EUROPEAN COMMUNITIES - MESURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

(COMPLAINT BY THE UNITED STATES)

Report of the Panel
WT/DS26/R/USA

Adopted by the Dispute Settlement Body on 13 February 1998
as modified by the Appellate Body Report

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I. INTRODUCTION

1.1 On 26 January 1996, the United States requested consultations with the European Communities, pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), Article 14 of the Agreement on Technical Barriers to Trade ("TBT Agreement"), Article 19 of the Agreement on Agriculture and Article XXII of the General Agreement on Tariffs and Trade 1994 ("GATT"), regarding the Council Directive Prohibiting the Use in Livestock Farming of Certain Substances Having a Hormonal Action and related measures (WT/DS26/1).

1.2 On 2 February 1997, pursuant to Article 4.11 of the DSU, Australia (WT/DS26/3) and New Zealand (WT/DS26/2), followed on 8 February by Canada (WT/DS26/4), requested to be joined in these consultations. The European Communities accepted these requests on 19 March 1996 (WT/DS26/5).

1.3 On 27 March 1996, the United States, Australia, Canada and New Zealand held joint consultations with the European Communities but failed to reach a mutually satisfactory solution.

1.4 On 25 April 1996, pursuant to Article 11 of the SPS Agreement, Article 14 of the TBT Agreement, Article 19 of the Agreement on Agriculture, Article XXIII:2 of the GATT, and Article 6 of the DSU, the United States requested the Dispute Settlement Body ("DSB") to establish a panel with standard terms of reference (WT/DS/26/6). The United States claimed that the EC measures:

> "... adversely affect imports of meat and meat products and appear to be inconsistent with the obligations of the European Communities under the General Agreement on Tariffs and Trade 1994, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, and the Agreement on Agriculture. The provisions of these agreements with which these measures appear to be inconsistent include, but are not limited to, the following:
>
> (1) General Agreement on Tariffs and Trade 1994, Article III or Article XI;
>
> (2) Agreement on the Application of Sanitary and Phytosanitary Measures, Articles 2, 3 and 5;
>
> (3) Agreement on Technical Barriers to Trade, Article 2; and
>
> (4) Agreement on Agriculture, Article 4.
>
> These measures also appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements".

1.5 On 20 May 1996, the DSB established a Panel in accordance with the request made by the United States. The agreed standard terms of reference of the Panel were (WT/DS26/7):

> "To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS26/6, the matter referred to the DSB by the United States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements".

1.6 Australia, Canada, New Zealand and Norway reserved their rights to participate in the Panel proceedings as third parties.

1.7 On 2 July 1996, the Panel was constituted with the following composition:

Chairman:	Mr. Thomas Cottier
Panellists:	Mr. Jun Yokota
	Mr. Peter Palecka

1.8 The Panel met with the parties on 10 October 1996 and 11 November 1996. It met with third parties on 10 October 1996. The Panel con-

sulted scientific and technical experts on 17-18 February 1997 in a meeting held jointly with the panel proceeding brought by Canada on the same EC measures.[1]

1.9 On 28 November 1996, the Chairman of the Panel informed the DSB that the Panel would not be able to issue its report within six months. The reasons for that delay are stated in document WT/DS/26/8.

1.10 The Panel issued its interim report to the parties on 7 May 1997. Following a request made by the European Communities pursuant to Article 15.2 of the DSU, the Panel held a further meeting with the parties on 4 June 1997. The Panel issued its final report to the parties to the dispute on 30 June 1997.

II. FACTUAL ASPECTS

1. The Measures at Issue

2.1 This dispute concerns EC measures, in particular Council Directive 81/602/EEC ("Directive 81/602/EEC"), Council Directive 88/146/EEC ("Directive 88/146/EEC") and Council Directive 88/299/EEC ("Directive 88/299/EEC").[2]

2.2 Directive 81/602/EEC prohibits the administering to farm animals of substances having a *thyrostatic action* or substances having an *oestrogenic, androgenic or gestagenic* action; the placing on the market or slaughtering of farm animals to which these substances have been administered; the placing on the market of meat from such animals; the processing of meat from such animals and the placing on the market of meat products prepared from or with such meat. The Directive provides two exceptions to the prohibition: one exception is provided for substances with an oestrogenic, androgenic or gestagenic action when they are used for therapeutic or zootechnical purposes and administered by a veterinarian or under a veterinarian's responsibility. The other exception was for oestradiol-17β, progesterone, testosterone, trenbolone acetate (or TBA) and zeranol - when they were used for growth promotion purposes and their use was governed according to the individual regulatory schemes maintained by EC member States. This exception was made pending an examination of the effects of these hormones on the health of consumers and the adoption of an EC rule. EC member States are obliged to apply their regulatory schemes to imports from third countries in a manner not more favourable than that applied to intra-EC trade.

2.3 Directive 88/146/EEC extends the prohibition imposed by Directive 81/602/EEC to the administration to farm animals of trenbolone acetate and ze-

[1] WT/DS48/6.

