1. The Chairman recalled that at its twenty-fourth meeting the Committee had had a preliminary discussion of the United States case against the EEC Directive (85/649/EEC) under Article 14.25 of the Agreement (TBT/Spec/18 and TBT/M/24, paragraphs 59-76) and had noted that the consultations under Article 14.2 between the two Parties would be continued. He had been informed by the United States delegation on 29 April 1987 that a mutually satisfactory solution could not be achieved through these consultations and that they requested that the Committee investigate the matter pursuant to Article 14.4 of the Agreement. The present meeting in restricted session had been convened to begin this investigation.

2. The representative of the United States informed the Committee that the discussions, held at political level and in the framework of the Agreement between the United States and the European Economic Community authorities in March and April 1987, had not revealed a possible issue to the matter. Therefore, his delegation had resumed its request for a Committee investigation of the EEC Animal Hormone Directive on 29 April 1987. By approving the Directive in question, the European Economic Community had nullified and impaired benefits that would have accrued to his country under the Agreement, in particular under Article 7.1 and 7.2, and had also disregarded the objective in the Preamble relating to the importance of international standardization work. The case had been raised under Article 14.25 because the United States considered that obligations under the Agreement were being circumvented by the Directive which had been drafted in terms of process and production method (PPM). Had the requirements been drafted in terms of the characteristics of the final product, the Directive would be subject to the substantive obligations in the Agreement such as non-creation of unnecessary barriers to trade, national treatment to imported products and non-discrimination among supplier countries. His delegation sought to restore the balance of rights and obligations under the Agreement and it had invoked the dispute settlement procedures under Article 14. According to the text of Article 14.25, the United States did not need to prove whether the European Community had intentionally circumvented obligations of the Agreement. He added that the case before the Committee involved a determination of the safety of meat products from livestock treated with anabolic substances. The mechanism for resolution of disputes under the Agreement envisaged the establishment of a technical expert group (TEG) to examine questions of a scientific nature upon the request of any Party to a dispute.

3. The representative of the United States presented a report, which had been prepared by the Food and Drug Administration (FDA) Centre for
Veterinary Medicine, entitled "Safety of Meat from Animals Treated with Naturally-Occurring and Synthetic Hormones". The report demonstrated the feasibility of setting safe residue levels for meat from animals implanted with hormonal substance instead of prohibiting the use of these substances. The permissible residue levels for the three principal naturally-occurring sex steroids covered in the EEC Directive were calculated by using 1 per cent of the daily de novo production rate of these substances in the human body, which represented permitted incremental increases of background levels in meat of 120 parts per trillion (ppt) for estradiol; 600 ppt for testosterone and 3 parts per billion (ppb) for progesterone. Samples of meat from steers treated with implants containing synovex-S (a compound of estradiol benzoate and progesterone) and synovex-h (a compound of estradiol benzoate and testosterone propionate) were analyzed by radioimmunoassay methods for hormone concentration. The results of the analyses showed that the increase in the levels of these hormones in treated animals were well within the levels considered safe. As for the synthetic sex steroids which were prohibited in the EEC Directive, zeranol was currently regulated with a withholding period of sixty-five days and a tolerance level of 20 ppb) which was above the levels detected in total residue studies, whereas trenbolone acetate was not approved for use in the United States for the time being.

4. The Codex Committee on Residues of Veterinary Drugs in Foods which had recently been convened by the Codex Alimentarius Commission would soon be meeting to study the issue of the safety of hormones. Prior to the drafting of the Directive the European Commission had sought a scientific assessment of the risk to the consumer of using anabolic agents in animals for growth promotion, and had charged an EEC Scientific Working Group with the toxicological evaluation of these substances. In this connection, he referred to a speech made by the Chairman of this Group in December 1986 which had been circulated to the Committee by the United States delegation. The first report of the Working Group in 1983 had stated that no question of safety arose in relation to the proper use of the three naturally-occurring hormones. Before the Working Group had finished its consideration of the two synthetic hormones, trenbolone and zeranol, the Commission of the European Communities had suspended the Working Group on the grounds that, in view of the impending ban on the use of anabolic agents, the scientific evidence was not required at this time. If the Commission had not disregarded the scientific advice that it had solicited, the Directive would have set permissible residue levels for these hormonal substances in meat products instead of a ban on their use in livestock breeding. The Community had submitted to the pressures from consumer groups in taking the action which had had the effect of creating unnecessary obstacles to the United States meat exports valued at US$80-100 million per year.

5. Member States of the European Economic Community had not endorsed the Directive unanimously: the United Kingdom had referred the legitimacy of the means by which the Directive had been adopted to the European Court of Justice. In addition, the United Kingdom would benefit from a one-year derogation from the implementation of the Directive. The national assembly of one other member State had postponed the adoption of the legislation for the national implementation of the Directive. The delayed implementation
of the ban in certain member States of the Community would distort trade with third countries.

