

WORLD TRADE ORGANIZATION
DISPUTE SETTLEMENT PROCEEDING
EUROPEAN COMMUNITIES -- MEASURES CONCERNING
MEAT AND MEAT PRODUCTS (HORMONES)

Comments on behalf of
Cancer Prevention Coalition
Public Citizen
Institute for Trade and Agricultural Policy

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October 4, 1996

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INTRODUCTION

The United States has brought to the World Trade Organization's (WTO) dispute settlement panel a challenge to the European Union's (EU) attempt to protect its consumers from the risks associated with eating meat from animals that have been treated with growth-promoting hormones. The United States claims that the EU's ban on trade in such meat is a discriminatory barrier to trade that is not justified by a legitimate health-protective purpose. However, as described in detail below, the EU's ban is not discriminatory because it is applied equally to domestic and foreign products. More importantly, the ban is a legitimate exercise of the EU's right to protect its people against a health risk and, as such, is acceptable despite any effect it might have on trade.

In light of scientific evidence that residues of growth hormones in meat may harm human health, the EU has determined that its consumers should be completely protected from this risk.

Although science is an appropriate consideration with respect to the identification of risk, determining the appropriate response to that risk is a political decision. For that reason, customary international law and GATT protect the EU's right to choose its appropriate level of protection from a risk to human health. The United States cannot, therefore, use a challenge before the WTO panel to force the EU to change its chosen level of protection. Thus, the United States challenge is essentially a claim that the

measure chosen by the EU to achieve the zero-risk level of protection is more trade-restrictive than necessary.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) states that a measure is not more trade restrictive than necessary unless there is another, less-restrictive measure that achieves the chosen level of protection. Therefore, to prove that the EU's ban is more trade-restrictive than necessary, the burden is on the United States to demonstrate that a less-restrictive measure that would achieve the same level of protection is reasonably available. The United States has not done so. To the contrary, the following analysis of the EU ban demonstrates that the ban is consistent with customary international law and GATT.

BACKGROUND

Growth Hormones

For several decades, meat producers have routinely treated livestock with natural and synthetic hormones to facilitate rapid growth. The United States Food and Drug Administration (FDA) has approved six hormones for use in increasing the rate of growth of beef cattle. These are the three naturally occurring hormones estradiol-17 β , progesterone and testosterone, and the three synthetic hormones trenbolone acetate, zeranol and melengestrol acetate (MGA). With the exception of MGA, these hormones are approved for administration in the form of pellets that are implanted in the ears of cattle. MGA is approved for

administration in cattle feed.¹ In 1995, 63 percent of all cattle in the United States and 90 percent of cattle raised in US feedlots were treated with growth hormones.²

As described in greater detail below, the use of hormones to promote growth in livestock results in residues of these hormones in meat from such livestock. These residues consist of levels or types of hormones that do not naturally occur in meat.

Hormones, including those used to promote growth in livestock, are known to be related to cancer in laboratory animals and in humans. As documented in detail below,³ there is extensive scientific data that consumption of hormones causes cancer in laboratory animals and, in some cases, in humans. In addition, the International Agency for Research on Cancer has noted that hormones may magnify the effects of other carcinogens:

Hormones may be essential to carcinogenesis by preparing the background on which tumours may ultimately arise Hormones may stimulate carcinogenesis by providing a background for subsequent tumorigenesis by chemical, physical or viral agents or by promoting the growth and metastasis of tumours once they have been initiated, or in a variety of other ways.⁴

Moreover, the growth hormones used in livestock cause estrogenic effects, including reduction in male human fertility, that are

1. Conversation with John Leighton, US FDA, Center for Veterinary Medicine, Division of Toxicology, Aug. 12, 1996.

2. Beef Facts Index -- Growth Promotants in Cattle Production (National Cattlemen's Beef Association, May 1995).

3. Pp. 36-56.

4. 21 IARC Monographs 62-63.

approximately 10,000 times higher than some pesticides that have long been recognized to be extremely dangerous to humans because of their estrogenic effects.⁵

The risks associated with consumption of growth hormones are not only theoretical. From 1979 to 1981, approximately 3,000 Puerto Rican infants and children experienced premature sexual development and developed ovarian cysts.⁶ The victims were found to have elevated levels of estrogen and the synthetic hormone zeranol in their blood and their symptoms were determined to have been caused by the consumption of meat products found to contain elevated amounts of estrogen. The same meat products were also associated with a contemporaneous increase in the rates of uterine and ovarian cancers in adult women.⁷

The EU Ban

Another incident resulting from the presence of hormones in meat led to the European Union to ban the use of growth hormones.

In 1980, the presence of the hormone diethylstilbene (DES) in meat used in baby food resulted in claims that infants that ate

5. A.L. Fisher et al., Estrogenic Action of Some DDT Analogues, 81 Proc. Soc. Expt'l Med. 439-441 (1952); W.H. Bulger & D. Kupfer, Estrogenic Activity of Pesticides and Other Xenobiotics on the Uterus and Male Reproductive Tract, in Endocrine Technology 1-33 (J.A. Thomas et al. eds. 1985); Affidavit of Samuel S. Epstein, M.D. (attached), para. 5(f) (hereafter "Epstein Aff."). See generally Theo Colborn, Dianne Dumanoski & John Peterson Myers, Our Stolen Future (1996).

