.1 *Parties shall take such reasonable measures as may be available to them to ensure that local government bodies and non-governmental bodies within their territories which operate conformity assessment procedures, as well as non-governmental regional bodies which operate conformity assessment procedures and of which one or more of their non-governmental bodies are member, comply with the provisions of Article 5, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging local government bodies or non-governmental bodies operating conformity assessment procedures to act in a manner inconsistent with any of the provisions of Article 5.*

7.2 *Parties shall ensure that their central government bodies rely on conformity assessment procedures operated by non-governmental bodies or local government bodies only if these latter bodies comply with the provisions of*

³²In May 1990, Canada proposed amendments to Article 2.1 of the Tokyo Round Agreement (MTN.GNG/NG8/W/77), noting that its proposal was linked to some other proposals, notably the EC proposal on conformity assessment procedures which suggested the need to take risk into account, and the Nordic proposal on different types of technical regulations and standards. Amendments to Article 2.1 were sought by incorporating the principles of proportionality and degressive application of technical regulations and standards. Canada stated that while the proposed amendments applied "to central government bodies, the additional obligations would also apply to local government and non-governmental bodies under the relevant provisions of Articles 3 and 4 [of the Tokyo Round Agreement]". The main focus of the proposal was to ensure national treatment and most favoured nation treatment, that technical regulations and standards or their application do not result in unnecessary obstacles to trade, technical regulations and standards are based on acceptable degree of risk and do not contain requirements higher than necessary to meet the objectives, that they are not maintained if the circumstances giving rise to their adoption cease to exist or if the changed circumstances can be addressed in a less trade-restrictive manner, and that they are not applied in a way that affects products originating from (or destined for) areas where the problem does not exist.

Article 5, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1."

97. The draft of the Agreement presented by the Chairman of the Group in July 1990 showed that there was no agreement on the provisions relating to procedures for assessment of conformity by local government and non-governmental bodies (MTN.GNG/NG8/W/83/Add.3). A number of alternative proposals were included in the Chairman's draft, namely:

"7.1 Parties shall take such reasonable measures as may be available to them to ensure that local government bodies and non-governmental bodies within their territories which operate conformity assessment procedures, as well as regional bodies which operate conformity assessment procedures and of which one or more of their bodies are member, comply with the provisions of Article 5, with the exception of Article 5, paragraph 2, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1. In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies operating conformity assessment procedures to act in a manner inconsistent with any of the provisions of Article 5.

7.2 Parties shall ensure that their central government bodies rely on conformity assessment procedures operated by non-governmental bodies or local government bodies only if these latter bodies comply with the provisions of Article 5, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1.

* * *

7.1 Parties shall ensure that local government bodies within their territories comply with the provisions of Articles 5 and 6, noting that:

7.1.1 Notification shall not be required in cases where a local government body acts only as a sub-contractor for a central government body; and

7.1.2 Contacts with other Parties referred to in Article 5, paragraphs 5 and 6, shall take place through the Party concerned.

(Proposal by Nordic countries of 18 July 1990)

7.2 Parties shall take such reasonable measures as may be available to them to ensure that non-governmental bodies within their territories which operate conformity assessment procedures, comply with the provisions of Articles 5 and 6, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1. In addition, Parties shall not take measures which have the effect of, directly or indirectly requiring or encouraging such bodies to act in a manner inconsistent with the provisions of Articles 5 and 6.

7.3 Parties shall ensure that their central government bodies rely on conformity assessment procedures operated by local government bodies or non-governmental bodies only if these latter bodies comply with the provisions of Articles 5 and 6, with the exception of Article 5, paragraph 5, sub-paragraph 2, and Article 5, paragraph 6, sub-paragraph 1.

* * *

7.1 *Parties shall take such reasonable measures as may be available to them to ensure that local government and non-governmental bodies within their territories which operate conformity assessment procedures comply with the provisions of Article 5, with the exception of notification requirements (5.5.2 and 5.6.1). In addition, Parties shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such bodies to act in a manner inconsistent with any of the provisions of Article 5 (and 6).*

7.2 *Parties shall ensure that their central government bodies rely on conformity assessment procedures operated by local government and non-governmental bodies only if these bodies comply with the provisions of Article 5, with the exception of notification requirements (Articles ... ; ...)"*.

98. Subsequent discussions resulted in a separation of the provisions relating to conformity assessment by local government bodies (Article 7 of the revised text which was circulated in MTN.GNG/NG8/W/83/Add.3/Rev.1) and those relating to conformity assessment by non-governmental bodies (Article 8 of the revised text). The revised text showed that there was agreement on Article 8, but not on Article 7 which addressed local government bodies. Two options were provided for Article 7 in MTN.GNG/NG8/W/83/Add.3/Rev.1, one in terms of first level of obligation and the other in terms of "best efforts" obligation. This issue was linked with the disciplines on preparation, adoption and application of technical regulations by local government bodies and non-governmental bodies (i.e. Article 3). Further discussion resulted in agreement on disciplines under Article 7 being reached in terms of "shall take such reasonable measures as may be available to them to ensure compliance".

99. The discussion on international and regional conformity assessment addressed the extension of the coverage of activities subject to disciplines under the Agreement, and the points raised in the United States proposal on regional bodies and Canada's proposal on disciplines for certification systems (MTN.GNG/NG8/W/35 and 69).³³ The draft of the Agreement presented by the Chairman of the Group in July 1990 (MTN.GNG/NG8/W/83/Add.3) showed that there was broad agreement on the first two paragraphs of the Article (shown in bold print), but not on the other paragraphs. The text of the Article in the draft text presented by the Chairman was as follows:

"Article 8

International and regional systems

8.1 *Where a positive assurance of conformity with a technical regulation or standard is required, Parties shall, wherever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein.*

8.2 *Parties shall take such reasonable measures as may be available to them to ensure that international and regional systems for conformity assessment in which relevant bodies within their territories are members or participants comply with the provisions of Article 5, with the exception of paragraph 1, sub-paragraph 1, having regard to the provisions of Article 8, paragraph 3. In addition, Parties shall not take any measures which have the effect of, directly or indirectly, requiring or encouraging such systems to act in a manner inconsistent with any of the provisions of Article 5.*

³³As discussed in the previous section, a number of aspects of the United States' proposal were incorporated in Articles 4 and 10 of the Agreement.

