

GENERAL AGREEMENT ON TARIFFS AND TRADE

RESTRICTED

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Committee on Technical Barriers to Trade

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REQUEST FOR A COMMITTEE INVESTIGATION PURSUANT TO ARTICLE 14:4 OF THE AGREEMENT

The following communication, dated 6 March 1987, has been received from the delegation of the United States.

THE EC ANIMAL HORMONE DIRECTIVE (85/649/EEC)

Background on the United States Case Under the Agreement

I. Introduction

In December, 1985, the EC agreed to additional rules for its meat certification system that will significantly affect exports from the United States. The rules are in the form of a directive that will ban the use of hormones in livestock used for meat production with effect from January 1, 1988. The United States believes that the new certification rules in the directive are without scientific basis and that implementation of the directive will create an unnecessary obstacle to international trade that will nullify or impair benefits accruing to the United States under the Agreement on Technical Barriers to Trade. The conviction that the EC directive is without scientific basis is shared by scientists around the world, including many European scientists.

The United States considers that the EC intended to circumvent its obligations under the Agreement when the directive was approved in 1985. The directive unnecessarily relies on a "process and production method" (PPM) rather than stipulating final characteristics of the product as would have been the case had the directive established a residue level for hormones in meat products (as do U.S. food safety rules).

Although this case involves PPMs, it is significantly different from the 1980 case raised by the United States concerning the United Kingdom's implementation of an EC directive on the spin chilling of poultry. It did not prove possible to resolve that earlier case due to two factors not found in the current case. First, the United States could not argue seven years ago that the directive intended to circumvent the Agreement's obligations, as it had been drafted way before the Code came into effect. Second, because the U.S. could not demonstrate that poultry sanitary conditions could be insured through other than the specification of a PPM, it could not allege that the spin chill requirements could have been drafted in terms of the characteristics of poultry.

In the current case, the United States will show that the EC's directive resorted to the incorporation of a PPM in the directive (and a ban on imports of meat not produced in accordance with this PPM) only in late 1985. The EC did so hastily in response to significant political pressure and before the competent international body -- the Codex Alimentarius -- could study the issue in its newly created committee on the residue of veterinary drugs. Circumvention of the Code became a political necessity in order to ensure that the EC was not subject to any multilateral limitations.

In addition, the United States can show that it is possible to issue standards that relate to the product's final characteristics while ensuring for the protection of public health and safety. Such residue standards are issued in the United States by the Center for Veterinary Medicine of the U.S. Food and Drug Administration (FDA).

II. Perishable Product

Article 14.6 of the Agreement states that the Committee will expeditiously handle disputes that related to perishable products. The goal is to resolve these problems within three months of the start of the Committee's investigation. Meat, offals and processed meat products are perishable. They are liable to spoil or deteriorate even when handled properly. Within minutes of slaughter, carcasses must be chilled to very close to 10 degrees centigrade to prevent the growth of bacteria and possible deterioration of the meat. The meat must be maintained at very low temperatures while being cut and processed. Offals are even more sensitive to the danger of spoilage. They must be very carefully chilled or deep frozen almost immediately after removal from the carcass.

Other than cooked meats, these products have very limited shelf life. Chilled meat should not be held more than 30 days. Even though frozen meat and offals can be held for longer lengths of time without spoilage, their quality drops unless they are maintained at temperatures of -18 degrees centigrade.

III. History of the Case

On January 12, 1987, the United States requested consultations with the EC under Article 14.1 of the Agreement concerning the EC's "Directive Prohibiting the Use in Livestock of Certain Substances Having a Hormonal Action" (85/649/EEC). Bilateral consultations were held in Brussels on February 2, 1987. As the EC Delegation did not indicate in bilateral consultations that it was prepared to make appropriate changes to the Directive and the way in which it is to be implemented, the U.S. Delegation provided the EC with a written proposal for resolving the matter on February 13, 1987 under Code Article 14.2. In this proposal, the U.S. suggested that the EC resolve this dispute by taking all necessary steps to ensure that appropriate sections of the Directive are rescinded, that those sections are not implemented, and that trade is not impeded. The EC has indicated that these proposals do not form the basis of a possible solution to the problem.