6. Samuel S. Epstein, The Chemical Jungle, Int'l J. Health Servs. 278 (1990).

7. Id.

the food developed breasts and that infant girls began menstruating.⁸ As European consumers became aware of the risks associated with consuming hormone-treated meat, demand for meats and meat products declined.⁹

In response to these events, the EU instituted a ban, effective on July 31, 1982, on the use in European livestock farming of substances having hormonal action and on the sale of animals treated with such substances or meat from such animals.¹⁰

The ban was based on the concern that the use of such substances "may be dangerous for consumers."¹¹ The ban did not, however, apply to the use of estradiol-17 β , progesterone, testosterone, trenbolone acetate or zeranol. Instead, the Directive provided that whatever national regulations concerning these five hormones

8. Brie and Hormones, The Economist, Jan. 7, 1989 at 22.

Although DES was known to cause cancer in laboratory animals as early as 1938, see Robert N. Proctor, Cancer Wars at 277 n.45 (1995), DES was used both as a growth promoter in livestock and as a treatment to prevent miscarriage in pregnant women until the late 1970s. In the late 1960s, the daughters of women treated with DES during pregnancy began developing a rare form of vaginal cancer. See Robert Meyers, D.E.S., the Bitter Pill at 93-110 (1983); Epstein, The Chemical Jungle at 277. Despite these facts, the United States did not ban the use of DES until approximately 1978. See generally Robert Meyers, D.E.S., the Bitter Pill (1983). See infra _____.

9. See EU Memo/95/153 (Nov. 21, 1995).

10. Council Directive 81/602/EEC, art. 2, 1981 O.J. (L 222) 33.

11. Id., preamble.

were already in place, including those that banned their use, would remain in place pending further study.¹²

In 1985, after further study of the five hormones left unregulated by Council Directive 81/602, the Council determined that assessments of the effect of these five hormones on human health "var[ied]" and decided to extend its ban on the use of hormones to fatten livestock to all hormones, including these five.¹³ In addition, because "it would be difficult to be certain of correct operation of the [ban] as a whole if animals so treated [with growth hormones] and the meat from such animals were to be traded," the Council banned intra-European trade in hormone-treated meat and, effective January 1, 1988,¹⁴ prohibited "the importation from third countries of animals and of meat from animals to which have been administered in any way whatsoever."¹⁵

The ban thus reflects the EU's decision to expose its consumers to zero risk from exposure to residues of hormones that differ in any way from those naturally occurring in meat, either in the form of increased amounts of natural hormones or residues of synthetic hormones.

The Codex Alimentarius Commission's Decision Concerning the Use of Growth Hormones in Livestock Production

12. Id., art. 5.

13. Council Directive 85/649/EEC, preamble, art. 5, 1985 O.J. (L 382) 229-30.

14. The United States was given an extra year to comply after it complained about the ban.

15. Id. art. 6.

The Codex Alimentarius Commission (Codex), which was established in 1962 by the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO) "to facilitate the world trade in foods [through] internationally accepted standards,"¹⁶ has addressed the use of several growth promoters in raising livestock. In 1995, Codex voted to permit estradiol-17 β , progesterone and testosterone, to be used as growth-promoters without any limitation. Codex also voted to adopt certain maximum residue limits (MRLs) for the synthetic growth-promoting hormones trenbolone acetate and zeranol.¹⁷ Codex has not reached any conclusion concerning the use of MGA.¹⁸

There is reason to question whether Codex's action with respect to growth hormones established "internationally accepted standards." Codex has traditionally adopted standards by consensus, which indicates that the standards are acceptable to all of the countries that participate in the work of Codex. Codex's adoption of the standards for growth hormones, however, was far from consensual. In 1991, the first time Codex considered adopting standards for the use of growth hormones, it

16. Introducing Codex Alimentarius (FAO/WHO Food Standards Programme 1987).

17. Report of the Twenty-First Session of the Joint FAO/WHO Codex Alimentarius Commission, ALINORM 95/37 at 9; Evaluation of Certain Veterinary Drug Residues in Food, Thirty-second Report of the Joint FAO/WHO Expert Committee on Food Additives at 17-28 (1988) (FAO/WHO Expert Committee 32d Report).