8.3 *Parties shall take such reasonable measures as may be available to them to ensure that international and regional systems for product certification and guides for certification bodies in which relevant bodies within their territories are members or participants, are formulated and applied so as to grant access for suppliers of like products originating in the territories of other Parties, under conditions no less favourable than those accorded to suppliers of like products originating in a member country, a participant country or in any other country, including the determination that such suppliers are able and willing to fulfil the requirements of the system. Access for suppliers is obtaining certification from an importing Party which is a member of or participant in the system, or from a body authorized by the system to grant certification, under the rules of the system. Access for suppliers also includes receiving the mark of the system, if any, under conditions no less favourable than those accorded to suppliers of like products originating in a member country or a participant country.*

8.4 *Parties shall ensure that their central government bodies rely on international or regional systems for certification of products and guides for certification bodies only to the extent that the systems and guides comply with the provisions of Article 5 and Article 8, paragraph 3.*

8.4 *Parties shall ensure that their central government bodies rely on international or regional conformity assessment systems only to the extent that these systems comply with the provisions of Articles 5 and 6, as applicable".*

100. The draft text suggested first level of obligations with regard to the reliance on international and regional conformity assessment systems by central government bodies, and second level of obligations on members with regard to international and regional systems for conformity assessment in which relevant bodies within their territories were members or participants. Two alternative texts were provided for Article 8.4.

101. Article 8.3 suggested in the Chairman's draft text was mentioned in Article 8.2 and in the first alternative text suggested for Article 8.4. Subsequent discussion resulted in deletion of Article 8.3 suggested in the Chairman's draft (see MTN.GNG/NG8/W/83/Add.3/Rev.1). Thus, the second alternative text for Article 8.4 was selected, and reference to Article 8.3 was dropped in the text of Article 8.2 of the Chairman's draft. Instead a reference to Article 6 (which addresses recognition of conformity assessment by central government bodies) was included; the second alternative text suggested for Article 8.4 already contained a reference to both Articles 5 and 6.³⁴

102. The separation of the provisions relating to conformity assessment by local government bodies and by non-governmental bodies into Articles 7 and 8 (see paragraph 98 above) meant that the Article dealing with international and regional systems became Article 9 (see MTN.GNG/NG8/W/83/Add.3/Rev.1). The disciplines with the revisions mentioned above were incorporated in the final text of the WTO TBT Agreement.

III. PROCESSES AND PRODUCTION METHODS (PPMS)

The Tokyo Round Negotiations and discussions of PPMs in the context of Article 14.25 of the Agreement

³⁴Article 6 was given in normal type in the Chairman's draft text (i.e. MTN.GNG/NG8/W/83/Add.3), showing divergence of views and the need for further work on this provision.

103. The Tokyo Round TBT Agreement defines the terms "Technical Regulation" and "Standard" solely in terms of product characteristics. Article 14.25 of the Agreement is the only provision containing a reference to PPMs.

104. At the request of the TBT Committee in June 1980 (TBT/M/3), the Secretariat prepared a factual (Tokyo Round) negotiating history of the definition of the term "Technical Specification" and of the provisions of Article 14.25 of the TBT Agreement inasmuch as the issue of PPMs was concerned. The substantive parts of that document (TBT/W/15) are reproduced in paragraphs 105-111 below.

105. In May 1975, the Sub-Group "Technical Barriers to Trade" agreed that the text drawn up in the pre-negotiating period should be used as a basis for its work. At that point PPMs were excluded from the scope of the draft Code by virtue of the definition of the term "standard", which read as follows:

"The term "standard" means any specification which lays down some or all of the properties of a product in terms of quality, purity, nutritional value, performance, dimensions, or other characteristics. It includes, where applicable, test methods, and specifications concerning testing, packaging, marking or labelling to the extent that they affect products rather than processes. It excludes standards which are prepared for use by a single enterprise, whether governmental, semi-governmental or non-governmental, either for its own production or purchasing purposes." (MTN/NTM/W/5).

106. In September/October 1975, based on the work of ISO/ECE the definition of the term "technical specification" in the draft Code was changed to include *"processes, conditions of growth, and production methods, which must be met to ensure health and safety"* (MTN/NTM/W/25). However, in January/February 1976, this reference was removed, so that the term technical specification was defined as:

"A document which lays down characteristics of a product such as levels of quality, performance, safety, or dimensions. It may include, or deal exclusively with, terminology, symbols, testing and test methods, packaging, marking or labelling requirements." (MTN/NTM/W/38).

107. Discussion of the issue continued and a proposal was made by the United States to modify the definition by the addition of the following language:

"For the purpose of this Code "technical specifications" includes processes and production methods, [which must be met to ensure health and safety"], [insofar as they are necessary to achieve the final product desired.]" [insofar as they affect the characteristics of the final product.]" (MTN/NTM/W/37)

At the meeting in May 1976, further discussion led to the removal of the square brackets so that the proposal read:

"For the purposes of this Code "technical specifications" includes processes and production methods insofar as they are necessary to achieve the final product desired." (MTN/NTM/W/50)

108. In March 1977 Group "Agriculture" initiated its review of the applicability of the draft Code to agricultural products. One point made in the discussion was that "appropriate definitions would need to be included if it is decided that the Code should also cover processing and production methods" (MTN/AG/W/21).