6. The representative of the United States further stated that the case concerned perishable products, not only because of the characteristics of meat but also because of the life-cycle of livestock. Cattle breeders in exporting countries would need to adapt their procedures to the requirements in the Directive in order to ensure continued trade after the ban entered into force. The Committee should therefore proceed with the matter expeditiously as stated in Article 14.6 of the Agreement.

7. The United States supported the work in appropriate international fora on the safe use of hormonal substances, which would assist governments in their legitimate role of ensuring the health and safety of their citizens. The FDA had published its procedures for the regulation of anabolic hormones in the Federal Register in 1985. No comments had been received from interested parties about the safety of these substances because United States' policies in this respect had been transparent and ensured maximum safety in the use of these substances.

8. The representative of the European Economic Community said that the case of the United States against the European Community Animal Hormone Directive related to the applicability of the Agreement to the PPM, a point of divergence between Parties that originated in the negotiations of the Agreement. His delegation would respond to the United States arguments not only as a party to the dispute but also in its capacity as a Party that had subscribed to the commitments under the Agreement solely in respect of specifications formulated in terms of product characteristics. PPMs were not subjected to the provisions of the Agreement except as stated in Article 14.25. He recalled that no later than the first year of the entry into force of the Agreement, the United States had raised a case against the United Kingdom on the spin-chilling of poultry, with a view to including PPM in the field of application of the Agreement. At that time, the European Community had opposed consultations under Article 14 paragraphs 1 and 2 of the Agreement on the grounds that the dispute settlement procedures could not be invoked to verify the conformity of a PPM with the Agreement. No consensus had been reached in the Committee on the substance of that case. Then, during the first three-year review of the Agreement the United States had proposed the establishment of a working party to examine the Agreement's coverage of PPM (TBT/12).

9. He stated that the dispute settlement procedures were being misused by the United States with a view to extending indirectly the coverage of the Agreement to PPM. In this connection, his delegation disagreed with the interpretation of the Agreement by the United States on two basic points. First, the European Community could not consent to a verification of how the PPM in question violated the obligations under the Agreement, because the Agreement did not bind Parties in this respect. The United States could always assert its rights on matters relating to PPM as a contracting party to the General Agreement. The allegations by the United States that the PPM in question nullified and impaired benefits accruing to this country under Articles 7.1, 7.2 and the Preamble of the Agreement were not acceptable. In a dispute involving PPM, procedures should be confined to
verifying the intention of the Party to circumvent its obligations. Previously in the case of spin-chilling of poultry, the delegation of the United States had previously claimed that the United Kingdom had implemented the EEC Directive with the intention of circumventing the obligations of the Agreement. Second, the United States had argued that it was feasible to replace the requirements which had been drafted in the EEC Directive in terms of a PPM - a prohibition on the use of anabolic hormones in livestock breeding - with specifications on permissible residue levels. They had used the same reasoning in the poultry case, since in 1980 they had tried to demonstrate that poultry sanitary conditions could be assured by replacing the PPM by specifications on characteristics of the product. He emphasized that the Agreement did not set any obligations for Parties to draft their requirements in terms of product characteristics instead of PPM, even if it was technically possible to do so. Therefore an eventual scientific finding on the possibility of substituting a specification expressed in terms of PPM by a product standard would have a purpose only if there existed an obligation in the Agreement which prohibited Parties from using PPM except in cases where a product specification had not been elaborated. So long as such a legal principle had not been established, Parties could choose to adopt requirements in terms of either PPM or product characteristics to ensure health and safety.

10. With regard to the application of the dispute settlement procedures the representative of the European Economic Community said that these should be used to resolve matters among Parties but not to obtain undue benefits regarding the coverage of the Agreement. He added that while the United States was entitled to call for a scientific justification of the appropriateness of using PPM in the context of disputes relating to Article XX of the General Agreement, it could not avail itself of such a right under the dispute settlement procedures of the Agreement. A scientific justification by a technical expert group (TEG) under Article 14.9 was relevant insofar as product specifications were concerned. If the United States claimed that a determination of circumvention could only be established on a scientific basis, they would be subjecting PPM to the obligations of the Agreement. Pursuant to the consultations among Parties held in 1983, on the procedures for dispute settlement in cases involving PPM, the Committee had recorded the conclusions which called for co-operation among Parties for the smooth functioning of these procedures. The Community had supported the tenor of these conclusions and would co-operate in the present case, provided its legal obligations were not prejudged by the functioning of dispute settlement procedures. The United States should also co-operate by confining the verification of the fact of circumvention, in terms of Article 14.25, to the legal aspects of the matter. If the United States argument prevailed at the legal level, the Committee would decide at a later stage whether an examination at the technical level was warranted. He added that the European Community authorities were also willing to find a satisfactory solution on the basis of the trade aspects of the problem.