18. Conversation with John Leighton, US FDA, Center for Veterinary Medicine, Division of Toxicology, Aug. 12, 1996.

was unable to reach consensus. Instead, 28 of 37 participating countries objected to adoption of the standards and forced a vote on the issue.¹⁹ Only 12 countries voted to adopt the standards, and the matter was postponed.²⁰

Codex considered the issue again in 1995. Although several countries were of the opinion that additional study was necessary before reaching a decision, a vote to postpone a decision on the standards pending further study was defeated by 31 to 28, with 5 countries abstaining.²¹ Unable to reach consensus concerning the proposed standards themselves, Codex was forced to a vote in which 33 countries voted in favor of adopting the standards, 29 voted against and 7 abstained.²²

Thus, the standards for growth hormones adopted by Codex were considered appropriate by less than a majority of the countries participating in the decision (and only slightly more than half of the voting countries). A nearly split Codex vote hardly indicates a general consensus concerning a purportedly scientific question. To the contrary, the need for a vote and the close results clearly show that there was significant doubt

19. Codex Commission Foils US Effort to Open Markets to Beef with Hormones, 21:27 Nutrition Week at 2 (Community Nutrition Institute, July 12, 1991).

20. Id.

21. Report of the Twenty-First Session of the Joint FAO/WHO Codex Alimentarius Commission, Rome, 3-8 July 1995, p. 9.

22. Id.

concerning the appropriateness of the Codex standards for these hormones.

The Codex experience with growth hormones demonstrates the fundamentally political nature of taking action based on conflicting scientific evidence concerning a potentially harmful substance. As William Ruckelshaus, former Administrator of the US EPA, has stated, "In science, the majority does not rule, as the history of science amply demonstrates."²³ However, turning science into action is an inherently political endeavor. Conflicting evidence must be weighed and risks and benefits must be balanced before action can be taken. These are political decisions that must be made by governments, which are responsible to the people who are directly affected by the outcome of the decisions. Codex, which is an international body purporting to use science to advance trade is ill-equipped to make such political decisions, as the failure to reach a consensus concerning growth hormones makes evident. Nevertheless, the United States argues that the EU should be required to abide by the Codex standards.²⁴

Fortunately, as is described in detail below, international law gives countries the right to make such political decisions by allowing them discretion in selecting their appropriate level of

23. W. Ruckelshaus, Risk, Science, and Democracy, in Issues Sci. & Tech. at 24 (Spring 1985).

24. European Communities -- Measures Concerning Meat and Meat Products (Hormones), First Submission of the United States, paras. 141-157 (Aug. 28, 1996) (hereafter "US Submission").

protection against an identified risk. If a country selects a level of protection higher than that provided by standards established by Codex, customary international law and the SPS Agreement allow it to implement more stringent measures than the Codex standards would provide. To make Codex-established standards a norm from which countries could not deviate would allow Codex to make political judgments that must instead be made at the national level. Neither customary international law nor the SPS Agreement permits such a result.

The EU's 1995 Scientific Conference

In November 1995, the EU convened the Scientific Conference on Growth Promotion in Meat Production. The Conference examined the available scientific evidence concerning the use of growth hormones and found that the limitations on the use of such hormones established in countries using them (such as the United States) and by various international committees (such as Codex), "are a reasonable safeguard of public health."²⁵

It is important to note that the EU Scientific Conference's conclusion was made in conjunction with its recognition of numerous risks and uncertainties associated with human consumption of growth hormones. Although it concluded that certain growth hormones present no risk to consumers, scientific

25. Report and Conclusions, Scientific Conference on Growth Promotion in Meat Production, 29 November - 1 December, 1995 (EU Scientific Conference Report) at 5.

evidence described in detail below²⁶ demonstrates that this conclusion was based on several mistaken assumptions and ignored important elements of risk analysis.

In light of these facts, and consistent with the Conference's overall conclusion that compliance with certain limitations on the use of growth hormones would provide a "reasonable safeguard of public health," the Conference's conclusion is legitimate only as a statement that, despite possible risks to human health from consumption of hormone-treated meat, the limitations established by national and international organizations are sufficient to attain a certain level of protection -- "reasonable safety" -- from those risks. This level of protection is different from the one chosen by the EU -- zero risk.

The risks and uncertainties identified by the Scientific Conference, as well as a substantial body of other scientific evidence described below, indicate that the limitations established by Codex and the FDA do not provide absolute protection against such risks. Legal analysis of the EU ban on trade in hormone-treated meat demonstrates that the ban is a legitimate means of achieving a zero-risk level of protection against the risks identified by the Scientific Conference, risks that are well supported by scientific evidence.

LEGAL ANALYSIS OF THE BAN

26. Pp. 48-52.

A stated purpose of GATT is to facilitate trade by reducing or eliminating tariffs. Because nontariff measures may also interfere with trade, GATT attempts to prevent such measures from being a substitute for tariffs. The core principle of such prevention is that imported products must not be treated less favorably than domestic ones. GATT enforces this national treatment principle by prohibiting discriminatory treatment of imported products. The EU ban on trade in hormone-treated meat does not discriminate against foreign products. Rather, it is a legitimate measure intended to protect the health of consumers from risks associated with residues of growth hormones in meat.

As described in greater detail below, the customary international law norm of the precautionary principle permits countries to take steps to protect human health. Consistent with this principle, GATT allows countries to implement measures genuinely intended to protect against risks to human health even if those measures constitute a barrier to trade. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is intended to distinguish genuine sanitary measures from those whose only purpose is to disguise attempts to protect domestic products from foreign competition.