109. At its meeting of March 1977 the Sub-Group "Technical Barriers to Trade" agreed on a text of the definitions for inclusion in the Draft Code (MTN/NTM/31). All reference to PPMs had been dropped again. The discussion of the definitions had been complex and controversial and no delegation wished to re-open them after this stage. The following definition of the term "technical specification" was therefore carried forward unchanged through successive drafts into the text of the Agreement itself. It reads:

"A specification contained in a document which lays down characteristics of a product such as levels of quality, performance, safety or dimensions. It may include, or deal exclusively with terminology, symbols, testing and test methods, packaging, marking or labelling requirements as they apply to a product.

Explanatory note:

This Agreement deals only with technical specifications relating to products. Thus the wording of the corresponding Economic Commission for Europe/International Organization for Standardization definition is amended in order to exclude services and codes of practice."

110. Further discussion of PPMs continued under the heading "scope of the Code" and at its meeting of September 1977, the Sub-Group considered a proposal by the United States that "processes and production methods should be subject to the provisions of the Code when they are directly related to the characteristics of a product" (MTN/NTM/W/95) and "agreed that a way should be found of ensuring that obligations under the Code are not circumvented by the drafting of technical specifications in terms of processes and production methods rather than in terms of the characteristics or performance of products." (MTN/NTM/W/120)

111. At the meeting of March 1979 the Nordic countries proposed that:

"the enforcement provisions could be invoked in cases where an adherent considers that obligations under the Code are being circumvented by the drafting of technical specifications in terms of processes and production methods rather than in terms of characteristics of products." (MTN/NTM/W/151)

During the autumn of 1978 the text of the Draft Code was simplified and revised. The first proposal for a revised text incorporated this proposal with one or two minor changes (MTN/NTM/W/192, Add.2). In December 1978, a number of changes were introduced to make the draft Code applicable to agricultural products but these did not modify the text of this paragraph in any significant way. The text was therefore carried forward into the Agreement as Article 14.25, which reads:

"The dispute settlement procedures set out above can be invoked in cases where a Party considers that obligations under this Agreement are being circumvented by the drafting of requirements in terms of processes and production methods rather than in terms of characteristics of products."

112. At its meetings in 1980-81 (TBT/M/4, 5, 6 and 7), the Committee examined the "Applicability of the Agreement to Processes and Production Methods". The discussions showed a divergence of views among Committee Members.³⁵

113. One view was that Article 14.25 had been aimed at finding a way to subject technical

³⁵The discussions in the Committee on this issue were given added focus by specific PPM-related issues brought before the Committee, e.g., the United Kingdom requirement for spin-chilling of poultry (see TBT/Spec/4 and 5).

specifications drafted in terms of PPMs to all of the basic objectives of the Agreement. PPMs had not been explicitly covered in its other provisions since several participants in the negotiations had not wanted to subject them to all of the Agreement's procedural requirements. Proposals made during the negotiations that would have specified those provisions of the Agreement to which PPMs would be subject had not been pressed on the understanding that complaints could be brought under Article 14.25 of the Agreement whenever trading problems resulted from PPMs, without limitation to the nature of the problem. Any interpretation of Article 14.25 that was restrictive and would limit Parties from complaining about substantive problems deriving from PPMs, such as discrimination in the application of a PPM-based measure, would be contrary to that understanding. It would also reduce the utility of the Agreement, particularly (although not solely) as it applied to trade in agricultural products. An elaboration of this point of view was circulated by the United States in TBT/W/24, along with an "Illustrative List of Processes and Production Methods" (TBT/W/33) and a "Definition and Case Studies" (TBT/W/46).

114. Another view was that measures based on PPMs were not covered directly by the substantive or the procedural provisions of the Agreement. Article 14.25 applied only if there was a deliberate attempt to escape or circumvent obligations under the Agreement by drafting requirements in terms of PPMs rather than product characteristics. The definitions in the Agreement referred only to product characteristics, and the Agreement therefore did not apply to PPMs except if they were used to circumvent its obligations. Certain proposals would have given more explicit recognition to the applicability of the Agreement to PPMs, but those proposals had not been accepted. It had been suggested at the time that if PPMs were to be covered by the Agreement, appropriate definitions would need to be inserted (MTN/AG/W/21). Since no such definitions had been included and no amendments to existing definitions had been made, it was clear that the Agreement did not cover PPMs.

115. At its meeting in June 1981 (TBT/M/7), the Committee noted that no consensus had been reached on the question of the applicability of the Agreement to PPMs, but in order to allow for an exchange of information on this subject the Committee took the following decision:

"Delegations may make submissions to the Committee relating to PPMs that might create unnecessary obstacles to trade, which will be circulated to the Committee but not consolidated into a single document in the form of an inventory. Delegations should also be free to submit any relevant working documents and case studies of how the Agreement's coverage of PPMs could lead to the elimination of trade barriers. The secretariat will follow normal practice in circulating any documents submitted by Parties on the subject." (TBT/16/Rev.8, paragraph H).

116. In September 1982, during preparations for the first three-year review of the operation and implementation of the Agreement, the United States proposed that the Committee should establish a working party to examine the subject of the Agreement's coverage of PPMs with the aim of arriving at a consensus interpretation (TBT/12). The proposal received support from some Committee Members, but others expressed various reservations about the usefulness of such an exercise, among them the view that PPMs were not covered by the Agreement and the issue therefore did not fall within the competence of the Committee and the view that the issue was not one of interpretation of the Agreement but rather of extension of its coverage (TBT/M/11,12,13).