11. He refrained from discussing fully the scientific aspects of the PPM in question so as not to create a precedent for extending the obligations of the Agreement to PPM. He felt it necessary, however, to describe the following properties of the EEC Directive, without prejudicing the legal
rights of the Community under the Agreement in this respect. The Directive did not concern any perishable products referred to in Article 14.6. Imports of meat products had not been stopped and the livestock was not a product which ran the risk of being damaged in terms of Article 14.6. Besides, the Directive would enter into force on 1 January 1988, and meat products treated with anabolic compounds could be exported to certain member States beyond that date. Therefore, accelerated procedures for settlement of disputes were not required in the present case.

12. Even if it were technically feasible to replace a measure prohibiting the use of hormones for livestock breeding by a measure laying down permissible residue levels in meat products, a scientific demonstration in this respect would not signify that both methods gave equivalent guarantees for the safety of the population. Scientific advice on the safety of these hormonal substances was based on the current stage of knowledge. The Community authorities had understood, with the experience of diethylstilboestrol (DES) that scientists were not infallible. The FDA had banned the use of DES as dangerous in poultry breeding but had continued to authorize its use for other purposes for another thirty years before it had been found to be carcinogenic. More recently, the Natural Residue Plan for 1987 of the Food Safety and Inspection Service of the United States Department of Agriculture allowed free sale of melangesterol (MGA) for use in the feed of heifers as a growth promoter. Although this orally active substance had been regulated as a suspect carcinogenic substance, its control would be limited to tests for residue levels in samples from heifers. Sex steroids could entail physiological changes in human body, in particular, in prepubertal children. They could have negative effects in infinitesimal amounts and they might also have a cumulative effect.

13. Whilst the FDA had determined that compounds of these substances were safe when used according to label instructions, in practice there was no control to determine whether breeders used implants according to prescriptions. Under a prohibition régime, these substances would be sold under the guarantee of a veterinarian who would register their therapeutic use. The Community authorities had studied the report of the Special Working Group of the Standing Veterinary Committee of the EEC on the risk to the consumer of residues of anabolic steroids and had decided not to run any risk because these anabolic substances had no beneficial effect except that of increasing the weight gain in livestock for meat production.

14. With regard to derogations provided for member States in the Directive, he said that the use of hormonal substances would be allowed only for livestock produced for the domestic market of the member State in question. The Directive also had provisions for imports of animals treated with therapeutic substances from third countries. Consultations were being held with interested exporting countries in order to establish conditions of access to such exports. Although his delegation was not legally bound to justify it, there would be no discrimination to imports from third countries in this respect.

16. The representative of Austria said that his delegation supported the views of the delegation of the European Economic Community on the
applicability of the Agreement to PPM and on the functioning of its dispute settlement procedures as regards PPM. The concerns with health and safety matters which had been at the basis of the EEC Directive were also shared in his country. The use of hormonal substances in foodstuffs had been banned by the Austrian Feedingstuff Law and Foodstuff Law some time ago.

17. The representative of Canada said that procedures under the Agreement for dispute settlement should be used to address the United States consideration that the European Community had circumvented the obligations of the Agreement by drafting regulations in terms of PPM rather than of product characteristics.

18. The representative of Japan said that his delegation shared the United States' interpretation of Article 14.25 and of the dispute settlement procedures.

19. The representative of New Zealand said that his authorities had supported the view in the negotiations that the Agreement should cover PPM. The terms of Article 14.25 entitled the United States to bring its case under the dispute settlement procedures of the Agreement. He disagreed with the European Community argument that the Committee would need to ascertain whether there had been an intention to circumvent the obligation on the part of the European Community. Rather, the discussion in the Committee should focus on the effects of drafting the EEC Directive in terms of a PPM instead of a product characteristic. He also noted that the European Community representative had a selective approach to the kind of dispute settlement provisions which may or may not be invoked under Article 14.25. He hoped that in the spirit of the commitments undertaken in the Ministerial Declaration on prompt and effective resolution of disputes in GATT, the European Community would give a wider meaning to the term "co-operate in the process of dispute settlement" in the conclusions recorded by the Committee in 1983 regarding Article 14.25 (TBT/M/14, paragraph 14).