In accordance with international law and the SPS Agreement, the EU chose to subject consumers to zero risk from hormone residues in meat. Scientific evidence supports the EU's decision to achieve a higher level of protection than would be provided by measures such as the standards approved by Codex or the United

States. The EU implemented its ban as a means of achieving its level of protection. Because no less restrictive measures are reasonably available to provide zero risk from hormone residues in meat, the ban is permitted by customary international law and the SPS Agreement even if it restricts international trade.

II. THE EU BAN ON TRADE IN HORMONE-TREATED MEAT IS NOT DISCRIMINATORY AND THEREFORE DOES NOT VIOLATE GATT

Through GATT, members of the World Trade Organization have taken steps to reduce barriers to trade and eliminate "discriminatory treatment in international commerce."²⁷ To this end, GATT contains several requirements to prevent discriminatory treatment of foreign goods and services. The basic prevention of discrimination is provided by the requirement that the products of any member country "be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."²⁸ Products imported from a member country must also be accorded the same treatment as products from any other member country.²⁹

One GATT panel has explicitly distinguished discriminatory measures from nondiscriminatory measures implemented on a nondiscriminatory basis, such as labelling requirements,

27. GATT, preamble.

28. Id. Art. III(4).

29. Id. Art. I(1).

ingredient disclosure regulations, and advertising bans, and stated that such nondiscriminatory measures would be consistent with Article III(4).³⁰ In addition, the panel stated that Thailand could regulate the overall supply or price of cigarettes to lessen cigarette use as long as it afforded imported cigarettes no less favorable treatment than domestic ones.³¹

As in the Thai cigarette case, the EU ban applies to trade in all hormone-treated animals and meat; it makes no distinction between foreign and domestic products or between US products and any other foreign products. The ban is therefore a completely neutral measure and is consistent with the anti-discrimination requirements of Articles I and III.

GATT provides further protection against discrimination against foreign products and services through Article XI, which provides:

No prohibitions or restrictions . . . shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party.

The United States admits that the EU ban is not a restriction on importation, but is instead an internal measure that, in the case of imports, is enforced at the border.³² This admission supports the conclusion that the EU ban is applied

30. Thailand -- Restrictions on Importation of and Internal Taxes on Cigarettes, 37th Supplement BISD 200, ¶ 77 (adopted 1990).

31. Id. ¶ 79.

32. US Submission, para. 180 n. 93.

neutrally with respect to domestic and foreign animals and meat and is therefore not a discriminatory measure that violates Article III. Moreover, even if the EU ban were considered a restriction on imports, it would be permitted by international law and GATT which specifically permit a country to take trade restrictive measures intended to protect human health.

III. THE EU BAN ON TRADE IN HORMONE-TREATED MEAT IS SUPPORTED BY INTERNATIONAL LAW AND GATT AS A LEGITIMATE SANITARY MEASURE

A. Customary International Law: The Precautionary Principle

Under customary international law, countries have the right to regulate activities and substances that may be harmful to human health even if no conclusive or overwhelming evidence is available as to whether the activity actually causes that harm, the precise degree of harm or the process by which it occurs.³³

33. The precautionary principle has been included in numerous multilateral international treaties and declarations. Examples of these include the Rio Declaration on Environment and Development, UN Conference on Environment and Development, U.N. Doc. A/CONF.151/5/Rev.1 (1992), reprinted in 31 I.L.M. 874 (1992) ("In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."); the Framework Convention on Climate Change, U.N. Doc. A/AC.237/18 (Part II)/Add.1 (1992), reprinted in 31 I.L.M. 849 ("The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures"); the Ministerial Declaration of the Second World Climate Conference, Nov. 7, 1990, reprinted in 1 Y.B. Int'l Env'l L. 473 (1990) (ministers and representatives of 137 countries agree to "protect the ozone layer by taking precautionary measures to control . . . emission of substances that deplete it"); the

This principle, called the precautionary principle, has been a part of domestic and international law for several decades and has become a "broadly accepted basis for international action."³⁴

The precautionary principle is based on the premise that science does not always provide the information or insights necessary to take protective action effectively or in a timely manner and that undesirable and potentially irreversible effects may result if action is not taken until science does provide such insights.³⁵ Because of its focus on the potentially serious implications of inaction, the precautionary principle "generally require[s] a greater obligation to exercise precaution in proportion to the risk of irreversible permanent damage to human

Second International Conference on the Protection of the North Sea, Ministerial Declaration 1 (1987) (ministers of the EEC and eight countries agree that the North Sea ecosystem should be protected through the reduction of pollution "even where there is no scientific evidence to prove a causal link between emissions and effects ('the principle of precautionary action')"); the World Charter for Nature, G.A. Res. 37/7, U.N. GAOR, 37th Sess., Supp. No. 51, U.N. Doc. A/Res/37/7 (1982), reprinted in 22 I.L.M. 455 (1983) ("Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed.").