117. Following informal consultations, at its meeting in October 1983 the Committee concluded on the functioning of Article 14.25 of the Agreement:

"The Committee recognizes that there are differences of views among Parties in respect to Article 14.25 In this context, where a Party considers that obligations under the Agreement are being circumvented by the drafting of requirements in terms of processes and production methods rather than in terms of characteristics of products, the Parties agree to cooperate in the process of dispute settlement." (TBT/M/14)

Further discussion in the Tokyo Round TBT Committee

118. The issue of PPMs arose again in 1988 in connection with the Committee's work on updating the definitions used in the Agreement in the light of the fifth edition of the ISO/IEC Guide 2 (1986). The Committee considered a Nordic proposal to update the definitions in such a way that the substance of the Agreement remained untouched (TBT/W/103), *inter alia* by amending the "Explanatory note" attached to the definition of a "Technical Specification" in the Agreement as follows:

"This Agreement deals only with technical specifications relating to products. Thus the wording of the corresponding Economic Commission for Europe/International Organization for Standardization definition is amended in order to exclude ~~services and codes of practice~~ **processes and services**".

Several Members of the Committee felt that this could amount to a substantive change to the Agreement, since although the ISO/IEC Guide contained a definition of the term "code of practice" neither that Guide nor the TBT Agreement contained a definition of the term "processes". They therefore expressed doubts about the interchangeability of the two terms. The Committee agreed to postpone further discussion of this proposal until after discussions had been held on the issue of PPMs raised in relation to the improvement, clarification and expansion of the Agreement in the context of the Uruguay Round negotiations (TBT/M/27 and 28).

The Uruguay Round Negotiations

119. At the first meeting of the Negotiating Group on MTN Agreements and Arrangements (NG8) in March 1987, the United States proposed negotiations aimed *inter alia* at clarifying the TBT Agreement's coverage in relation to PPMs (MTN.GNG/NG8/W/1 and NG8/1). As mentioned above, the bulk of the subsequent discussion on the issue took place in the TBT Committee, which reported regularly to NG8 where the changes to the Agreement were formally negotiated.

120. In February 1988 the United States presented a draft proposal to amend the definition of the term "Technical Specification" and to amend Article 14.25 of the Agreement (MTN.GNG/NG8/W/24)³⁶:

Technical Specification

A specification contained in a document which lays down characteristics of a product such as levels of performance, quality, safety or dimensions. It may include, or deal exclusively with terminology, symbols, testing and test methods, packaging, marking or labelling requirements, processes, conditions of growth and production methods.

Article 14.25

The dispute procedures set out above can be invoked in cases where a Party considers that benefits under this Agreement are being nullified or impaired by the drafting of requirements in terms of processes and production methods rather than in terms of characteristics of

³⁶ As mentioned earlier, all proposals made to the NG8 relating to the renegotiation of the Agreement were issued concurrently as TBT documents.

products."

121. The United States said its proposal would extend all major disciplines in the Agreement to technical specifications based on PPMs. Lack of full coverage of PPMs seriously weakened the effectiveness of the Agreement by excluding a growing body of regulations from its disciplines. The intention was not to discourage the use of PPMs but rather to eliminate potential trade barriers to both industrial and agricultural trade posed by PPM-based requirements. Full extension of the provisions of the Agreement to PPM-based requirements would strengthen the Agreement and make it more effective in reducing arbitrary or unnecessary technical barriers to trade (MTN.GNG/NG8/6). In the TBT Committee the United States clarified its proposal further, noting that in due course it would be necessary to address the question of the definition of the term "PPM", that an alternative to amending Article 14.25 would be to delete it altogether, and that the purpose was not to establish a preference for technical specifications drafted in terms of product characteristics as opposed to those drafted in terms of PPMs (TBT/M/27).

122. In commenting on the US proposal (MTN.GNG/NG8/6 and 8, TBT/M/28 and 29), some participants expressed concerns about the feasibility and desirability of making national requirements based on PPMs mandatory in international trade. However, a good deal of support was expressed for extending the coverage of the TBT Agreement to ensure that PPM-based measures did not cause unnecessary barriers to trade. Many felt that if a Party chose to base a requirement on PPMs rather than on product characteristics in order to achieve a particular objective, and if this constituted a technical barrier to trade, then the PPM-based requirement should be subject to the provisions of the Agreement.

123. There was a widely held view that Article 14.25 did not provide a suitable basis for pursuing further the extension of the coverage of the Agreement to include PPM-based measures. It was noted that its operation had proved unsatisfactory because of lack of agreement among Parties on its application. Some participants felt that the issue of circumvention of the obligations of the Agreement through the use of PPM-based measures was secondary to the need to spell out clearly the application of the substantive provisions of the Agreement to PPMs. Some felt also that maintaining this provision might imply the establishment of a hierarchy, under which requirements drafted in terms of PPMs were to be used only in residual cases when the use of requirements drafted in terms of product characteristics were not feasible.

124. There was more support for the approach suggested in the US proposal to change the definition of "Technical Specification", although some participants doubted that this alone would be sufficient to extend the provisions of the Agreement satisfactorily to PPMs. In particular, they felt that separate conformity assessment provisions would be needed to ensure that determination of conformity with PPM-based measures did not in itself cause unnecessary trade restriction. Some felt also that the Agreement should accommodate the use of PPM-based measures only in exceptional cases, where requirements drafted in terms of product characteristics were not practical (TBT/M/28).

125. Several participants felt there was a need for a clear definition of PPMs if their coverage under the Agreement was to be established, and in January 1989 a draft proposal containing "Suggested definitions related to PPMs" was submitted by the United States (TBT/W/108/Add.1):

"1. Process or Production Method (PPM):

One or more planned actions in a series of conditions or operations (e.g. mechanical, electrical, chemical, inspection, test) by means of which a material or product advances from one stage to its final state. PPMs include conditions of growth as well as controlled treatments that subject materials or products to the influence of one or more types of energy (e.g. human, animal, mechanical, electrical, chemical, thermal) as required to achieve a desired reaction,

change, result or performance.

2. *PPM Standard (or PPM provision within a product or process standard):*

Standard or provision that specifies the process or production method to be employed in one or more stages in the design, manufacture, delivery, installation, treatment, or utilization of equipment, structures or products, or that specifies methods or conditions in accordance with which a product is to be grown or raised. Testing or certification for conformity with these methods, rather than the characteristics of the final product, is required in conjunction with one or more steps in the process."