[2] Other measures relevant to the dispute are contained in Directives 72/462/EEC, 81/602/EEC, 81/851/EEC, 81/852/EEC, 85/358/EEC, referenced in Directive 88/146/EEC; the decisions, control programme and derogations referred to in Article 6(2), Article 6(7) and Article 7, respectively, of Directive 88/146/EEC; and any amendments or modifications, including Directives 96/22/EC and 96/23/EC.

ranol for any purpose, and oestradiol-17β, testosterone and progesterone for fattening purposes. However, the Directive maintains the permission to administer these three natural hormones to animals for therapeutic and zootechnical purposes under prescribed conditions; in particular, therapeutic treatment is defined to mean the administering to an individual animal of any of the substances which are authorized to treat a fertility problem diagnosed on examination by a veterinarian. The products which are used for therapeutic treatment may be administered only by a veterinarian, in the form of an injection (to the exclusion of implantation) to farm animals which have been clearly identified. Such treatment must be registered by the veterinarian and these animals may not be slaughtered before expiry of the period fixed. In the case of animals at the end of their reproductive career, the treatments are prohibited from being administered during the fattening period following the end of their breeding life. Article 4 of directive 88/146/EEC explicitly requires that undertakings in the EC member States producing the prohibited hormones, those companies authorized to market these hormones for whatever purposes and undertakings producing pharmaceutical and veterinary products based on those substances, must keep a detailed register recording (in chronological order) the quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary products. The importation from third countries of animals and meat from animals to which have been administered substances with thyrostatic, oestrogenic, androgenic or gestagenic action is prohibited.[3] However, under certain conditions, Article 7 of Directive 88/146/EEC allows trade in those animals and meat from those animals treated for therapeutic or zootechnical purposes, including imports from third countries.[4]

2.4 Directive 88/299/EEC lays down the conditions for applying the derogations, provided for in Article 7 of Directive 88/146/EEC, from the prohibition on trade in certain categories of animals and their meat. The first derogation of the

[3] Article 6(7) of Directive 88/146/EEC requires the establishment of a control programme as regards imports from third countries to ensure that imports do not receive more favourable treatment than EC products. This control programme also provides for rules on the frequency of controls on imports from each third country and on guarantees offered by the inspection regulation of third countries. Such checks on imports are now carried out in accordance with Directives 91/496/EEC and 90/675/EEC.

[4] Article 7 of Directive 88/146/EEC allows derogations in respect to trade in animals intended for reproduction and reproductive animals at the end of their career (and in respect of meat from these various animals, taking into account the guarantees given), which in the course of their existence have been treated under the provisions of Article 4 of Directive 81/602/EEC. This article authorizes the administration to farm animals of substances with oestrogenic, androgenic or gestagenic action approved in accordance with the Directives on veterinary medical products (other than substances referred to in Article 3 of Directive 81/602/EEC) for therapeutic use, synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos. The administering of these substances shall be effected by a veterinarian, however, EC member States may allow the synchronization of oestrus and the preparation of donors and recipients for the implantation of embryos to be done not by a veterinarian but under his direct responsibility.

Directive requires EC member States to authorize trade in animals intended for reproduction and reproductive animals at the end of their career (and of meat of such animals) which, during their reproductive career, have undergone one of two categories of treatments: The first category is therapeutic treatment with one of the following substances: oestradiol-17β, testosterone and progesterone; and those derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application which appear in a list of approved products. The second category is the administration of substances having an oestrogenic, androgenic or gestagenic action for synchronization of oestrus, termination of unwanted gestation, the improvement of fertility and the preparation of donors and recipients for the implantation of embryos, provided that the products in which they are contained appear on a list of approved products and with the respect of strict conditions of use concerning, in particular, the respect of the withdrawal period, the monitoring of those conditions of use and of the means of identification of the animals. In addition, Articles 3 and 4 of this Directive provide that trade between the EC member States of the European Communities in animals intended for reproduction and reproductive animals and meat from such animals is allowed only if all the conditions laid down in the Directive are respected, in particular as regards the waiting period and the requirement that animals have not received any of the above treatments with any of the above substances during the fattening period following the end of their breeding life. The EC stamp may be affixed to the meat only if the waiting time ended before the animals are slaughtered. The second derogation in Directive 88/299/EEC allows imports from third countries of treated animals and meat of such animals under guarantees equivalent to those for domestic animals and meat.

2.5 Directive 96/22/EC will replace Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as from 1 July 1997. It will maintain the prohibition on the use of these hormones for growth promotion purposes; extend the prohibition on the use of beta-agonists; restrict the use of the hormones at issue for therapeutic or zootechnical purposes, reinforcing in particular the role of the veterinarian; and reinforce the provisions on control and testing. Penalties and sanctions in case of violations are to be increased where checks detect the presence of prohibited substances or products or residues of substances administered illegally. Such substances or products will be confiscated and any treated animals or meat placed under official supervision until penalties have been applied.