34. Philippe Sands, The Greening of International Law: Emerging Principles and Rules, 1 Global Legal Studies J. 293, 301 (1994). See generally Interpreting the Precautionary Principle 262 (Tim O'Riordan & James Cameron eds. 1994).

35. See E. Hey, The Precautionary Principle in Environmental Policy and Law: Institutionalizing Caution, 4 Geo. Int'l Env'l L. Rev. 303, 308-09 (1992).

life or health."³⁶ Carcinogens like growth hormones present precisely this situation, because cancer is frequently irreversible and possible cures are almost always extremely costly.

The importance of the precautionary principle is demonstrated by numerous instances in which precautionary action by governments prevented serious harm. For example, by taking precautionary steps with respect to possible risks from the use of thalidomide, the United States avoided a potentially disastrous epidemic of birth defects.

In the 1950s, thalidomide was discovered to be a very effective sedative and anti-emetic. Tests in laboratory animals showed no negative effects. As a result, thalidomide became a favorite non-prescription sleep-aid in West Germany and elsewhere, even being sold in a liquid form for children, and was used by pregnant women to prevent nausea. In subsequent years, however, some long-term users of the drug began complaining of neurological problems.

At about the same time, FDA was considering an application for approval of thalidomide for use in the United States. An FDA scientist familiar with the fact that drugs can affect fetuses and newborns completely differently from adults learned about the reports of possible side-effects associated with long-term use of

36. James E. Hickey, Jr. & Vern R. Walker, Refining the Precautionary Principle in International Environmental Law, 14 Va. Env'l L.J. 423, 436 (1995).

thalidomide and became concerned over the proposed use of the drug to prevent nausea during pregnancy. She therefore requested more data to show that the drug was safe during pregnancy. Before the manufacturer of the drug could provide such information, reports arrived from Europe noting an alarming increase in the number of babies born with deformities and a Canadian doctor reported that such effects might result from the use of thalidomide during pregnancy. Although the precise mechanism by which thalidomide affected fetuses was not understood -- in fact, the mechanism remained unclear into the 1980s -- FDA took a precautionary approach and refused to approve the use of thalidomide in the United States.

Thalidomide is estimated to have been responsible for deformities in more than 10,000 babies in the countries in which it was approved. Through its precautionary action, the FDA prevented a similarly devastating experience in the United States.³⁷

The dangers of failing to take precautionary action are not simply hypothetical. The case of DES is a perfect example. When DES was first approved by the FDA for use as a growth promoter in meat animals, scientific evidence demonstrated that the hormone caused cancer in laboratory animals.³⁸ Use of the hormone was nevertheless approved on the basis of a determination that there

37. Max Sherman & Steven Strauss, Thalidomide: A Twenty-Five Year Perspective, 41 Food, Drug, Cosm. L.J. 458-466 (1986).

38. Epstein, The Chemical Jungle at 277.

would be no unacceptable risk to humans as long as no DES residue could be measured in meat from animals treated with DES.³⁹ In 1960, Dr. Thomas Carney, vice-president of Eli Lilly & Company, a major DES manufacturer, and chairman of the Pharmaceutical Manufacturers' Association's Committee for the Study of Carcinogenic Substances, testified before the US Congress in opposition to legislation that would prohibit the use of carcinogenic food additives. Dr. Carney testified that

DES's safety in man and animals has been fully established for years Under the Delaney amendment, this completely safe and very valuable chemical could never have been developed and introduced in animal feeds and its many benefits to farmers and consumers would never have been realized I should emphasize that there is no detectible residue in beef or sheep which have been fed [DES] under recommended conditions; so it cannot cause any side effects.⁴⁰

In the early 1970s, the daughters of women treated with DES during pregnancy began developing a rare form of vaginal cancer.⁴¹

This caused FDA to reevaluate the evidence concerning the safety of DES and to determine that the drug presented a risk even at residue levels below the smallest detectable amounts.⁴² This finding eventually led to a ban on the use of DES in the United

39. See Margaret Ann Miller & John K. Leighton, Risk Assessment Strategies for Hormones and Hormone-Like Substances at 2-3 (US FDA 1995).

40. Quoted in D.E.S., the Bitter Pill at 194.

41. See Robert Meyers, D.E.S., the Bitter Pill (1983); Epstein, The Chemical Jungle at 277.

42. D.E.S., the Bitter Pill at 194.

States.⁴³ However, the failure to take precautionary action in response to evidence that DES caused cancer in laboratory animals resulted in irreparable injury to thousands of people exposed to the drug.

As the examples of thalidomide and DES demonstrate, the precautionary principle is essential if governments are to be able to fulfill their responsibility to protect against harm to human health. Moreover, as a rule of international law, the precautionary principle should guide the interpretation of other agreements relating to the protection of human health. The Vienna Convention on the Law of Treaties provides that treaties are to be interpreted in light of "any relevant rules of international law applicable in the relations between the parties".⁴⁴ Therefore, the GATT rules relating to the protection of human health should be interpreted as consistently as possible with the precautionary principle. Fortunately, as described in the following sections, both the SPS Agreement and Article XX(b) of GATT support the right of a country to take precautionary health-protective measures by choosing the level of protection it determines to an appropriate response to a given risk.