There was little recorded discussion of this proposal (TBT/M/30 and 31).

126. One general reservation expressed by one participant at this time, which was repeated throughout most of the remainder of the TBT Committee's discussion of extending the Agreement to cover PPMs, was that the traditional field of application of PPM-based requirements had been agriculture and that the whole issue should therefore be more properly discussed and settled in its entirety in the Negotiating Group on Agriculture (NG5), in the context of developing rules on the use of sanitary and phytosanitary measures. Other participants agreed on the importance of discussing PPM-based agricultural requirements in NG5, but did not consider this needed to be done to the exclusion of further discussion of the issue in the context of the TBT Agreement. They felt that any necessary adjustments to ensure consistency with the results of discussion in NG5 could be made at the appropriate time.

127. In November 1989, a new proposal to incorporate PPMs within the scope of the Agreement and to make its coverage of PPMs clearer was submitted by New Zealand (MTN.GNG/NG8/W/58). The operative parts of the proposal read:

"1. Annex 1.1

Amend the definition of Technical Specification as follows:

A specification contained in a document which lays down characteristics of a product such as levels of quality, performance, safety or dimensions. It may include, or deal exclusively with terminology, symbols, testing and test methods, packaging, marking or labelling requirements as they apply to a product.

It may also include processes and production methods insofar as they are necessary to achieve the required characteristics of a product.

This definition is intended to make clear that the processes and methods that must be used in the production of a product are covered by the Agreement. The product coverage of the Agreement is defined in existing Article 1.3, which does not require any change.

A separate definition of "process and production method" could also be incorporated in Annex 1, as follows:

Means by which or conditions under which a product advances to its final state.

New Zealand does not believe a definition is absolutely necessary, but acknowledges that several participants favour devising one. While New Zealand has no specific objection to the U.S. definition, our preference is for a broader and simpler overall definition, as there does not appear to be much disagreement over what constitutes a process and production method.

2. Article 2.4

To be amended as follows:

Wherever appropriate, Parties shall specify technical regulations and standards in terms of performance rather than design or descriptive characteristics, or processes and production methods.

This makes PPMs the third element of the hierarchy of types of regulation or standard. By establishing a preference for other types, it will discourage the use of PPMs in an arbitrary way, when another type is available. There may well be cases where a PPM will be more appropriate than another type of standard even when either could be used. It would be up to the party imposing this PPM to explain, on request, why the PPM was appropriate in this case. A typical case would be where suitable testing methods are unavailable or impractical, eg. in food irradiation or pressure vessels.

3. New Article 5.2 BIS

Parties shall ensure that in determining conformity with technical regulations and standards based on processes and production methods, their central government bodies also accept PPMs used in exporting Parties which differ from their own, provided they are satisfied that the PPMs in the exporting Parties provide equivalent guarantees in terms of the objectives of the technical regulations and standards. Parties shall ensure that their central government bodies make every effort to reach agreement on conformity, or equivalency of PPMs, through consultation. To this end, exporting Parties shall make available all relevant information to importing Parties, and shall ensure they have adequate access to facilities they require for the purpose.

This article recognizes that when they do use PPM regulations/standards, in order to minimize the risk of unjustified obstacles to trade, Parties should be prepared to accept PPMs, which while not identical, can be shown to be just as effective in meeting the objectives of the PPM regulation/standard. These objectives of course would be those that are legitimate under the terms of the Agreement.

4. Article 14.25: Delete

As it would no longer be possible to circumvent the provisions of the Agreement simply by drafting a regulation or standard in terms of a PPM, this specific dispute settlement provision becomes superfluous. PPMs would be subject to the same set of dispute settlement provisions as other regulations and standards."

128. In introducing its proposal (MTN.GNG/NG8/14 and TBT/M/33), New Zealand added that the substantive disciplines of the Agreement, such as transparency, national treatment, and the use of international standards, were equally appropriate for PPM-based measures. Specific PPM-related provisions were required in the determination of conformity, where the cooperation of the exporting country would be needed since the testing procedures of Article 5.1 could not be applied because of the nature of PPMs. The principle of equivalency was necessary to allow exporting parties to meet a PPM-based regulation or standard by using a PPM which might not be identical but which had equivalent effects.

129. Considerable support for the proposal by New Zealand, in particular its intent and the introduction of the principle of equivalence for PPM-base measures, was expressed in both NG8 and the TBT Committee, although one participant continued to express reservations about proceeding any

further in the context of the TBT Agreement as long as the issue of PPM-based measures was still under consideration in NG5 (TBT/M/33, 34, 35 and 36).

130. Three aspects of the New Zealand proposal received particular attention.

(i) The Definitions in Annex 1 of the Agreement

131. New Zealand explained that the intent of its proposal to amend the definition of "Technical specification" had not been to include all kinds of PPMs, but only those that were necessary to ensure certain legitimate objectives of quality in a final product such as its strength, purity or safety. A PPM that was required for religious purposes, for example, did not have any direct effect on the quality or the final characteristics of a product and would therefore not be covered. Many participants said they supported the intent of this proposal, but some felt the phrase "It may include processes and production methods insofar as they are necessary to achieve the required characteristics of a product" required further elaboration to make that intent clear.

132. One participant felt the use of PPM-based measures should be viewed in a larger context, both from the point of view of the different problems raised by those related to agricultural and industrial products and from the point of view of the use of certain PPMs related to concepts such as protection of environment, social order, and workers' health and safety.

133. In June 1990, the Nordic countries presented new proposals (MTN.GNG/NG8/W/79) for the drafting of the definitions in the Agreement to take account of draft amendments to the ISO/IEC Guide 2. The proposal read, in part, that for the purposes of the Agreement the following exceptions would apply to the ISO/IEC definitions of terms:

"(a) Services (and processes) shall be excluded from the coverage of the definitions.