IV. Nullification or Impairment of Code Benefits

The January 1, 1988, implementation by the EC and its individual Member States of the animal hormone directive will nullify or impair benefits accruing to the United States under the Code; impede the attainment of the Code's objectives; significantly affect U.S. trade to the Community; and, would be in direct violation of a number of EC obligations under the Agreement.

Code Article 7.1 specifies that certification systems shall not have the effect of creating unnecessary obstacles to international trade. The U.S. can demonstrate conclusively that the Directive's requirements that meat be certified as coming from animals not treated with hormones is unnecessary. The fact that U.S. meat exports cannot be so certified will result in this certification system's being an obstacle to international trade.

Code Article 7.2 obligates the EC and its Member States to ensure that meat imported from the United States is treated no less favorably than meat of national origin. The enforcement issues surrounding the ban are such that they may result in the treatment of imports in a manner that is different from their treatment of domestic products.

Code Article 14.25 of the Agreement recognizes that benefits under the Agreement can be impaired -- and dispute settlement procedures invoked -- in cases such as this, wherein the United States considers that EC and Member State obligations under the Agreement are being circumvented by the Directive's reliance on a code of practice rather than the stipulation of a specification on the final characteristics of the product (such as a residue level of hormonal substances in livestock products).

Finally, the Agreement, in its preamble, recognizes the important contribution that international certification systems can make toward furthering the objectives of the GATT and, consequently, encourages their development. The EC hormone directive would impede the attainment of this objective of the Agreement. The United States believes that the proper forum for an international decision on the safety of the use of hormones for growth promotion is the Codex Alimentarius Committee "Committee on Residues of Veterinary Drugs in Foods", which was created in July, 1985. The relevant hormonal compounds were given high priority by the first session of this Committee in October, 1986. The decision on the safety of these compounds should be based upon all available scientific information on the subject and be made by a body of impartial scientific experts in the field. Such a committee will meet in June 1987, at the request of the Codex Committee, to evaluate these compounds and report its findings to the Codex Committee.

V. Safety of Using Hormones

In the view of the United States, meat from animals properly treated with approved naturally-occurring and synthetic hormones is safe for human consumption. In this regard, the United States believes that the approach of the U.S. Food and Drug Administration (FDA) for the regulation of natural and synthetic hormones is rational, logical and scientifically justifiable. The European Community's decision to ban the use of anabolic hormones for growth promotion in food-producing animals has led to numerous discussions regarding the safety of these compounds. The question generally asked is whether the use of either the naturally occurring sex steroids (estradiol, progesterone and testosterone) or the synthetic hormones (such as zeranol), produce any harmful effect on consumers of meat from treated animals. The FDA has determined that these compounds are safe when used according to label directions. The FDA has developed a rational and scientifically sound procedure for the establishment of safe levels of human exposure to these compounds resulting from their use in animals.

New, highly sensitive, analytical methods can detect extremely small amounts of naturally-occurring sex steroids in meat. Studies using these techniques have demonstrated that the increase in the levels of these compounds in meat of treated animals is extremely small when compared to the normal daily human production rates of these hormones. For example, a 500 gram portion of meat from treated cattle contains 15,000 times less estradiol than the average daily amount produced by men and several million times less than the daily amount produced by pregnant women. Therefore, consumers will not be at risk by eating meat from animals treated with estradiol since the amount of added hormones is negligible compared to the consumers' own daily production rate. The same situation also applies to testosterone and progesterone. No physiologic effect could be expected in consumers eating meat containing additional hormone that was equal to one percent or less of the amount produced daily. The FDA has calculated a safe level in treated animals of 120 parts per trillion (ppt) for estradiol, 3 parts per billion (ppb) for progesterone, and 600 ppt for testosterone. Using somewhat similar methods, the FDA has established safe level in treated animals for the synthetic hormone zeranol.