B. The SPS Agreement and Article XX(b)

GATT recognizes the right of countries to take measures to protect human health even though such measures may also restrict

43. See generally, id. at 189-202.

44. Vienna Convention on the Law of Treaties, Art. 31.3(c), U.N. Doc. A/CONF. 39/27, 8 I.L.M. 679 (1969).

international trade. Article XX(b) of GATT and the SPS Agreement both protect a country's right to take steps that are "necessary for the protection of human, animal or plant life or health" even if those steps interfere with trade in a manner that would otherwise be inconsistent with the GATT.⁴⁵ As one GATT dispute panel has stated, by creating such exceptions to the general trade rules, the member nations have made clear that countries may "give priority to human health over trade liberalization."⁴⁶ The Thai cigarette panel recognized the right of countries to take measures to protect against risks to human health even though such measures might have the effect of restricting trade.⁴⁷

Simply invoking health risks, however, does not relieve a country of the obligations of the national treatment principle of Article III(4). Therefore, GATT includes several provisions intended to distinguish between measures that are genuinely intended to protect public health and those that constitute arbitrary or unjustified discrimination or disguised restrictions on trade.

A health-protective measure that is discriminatory -- i.e., one that, unlike the EU ban on hormone-treated meat, applies to domestic products or services differently than to foreign ones -- is nevertheless legitimate as long as it does not discriminate

45. SPS Agreement, Art. 2(1). See also GATT, Art. XX(b).

46. Thailand -- Restrictions on Importation of and Internal Taxes on Cigarettes, ¶ 73, GATT BISD 37S/200 (Nov. 1990).

47. Id.

"arbitrarily or unjustifiably."⁴⁸ If the discriminatory treatment is predicated on a genuine need to protect human health and is applied to all countries equally, the discrimination is unlikely to be considered arbitrary or unjustified.⁴⁹ Thus, even if the EU ban were discriminatory, it would be legitimate because it is predicated on a genuine need to protect against the risk to human health posed by residues of growth hormones in meat and is applied equally to all countries.

As previously explained, however, the EU ban applies equally to domestic and foreign products and therefore is not discriminatory. Such a non-discriminatory measure is legitimate under GATT as long as it is not "applied in a manner which would constitute a disguised restriction on international trade."⁵⁰ This requirement is not intended to restrict the right of countries to take legitimate protective measures, but to avoid the "abuse or illegitimate use of the exceptions [such as for sanitary measures] to substantive [GATT] rules."⁵¹

48. SPS Agreement, Art. 2(3); GATT Art. XX.

49. See United States -- Prohibitions of Imports of Tuna & Tuna Products from Canada, 29th Supp. BISD at 91 (adopted Feb. 22, 1982) (discrimination against Canada not arbitrary or unjustifiable because similar actions had been taken against other countries for similar reasons).

50. SPS Agreement, Art. 2(3); GATT Art. XX.

51. United States -- Standards for Reformulated and Conventional Gasoline, Report of the Appellate Body, AB-1996-1 at 25 (29 Apr. 1996) ("The fundamental theme" of the prohibition against arbitrary or unjustifiable discrimination and disguised restrictions on international trade in the application of Article XX "is to be found in the purpose and object of avoiding abuse or

The United States argues that the EU's ban is a disguised restriction on international trade simply because the EU has recognized that the ban has effects that restrict trade in a manner that benefits the EU. Specifically, the United States points to the EU's recognition that "the ban would help reduce surplus supplies of meat in the EC and lower the cost of the EC's Common Agricultural Policy."⁵² However, the mere fact that a sanitary measure has effects that restrict trade does not make it a "disguised restriction on international trade," as the United States claims.⁵³ To the contrary, the entire purpose of the requirements of the SPS Agreement is to distinguish between legitimate and illegitimate measures that restrict trade -- those that have a legitimate health-protective purpose as defined by the Agreement are permitted despite their resulting trade restrictions and those that do not are prohibited.

If the mere existence of a trade-restrictive effect were enough to label a measure a disguised restriction on trade, the detailed requirements of the SPS Agreement would have no meaning.

As noted above, the Thai cigarette panel recognized that necessary sanitary measures do not necessarily constitute a disguised restriction on trade simply because they interfere with trade. In particular, the panel acknowledged that an across-the-

illegitimate use of the exceptions to substantive [GATT] rules.").