(b) For the term "Standard" the following definition shall apply.

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products, (processes and production methods) with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product."

(ii) Article 2.4 of the Agreement

134. New Zealand's proposal (MTN.GNG/NG8/W/58) to amend Article 2.4 of the Agreement received most attention from the point of view of the hierarchy it established between different types of technical specifications. One view was that the rationale for establishing any hierarchy at all among types of requirements was unclear and difficult to defend. Another view was that the concept of hierarchy should not exclude the possibility of using PPM-based measures, which were becoming of increasing importance to the production and trade of industrial products, particularly high-technology products, and which in certain cases were not only the preferable way but indeed the only way to regulate product quality. However, requirements drafted in terms of product characteristics should be preferred generally to PPM-based requirements since generally they were less trade-restrictive. The main reasons given were: the determination of conformity with product requirements could be made both in the importing and the exporting country, whereas conformity with PPMs-based requirements could be evaluated only on the site of production which made this type of assessment expensive; according to the practice of standardization at the national and international level,

technical specifications were drafted in terms of characteristics of products rather than in terms of PPMs unless under exceptional circumstances when it was not possible to achieve the purpose of the requirement through product characteristics; PPM-based regulations could restrict foreign suppliers' choice of technology and might compel them to use an inferior or less efficient technology or methodology, and restrain their ability to adopt a more cost-competitive means of producing a product or to achieve targets relating to product quality.

135. In April 1990, the Nordic countries proposed a new draft for Article 2.4 to address the issue of hierarchy in terms of the trade restrictiveness of the measure chosen (TBT/W/143):

"Parties shall ensure that in preparing technical regulations in the choice between different ways to present the necessary requirements (on performance, marking or design of the products, or on processes and production methods) they use those which are least trade restrictive except in cases when this for technical or economic reasons is not feasible."

In introducing their proposal, the Nordic countries said that it gave sufficient guidance to Parties for the drafting of technical regulations in the least trade restrictive way but allowed them flexibility in choosing between types of technical regulations (TBT/M/37). If an exporting Party considered that the specification used was not the least trade restrictive it should have the possibility of entering into consultations with the importing Party. If a dispute arose, it would be up to the exporting Party to demonstrate that a less trade restrictive method for specifying the technical regulation in question existed which was also economically and technically feasible.

136. While some delegations considered the Nordic proposal to be more flexible in accommodating PPM-based measures and therefore more realistic than the New Zealand proposal, some concern was expressed that it involved technical as well as commercial and economic judgements which could undermine the objectiveness of the provisions of Article 2.4.

137. The issue of "least trade restrictiveness" of measures continued to be discussed in the Committee in the context of amendments to Article 2 of the Agreement. In May 1990, for example, Canada proposed a new draft for Article 2.1 (MTN.GNG/NG8/W/77) which aimed to ensure that technical regulations and standards, including those based on PPMs, did not create unnecessary obstacles to trade. One element of Canada's proposal which appears to have been addressed directly to the issue of PPM-based measures read:

"With respect to their central government bodies:

2.1 Parties shall ensure that technical regulations and standards are not prepared, adopted or applied with a view to creating obstacles to international trade. Furthermore, products imported from the territory of any Party shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country in relation to such technical regulations or standards. They shall likewise ensure that neither technical regulations nor standards themselves nor their application have the effect of creating unnecessary obstacles to international trade. In so doing, Parties shall, inter alia, ensure that technical regulations and standards including changes thereto:

2.1.4. are not applied in such a way as to affect imported products either originating in geographic areas where the problem being addressed does not occur or destined for industrial or consumer applications where the problem does not exist;"

There was no recorded discussion of this particular aspect of Canada's proposal relating to PPM-based measures (TBT/M/38), and further development of disciplines to avoid unnecessary barriers to trade, such as proportional and degressive application of technical regulations and standards, proceeded

without particular reference to PPM-based measures.

(iii) Conformity assessment

138. Support was expressed for New Zealand's proposal (MTN.GNG/NG8/W/58) to include new conformity assessment provisions in the Agreement addressed specially to PPM-based requirements. Several participants felt that issues of conformity assessment were closely related to concepts of PPMs and their coverage by the Agreement, and that the principle of equivalence was important in the context of the assessment of the conformity of products to PPM-based measures.

139. From December 1989 to May 1990, new provisions were drafted to cover conformity assessment procedures and the recognition of conformity assessment. Certain proposals in this regard made it clear they were designed to cover the assessment of the conformity of products with PPM-based standards. One direct reference to PPM-based measures was contained in a U.S. proposal (MTN.GNG/NG8/W/52/Rev.1) of February 1990 on Product Approval Procedures, which called for a reasonable interval to be provided between the publication of requirements concerning product approval and their entry into force "in order to allow time for producers in exporting countries, and particularly in developing countries, to adapt their products or methods of production to the requirements of the importing country." However, the tendency at this time seems to have been to rely upon extending coverage to PPM-based measures through the definitions of technical regulations, standards and conformity assessment in the Annex to the Agreement rather than directly into the text of the Agreement as had been proposed by New Zealand. For example, a Nordic proposal (MTN.GNG/NG8/W/50) of August 1989 on Testing and Inspection Procedures contained a provisional definition of "evaluation of conformity" as "systematic examination of the extent to which a product, process or service fulfils specified requirements". An EC proposal of March 1990 on Conformity Assessment (MTN.GNG/NG8/W/72) dealt exclusively with product requirements and explicitly excluded PPM-based measures, leaving the question of coverage of PPM-based measures to be decided in the context of separate discussions.

Preparation of the Brussels Text of the TBT Agreement

140. As mentioned earlier, the Chairman of NG8 circulated a draft text of the TBT Agreement in July 1990 (MTN.GNG/NG8/W/83/Add.3). Although several aspects of the text were already relatively well developed at this stage, most questions relating to coverage of PPM-based measures by the Agreement remained open and were reflected in the text through the inclusion of the original proposals that had been made.