20. The representative of Finland, speaking on behalf of the Nordic countries, stated that the divergence of views among Parties on the issue of PPM had its origin in the lengthy negotiations in the Tokyo Round about including agricultural products in the coverage of the Agreement and extending its main obligations to PPM. The final balance reached in these negotiations subjected industrial and agricultural products to the provisions of the Agreement but not the PPM. On the other hand, Article 14.25 was introduced in the Agreement in order to prevent the Agreement from being undermined by countries which drafted requirements in terms of processes and production methods instead of product characteristics. Thus, the PPM were covered by the Agreement to the extent that they related to the exceptional cases of circumvention stated in Article 14.25. The Nordic delegations favoured a narrow interpretation of Article 14.25 under which Parties would raise PPM issues under the Agreement only in those exceptional cases, so that the exception did not become the rule. However, he joined other delegations who stated that the United States had the right to invoke the dispute settlement procedures in terms of Article 14.25. Because the present investigation had just begun, the Nordic delegations reserved their position on the substance of the
Meanwhile, as regards the procedural aspects, he suggested that the Committee select the appropriate procedures in the following order: at the outset, the Committee should investigate whether obligations under the Agreement were being circumvented. Once the Committee had verified circumvention it would be appropriate to investigate if the PPM in the EEC Directive created unnecessary obstacles to trade.

21. The representative of the United States acknowledged that his country had a keen interest in the subject of extension of the applicability of the Agreement to PPM and that his delegation had suggested that the negotiations in the Uruguay Round address this subject. However, his delegation's sole purpose in raising the present case was to restore the balance of rights and obligations under the Agreement in this exceptional case by the intermediary of the provisions of Article 14.25 as they had been conceived when the Agreement had been drafted. He therefore supported the suggestion by the Nordic spokesman that the Committee should review the issue of circumvention of the obligations under the Agreement. He emphasized that Article 14.25 did not limit the procedures that could be invoked to settle disputes. Furthermore, the language of Article 14.25 did not require that proof of "intention" to circumvent be produced but that a Party considered that obligations "were being circumvented".

22. The representative of the European Economic Community said that his delegation would co-operate in the dispute settlement procedures so long as they were not used to ascertain whether the PPM in question had complied with various obligations in the Agreement. Such a verification would imply an extention of the coverage of the Agreement to PPM in a way which was not provided for in Article 14.25. In respect of PPM, Parties were bound by an obligation not to circumvent. Article 14.25 should therefore be used in exceptional cases where a Party considered that this obligation had not been fulfilled. Therefore, the procedures invoked under Article 14.25 should be used to examine the event of circumvention in such exceptional cases. He reiterated that as long as this legal question had not been settled, a technical consideration of the matter would not be required.

23. The representative of Finland, speaking on behalf of the Nordic countries, said that the establishment of a panel to examine the legal aspects of the dispute did not exclude the use of technical advice because the procedures governing panels (Annex 3 of the Agreement) allowed a panel the possibility of seeking technical advice. Even if a party to the dispute considered that the finding of a TEG was indispensable to prove that the PPM had created unnecessary barriers to trade, such a TEG could be established once the fact of circumvention had been established. However, the procedures were still at the stage of Committee investigation under Article 14.4, which provided a time limit of three months. He suggested, supported by the representative of the European Economic Community, that the Committee should invite the Chairman to make his good offices available to the Parties to the dispute so that a mutually satisfactory solution of the matter could be found within that period.

24. The representative of the United States said that the Agreement did not limit dispute settlement procedures which could be invoked under Article 14.25 to a determination of circumvention of obligations. All procedures provided in Article 14, paragraphs 1 to 26 could be invoked,
including those which involved considerations of a technical nature. Moreover, the Agreement did not set any order of priority to the dispute settlement procedures invoked under Article 14.25. The sequence of the provisions on dispute settlement procedures under Article 14 and, in particular, the text of Article 14.14 on panels made it clear that, if requested, a TEG under Article 14.9 would be established prior to a panel under Article 14.14. Also, Article 14.17 suggested that a report by a TEG might be used as the basis of a panel’s consideration of issues of a technical nature. When deciding how to proceed with the investigation, the Committee would need to establish a list of points that should be examined. One of these would be to verify the event of circumvention. But by its very nature, the present case also involved technical aspects which would require consideration by experts.

25. The representative of the European Economic Community said that Parties were bound by the Agreement in respect to PPM only in the exceptional circumstance of circumvention. However, it would be inappropriate to try to establish the fact of circumvention by proving that the scientific justification for the PPM was not well-founded. In the first stage, the Committee should investigate whether, as suggested by the United States, the European Community had sought to circumvent its obligations. The Committee should examine the relevant obligations of the European Community when a finding had been made that the circumvention had taken place.

26. In concluding the discussion, the Chairman invited Parties to address any questions they may have on the case to the parties to the dispute by 15 June 1987.

27. The Committee took note of the statements made. It also invited the Chairman to provide his good offices in the informal consultations that might be held among parties to the dispute.

28. It was also agreed that the Committee would pursue its investigation in a meeting to be held on 24 June 1987 in restricted session.