52. US Submission, paras. 5, 27-31.

53. Id., paras. 137-140.

board advertising ban might have a disproportionate impact on new foreign suppliers that did not yet have a share of the market, but noted any such effect was unavoidable under the ban, which was a legitimate sanitary measure.⁵⁴

As the Thai cigarette case demonstrates, as long as the EU ban is a legitimate sanitary measure under the SPS Agreement, it is not a disguised restriction on trade simply because the EU may obtain other benefits from the ban. The United States has taken the same position, stating that, under the SPS Agreement,

[a]s long as a food safety measure is consistent with the other provisions of the SPS Agreement, it is unlikely that it would constitute a "disguised restriction on trade." The other provisions of the Agreement -- such as the requirement to base SPS measures on scientific principles -- are designed to ensure that measures are truly intended to protect food safety. . . . [I]t is important to note that the mere fact that a food safety measure may have a disproportionate effect on importers is not sufficient to qualify it as a disguised restriction on trade.⁵⁵

The USTR explained its interpretation by using an example that is analogous to the EU's ban on trade in hormone-treated meat. The USTR stated that a ban on listeria-contaminated cheese -- which would affect imported cheese more than domestic cheese because the types of cheese most prone to listeria contamination are imported -- would not constitute a disguised restriction on trade because it "applies equally to US and foreign cheese

54. Thailand -- Restrictions on Importation of and Internal Taxes on Cigarettes, ¶¶ 73-74, GATT BISD 37S/200 (Nov. 1990).

55. Report on US Food Safety and the Uruguay Round, Protecting Consumers and Promoting US Exports at 8 (USTR Report on Food Safety) (USTR June 1994).

producers."⁵⁶ Likewise, even if the EU's ban on trade in hormone-treated meat affects imported meat more than domestic meat, it is a legitimate health protective measure that does not violate GATT as long as it satisfies the requirements of the SPS Agreement.

C. **The European Union Legitimately Selected Zero Risk as Its Appropriate Level of Protection Against the Risks of Exposure to Growth-Promoting Hormones**

When a nation identifies a potential risk to human health from an activity or a substance, it must decide whether and to what extent to take steps to protect against that risk. While science plays an important role in identifying the existence of a risk, the decision concerning the appropriate response to that risk is purely political. It requires weighing the evidence, which may be conflicting, that the risk exists. More significantly, it requires weighing how much the citizens of the country fear the particular risk and how much, if at all, they value the benefits that the activity or substance provides.

By balancing concern about the risk against the value of the activity or substance, the government of a country can determine what amount of that risk is acceptable to its citizens and, therefore, what level of protection against that risk it must strive to attain. This decision goes to the heart of what governments do -- determining a course of action based on the fears and values of citizens. Because of the essentially political nature of the choice of a level of protection against

56. Id.

risk, customary international law and the SPS Agreement protect the right of countries to make this choice.

The SPS Agreement explicitly protects a country's freedom to choose the level of protection it considers appropriate. The Preamble to the Agreement states that the Agreement is not intended to require countries "to change their appropriate level of protection of human, animal or plant life or health." An amendment to the final draft of the preamble reinforced this important principle. Although earlier drafts of the Agreement expressed an unqualified desire to harmonize national SPS measures, the final draft was amended to emphasize that such harmonization was not intended to require countries "to change their appropriate level of protection of human, animal or plant life or health."⁵⁷ This amendment reflected the agreement of the negotiators of the SPS Agreement that

each government is free to choose the levels it considers appropriate for the protection of human, animal or plant life or health and of the environment and that no country should be prevented from taking measures necessary to achieve those levels subject to the requirement, inter alia, that the measures are in accordance with the provisions of the Agreement.⁵⁸

57. SPS Agreement preamble; compare Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Dunkel Draft), GATT Doc. MTN.TNC/W/FA, sec. L, pt. C, p. L.35 (Dec. 20, 1991).

58. Letter from Peter D. Sutherland, GATT Director-General, to Ambassador John Schmidt, Chief US Negotiator, Dec. 15, 1993.

The freedom of each country to choose its level of protection is emphasized in the Agreement's definition of "appropriate level of protection":

The level of protection deemed appropriate by the country establishing [the SPS] measure to protect human, animal or plant life or health within its territory. Note: Many parties otherwise refer to this concept as the "acceptable level of risk."⁵⁹

Pursuant to its right to do so, the European Union has selected zero risk as its appropriate level of risk with respect to exposure to residues of growth hormones in meat. The United States' own interpretation of the SPS Agreement supports the EU's choice of its level of protection. The United States has recognized that the SPS Agreement's definition of appropriate level of protection

explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its level of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment.⁶⁰

59. SPS Agreement, Annex A para. 5.

60. The Uruguay Round Agreements Act, Statement of Administrative Action at 89 (US Statement of Administrative Action). See also USTR Report on Food Safety at 4, 6 ("**[T]he requirement for a scientific basis applies to SPS measures; it does not apply to the level of food safety that those measures are designed to achieve. . . . [T]he Agreement specifically preserves the right of governments to choose the level of risk they find acceptable**" (emphases (both bold and underline) in original)).

The United States argues that the EU has not really chosen a zero risk level of protection because the EU's ban permits the use of natural growth hormones for therapeutic purposes.⁶¹ This is incorrect, however, because the ban explicitly regulates the therapeutic use of hormones to ensure that such use will not result in hormone residues that differ from those that occur naturally in meat.