2. The Substances at Issue (Hormones)

2.6 Hormones (chemicals) produced by the bodies of humans and animals are called endogenous or natural hormones. (Phyto-hormones are produced by some plants.) Compounds chemically synthesized to mimic the effect of natural hormones are called synthetic or xenobiotic hormones. Natural hormones are secreted into the blood stream by specialized cells and travel throughout the body. Hormones act by binding protein receptors present in hormone-responsive tissues. The receptor undergoes a conformational change, binds to specific DNA

sequences and regulates specific genes within a cell. Synthetic hormones may differ from endogenous (natural) hormones in their rate of metabolism and excretion.

2.7 Hormones function in four broad areas: reproduction; growth and development; maintenance of the internal environment; and production, utilization and storage of energy. One hormone can have multiple actions. For example, the male hormone testosterone controls many processes from the development of the fetus to libido in the adult. One function may be controlled by multiple hormones: the menstrual cycle involves oestradiol, progesterone, follicle-stimulating hormone and luteinizing hormone.

2.8 Of the six hormones involved in this dispute, three are naturally occurring hormones produced by humans and animals: oestradiol-17β, progesterone and testosterone (hereafter also referred to as natural hormones). Oestradiol-17β is a sex steroidal hormone with oestrogenic action (i.e., responsible for female characteristics); testosterone is a sex steroidal hormone with androgenic action (i.e., responsible for male characteristics); progesterone is a sex steroidal hormone with gestagenic action (i.e., responsible for maintaining pregnancy). These three hormones are produced throughout the lifetime of each individual and are required for normal physiological functioning and maturation. Hormone levels vary with the tissue, with the species of animal and with the sex and individual. Hormone levels vary most dramatically with puberty, pregnancy and castration.

2.9 The other three hormones involved in this dispute are artificially produced hormones: trenbolone, zeranol and melengestrol acetate (MGA) (hereafter also referred to as synthetic hormones). These hormones mimic the biological activity of the natural hormones. Trenbolone mimics the action of testosterone; zeranol mimics the action of oestradiol-17β; and MGA mimics progesterone.

2.10 In the United States, the three natural hormones may be used for medical treatment (therapeutic). Oestradiol-17β is also permitted for zootechnical purposes. In the United States the six hormones are also approved for growth promotion purposes. Three of the hormones used for growth promotion purposes, trenbolone, zeranol, and MGA, have no zootechnical or therapeutic uses. For growth promotion purposes, five of these hormones (except MGA) are formulated as pellets (with approved and fixed amounts of compound) designed to be implanted in the ear of the animal. The ear is discarded at slaughter. MGA is administered as a feed additive.

3. The Codex Alimentarius Standards

2.11 The SPS Agreement makes reference, in a number of provisions, to "the relevant international standards, guidelines and recommendations". Annex A:3(a) of the SPS Agreement states that the international standards, guidelines and recommendations relevant for food safety are those established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide

residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.

2.12 The Codex Alimentarius Commission (hereafter the "Codex Commission") is a joint FAO/WHO advisory body established to implement the Joint FAO/WHO Food Standards Programme. The purpose of this programme is to protect the health of consumers and to ensure fair practices in food trade through the elaboration of food standards. These standards, together with notifications received from governments with respect to their acceptance or otherwise of the standards, constitute the Codex Alimentarius. The Codex Alimentarius (hereafter "the Codex") is thus a collection of internationally adopted food standards presented in a uniform manner.

2.13 Membership of the Codex Commission is open to all member Nations and Associate members of FAO and/or WHO and is composed of government representatives of these members. Most of its members, including the United States and the EC member States, are WTO Members. The European Communities has an observer status in the Codex Commission. The Codex Commission has established a number of subsidiary bodies, including the Codex Committee on Residues of Veterinary Drugs in Food ("CCRVDF").

2.14 The technical and scientific analysis of veterinary drugs, food additives and some other substances in foods and beverages is not undertaken by the Codex Commission itself but independently by the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"). The JECFA is composed of independent scientists who serve in their individual capacities as experts, not as representatives of their governments or organizations. The goal of the JECFA evaluation of veterinary drugs is:

> "to establish safe levels of intake by setting Acceptable Daily Intakes (ADI) and to develop maximum residue limits when veterinary drugs are used in accordance with good veterinary practice".[5]

(a) The Elaboration of Codex Standards

2.15 The elaboration of Codex standards involves an 8-step process:

> *Step 1:* The Codex Commission decides to elaborate a standard and identifies which subsidiary body or other body should undertake the work, taking into account the "Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies". Decisions to elaborate standards may also be taken by subsidiary bodies of the Codex Commission subject to subsequent approval by the Codex Commission or its Executive Committee.

[5] Codex Alimentarius, Vol.3, Residues of Veterinary Drugs in Foods, p.vi.