141. The Chairman had stated in his introductory note to the draft text that the "... text in **bold** type represents areas of broad convergence without prejudging its final acceptance by any participant. However, it is necessary to note that, while there is a large majority supporting these issues, sometimes with different views, ... one other delegation has reserved its position on the extension of the Agreement to Processes and Production Methods. The text appearing in normal type represents areas where there are divergences, sometimes fundamental, or where further work is needed."

142. The relevant parts of the draft text of the Agreement read as follows:

"Article 2 *Preparation, adoption and application of technical regulations by central government bodies*

With respect to their central government bodies:

2.2 Parties shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. In so doing, Parties shall, inter alia, ensure that technical regulations:

2.2.4 are not applied in such a way as to affect products either originating in geographic areas where the problem being addressed does not occur or destined for industrial or consumer applications where the problem does not exist;

2.5 Wherever appropriate, Parties shall specify technical regulations in terms of performance rather than design or descriptive characteristics.

2.5 Whenever appropriate, Parties shall specify technical regulations and standards in terms of performance rather than design or descriptive characteristics, or processes and production methods.

2.9 Except in those urgent circumstances referred to in Article 2, paragraph 6, Parties shall allow a reasonable interval between the publication of a technical regulation and its entry into force in order to allow time for producers in exporting countries, and particularly in developing countries, to adapt their products or methods of production to the requirements of the importing country.

Article 4 Preparation, adoption and application of standards

With respect to their central government bodies:

Article 4bis

Whenever a Party has reached an agreement with any other party on issues related to standards and technical regulations (including processes and production methods) which may have a significant effect on trade, at least one Party to the agreement shall notify other Parties through the GATT secretariat of the products to be covered by the agreement and a brief description of the agreement. Parties concerned are encouraged to enter, upon request, into consultations with other Parties for the purpose of concluding similar agreements or of arranging for the participation in such agreements.

Article 5 Conformity with Technical regulations and Standards

5.8 Except in those urgent circumstances referred to in Article 5, paragraph 6, Parties shall allow a reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force in order to allow time for producers in exporting countries, and particularly in developing countries, to adapt their products or methods of production to the requirements of the importing country.

Article 6 [Recognition of Conformity Assessment]

Parties shall ensure that in assessing conformity with technical regulations and standards based on processes and production methods, their central government bodies also accept PPMs used in exporting Parties which differ from their own, provided they are satisfied that the PPMs in the exporting Parties provide equivalent guarantees in terms of the objectives of

the technical regulations and standards. Parties shall ensure that their central government bodies make every effort to reach agreement on conformity, or equivalency of PPMs, through consultation. To this end, exporting Parties shall facilitate the provision of relevant information to importing Parties. They shall also facilitate the carrying out of inspections or spot checks in their territories by importing Parties when these are necessary for this purpose.

6.1 *Parties are encouraged to:*

6.1.2 *accept the results of conformity assessment procedures in other Parties, even when those procedures differ from their own, provided they offer an assurance equivalent to their own that products conform with the applicable technical regulations or standards.*

ANNEX 1

TERMS AND THEIR DEFINITIONS FOR THE SPECIFIC PURPOSES OF THIS AGREEMENT

1. *The terms presented in the fifth edition of the ISO/IEC Guide 2, General Terms and Their Definitions Concerning Standardization and Related Activities, and in the amendment sheet adopted ... 1990 to this Guide, shall when used in this Agreement have the same meaning as given in the definitions in the said Guide and in the amendment sheet therefore with the following exceptions.*

1.1 *Services [and processes] shall be excluded from the coverage of the definitions.*

1.2 *Standard*

For the term "Standard" the following definition shall apply.

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products, (processes and production methods) with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product.

Explanatory note:

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This agreement deals only with technical regulations, standards and conformity assessment procedures related to products (processes and production methods). Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purposes of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This agreement covers also documents that are not based on consensus.

Technical regulations
(to be worked out)

Processes and production methods

Means by which or conditions under which a product advances to its final state.

One or more planned actions in a series of conditions or operations (e.g. mechanical, electrical, chemical, inspection, test) by means of which a material or product advances from one stage to its final state. PPMs include conditions of growth as well as controlled treatments that subject materials or products to the influence of one or more types of energy (e.g. human, animal, mechanical, electrical, chemical, thermal) as required to achieve a desired reaction, change, result or performance.

PPM Standard (or PPM provision within a product or process standard)

Standard or provision that specifies the process or production method to be employed in one or more stages in the design, manufacture, delivery, installation, treatment, or utilization of equipment, structures or products, or that specifies methods or conditions in accordance with which a product is to be grown or raised. Testing or certification for conformity with these methods, rather than the characteristics of the final product, is required in conjunction with one or more steps in the process."

2.6 Conformity assessment procedure

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Note: Conformity assessment procedures include inter alia procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

Conformity assessment procedure

Any technical procedure used, directly or indirectly, to give positive assurance that a product conforms with the applicable technical regulations or standards.

Explanatory note:

For the purposes of this Agreement, possible conformity assessment procedures or elements thereof are, inter alia, a manufacturer's declaration of conformity regarding the product or the quality assurance system used; the submission or availability of information regarding the product or the quality assurance system used; testing or inspection of the product or the quality system used; certification of the product or registration of the quality assurance system used; application of a mark of conformity; accreditation of testing laboratories, inspection bodies, or certification bodies; type approval, lot approval or unit approval of the product or approval of the quality assurance system used; good manufacturing practices; good laboratory practices; good clinical practices."

143. NG8 met informally in September and October, and on 30 October 1990 it presented its final draft of the TBT Agreement to the Group of Negotiations on Goods for submission to the Brussels Ministerial meeting (MTN.GNG/NG8/W/83/Add.3/Rev.1). NG8 identified a number of outstanding issues it said would have to be settled through further informal consultations. These did not contain any reference to PPM-based measures.

144. In the text submitted to the Brussels meeting, the majority of the direct references to PPM-based measures had been dropped from the text, but the references were retained in the definitions. Those parts of the text of the Agreement in the 1990 Draft Final Act which appear

relevant in the light of past and later negotiations read as follows:

"Article 2: Preparation, adoption and application of technical regulations by central government bodies

With respect to their central government bodies:

2.7 Parties shall give positive consideration to accepting as equivalent technical regulations of other Parties, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

2.8 Wherever appropriate, Parties shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

2.12 Except in those urgent circumstances referred to in Article 2, paragraph 10, Parties shall allow a reasonable interval between the publication of a technical regulation and its entry into force in order to allow time for producers in exporting Parties, and particularly in developing country Parties, to adapt their products or methods of production to the requirements of the importing Party.

Article 5 Procedures for assessment of conformity by central government bodies

5.9 Except in those urgent circumstances referred to in Article 5, paragraph 7, Parties shall allow a reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force in order to allow time for producers in exporting Parties, and particularly in developing country Parties, to adapt their products or methods of production to the requirements of the importing Party.

Article 6 Recognition of conformity assessment by central government bodies

With respect to their central government bodies:

6.1 Without prejudice to the provisions of Article 6, paragraphs 3 and 4, Parties shall ensure, whenever possible, that results of conformity assessment procedures in other Parties are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

ANNEX 1

TERMS AND THEIR DEFINITIONS FOR THE PURPOSE OF THIS AGREEMENT

1. Technical regulation

Document which lays down characteristics for products, processes and production methods including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

2. Standard

*For the term "Standard" the following definition shall apply:
Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products, processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.*

Explanatory note:

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This agreement deals only with technical regulations, standards and conformity assessment procedures related to products processes and production methods.

3. Conformity assessment procedures

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note:

Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

The final phase of the negotiations

145. Consultations on further revisions to the Brussels text of the TBT Agreement were taken up in October 1991 under the authority of the Rule-Making Group. In the area of PPM-based measures, those consultations focused exclusively on the definitions contained in Annex 1 of the Agreement.

146. During informal consultations in October 1991, the question of the coverage of PPM-based measures by the Agreement was discussed. A proposal by Mexico to clarify the coverage of PPM-based measures in the definitions of "Technical regulations" and "Standards" was accepted, and following further discussions it was agreed that the words "or related" should be inserted into the phrase "... products, processes and production methods ..." in three places in the working text. In introducing its proposal, Mexico made it clear that the intent was to exclude PPMs unrelated to the characteristics of a product from the coverage of the Agreement. Corresponding changes were not made in two other places in the definitions in which similar phrases appeared. The definitions contained in the text submitted in October 1991 to the Rules-Making Group (MTN.GNG/RM/W/7)

read in part:

1. Technical regulation

Document which lays down characteristics for products or related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

2. Standard

*For the term "Standard" the following definition shall apply:
Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.*

Explanatory note:

*The terms as defined in ISO/IEC Guide 2 cover products, processes and services.
This agreement deals only with technical regulations, standards and conformity assessment procedures related to products or related processes and production methods.*

It should be noted that this text of the Agreement was drawn up on the assumption that there would be a separate Agreement on Sanitary and Phytosanitary Measures.

147. At informal consultations held under the authority of the Rules-Making Group in December 1991, Mexico proposed that the word "their" should be inserted into the definition of "Technical regulation". Records of those consultations indicate that Mexico stated the change would be "in the interests of additional clarity and to ensure that the Agreement will only address a narrow selection of processes and production methods". The change was reflected in the text of the "Agreement (1991) on Technical Barriers to Trade" in MTN.TNC/W/FA.

148. In April-June 1992, the Legal Drafting Group addressed the TBT Agreement. A note prepared by the Secretariat for the Group (numbered 940 and dated 10 June 1992) included the following drafting suggestion:

"Annex 1, paragraph 2 definition of the term "standard"

On the second line, it was suggested to align this definition with the definition of the term "technical regulation" in paragraph 1 by replacing the words "or characteristics for products or related processes and production methods" by "or product characteristics or their related processes and production methods".

149. In an "Informal Note by the Secretariat" numbered 941 and dated 10 June 1992 it was noted that at informal meetings held in April and May 1992 the Legal Drafting Group discussed rectifications to the TBT Agreement and a certain number of changes were agreed on. Changing the definition of the term "standard" was not among them.

150. No further discussion of the issue was recorded until informal consultations held on 1 December 1993 on unresolved points in the Draft Final Act handed down by the Legal Drafting

Group. At the end of those consultations three points remained outstanding, one of which was a proposal by Mexico to align the definition of "Standard" with that of "Technical regulation". All but one of the delegations involved in those consultations which expressed an opinion stated that they were prepared to accept Mexico's proposal as an improvement to the text. However, two other proposals for changes to the text tabled by the United States did not find consensus support, and consequently the text remained unchanged. Several delegations involved in those consultations expressed a view at the time that since the change proposed by Mexico was not one of substance, they were prepared to leave it in abeyance to be taken care of in a legal drafting exercise which it was planned to hold early in 1994, after agreement on the Final Act.

151. Further informal consultations were held on 9 and 11-14 December 1993 to finalize the text of the TBT Agreement. Many participants expressed reluctance at this point to re-open the text to any changes at all. An informal, compromise solution covering all three outstanding points of the text was put forward during informal consultations among a limited number of participants on 11 December. It contained the following language for the definition of "Standard":

"Document approved by a recognized body that provides, for common and repeated use, rules, guidelines, product characteristics or processes and production methods related to product characteristics, with which compliance is not necessary."

The compromise solution did not prove acceptable, and the wording for "Definitions" in Annex 1 of the TBT Agreement which had been agreed on in December 1991 in MTN.TNC/W/FA was therefore carried forward into the WTO text of the Agreement.