The hormones approved for therapeutic uses are those that occur naturally in meat -- estradiol, progesterone and testosterone.⁶² Hormones used for therapeutic treatment may only be administered by a veterinarian.⁶³ This ensures that the hormones are not administered improperly. Most significantly, the animals to which the hormones are administered for

The Uruguay Round Agreements Act Statement of Administrative Action

represents an authoritative expression by the Administration concerning its views regarding the interpretation and application of the Uruguay Round agreements, both for purposes of U.S. international obligations and domestic law.

Furthermore, the Administration understands that it is the expectation of the Congress that future Administrations will observe and apply the interpretations and commitments set out in this Statement. Moreover, since this Statement will be approved by the Congress at the time it implements the Uruguay Round agreements, the interpretations of those agreements included in this Statement carry particular authority.

US Statement of Administrative Action at 1.

61. US Submission, para. 155.

62. Council Directive 85/649/EEC, art. 2, 1985 O.J. (L 382) 229-30.

63. Id., art. 3(b).

therapeutic purposes are to be clearly marked and may not be slaughtered before the end of a waiting period.⁶⁴ This practice ensures that any meat from animals receiving therapeutic treatment with natural hormones will not contain residues of hormones that differ from the hormones that are naturally present in the meat. These requirements ensure that the therapeutic administration of naturally occurring growth hormones does not contravene the EU's objective of achieving zero risk from hormone residues that differ from those that naturally occur in meat.⁶⁵

The United States has not claimed that the EU should permit the importation of meat that has been therapeutically treated with hormones pursuant to the regulations described above or that it has such meat available for export to the European Union. Instead of limiting its challenge to therapeutically treated meat, the United States has challenged the EU ban in its entirety, arguing that the EU should be required to allow imports of meat from animals treated with hormones to promote growth. As demonstrated below, using hormones to promote growth results in residues of hormones that pose risks to human health. These risks are not present when hormones are used therapeutically under the restrictions imposed by the European Union. Therefore, the EU's ban, including the restrictions on the therapeutic use

64. Id.

65. See Epstein Aff., para. 6.

of hormones, is consistent with the EU's choice of zero-risk as its level of protection.

The SPS Agreement states that, in choosing their appropriate level of protection, countries "should . . . take into account the objective of minimizing negative trade effects."⁶⁶ An early draft of the Agreement required countries to consider the effect on trade of the level of protection they chose, but the countries rejected a mandatory requirement in favor of a hortatory one.⁶⁷ The use of the non-mandatory language reflects the Agreement's emphasis on countries' right to take the steps necessary to choose the appropriate level of protection against risk and the political, not economic, nature of that choice.⁶⁸ Although the EU could minimize the effect on trade of its concern over the risks associated with growth hormones by selecting a lower level of

66. SPS Agreement, Art. 5(4) (emphasis added).

67. See Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN.TNC/W/55/Rev.1, p. 167 ("Contracting Parties shall . . . take into account the objective of maximizing trade opportunities.").

68. The SPS Agreement makes clear that, with respect to human health risks, economic factors such as "loss of production or sales" if the potentially harmful agent enters the country's territory, "the costs of control[ling]" such entry and "the relative cost effectiveness of alternative approaches to limiting risks" are irrelevant to risk assessment or the determination of the appropriate measures to be used to protect against that risk.

Compare SPS Agreement, Art. 5(2) (setting forth the factors enumerated in the text above) with id., Art. 5(3) (making economic factors relevant in "assessing the risk to animal or plant life or health" (emphasis added)). The United States agrees with this position. See US Statement of Administrative Action at 92 ("The factors in [paragraph 18] apply only with respect to [SPS] measures to protect animal or plant life or health, not to human life or health.").

protection, it cannot be required to do so when it has determined that considers a higher level of protection is appropriate.

The SPS Agreement thus requires that the EU's choice of a level of protection be respected. The WTO panel should not allow the United States to use a challenge under the SPS Agreement to force the EU to accept the United States' chosen level of protection, which is lower than the level that the EU has determined to be appropriate. To do so would not only be inconsistent with the SPS Agreement, it would make that Agreement an obstacle to a country's right to take precautionary sanitary measures. This would violate international law, which requires that the SPS Agreement be interpreted as consistently as possible with the precautionary principle.⁶⁹

D. **There is Ample Evidence of Risk for the EU to Maintain a Higher Level of Protection than Codex's Standards Would Provide**

The EU Scientific Conference recognized certain risks and uncertainties associated with human consumption of hormone treated meat. These risks are supported by a substantial body of other scientific evidence. Despite this evidence, the EU Scientific Conference nevertheless determined that the limitations on the use of growth hormones established by certain domestic and international bodies, such as Codex, are a "reasonable safeguard of public health." "Reasonable safety" is

69. See supra n. 44.

a level of protection that is lower than the EU's zero risk level of protection.

If the EU had wanted to obtain less than absolute protection against these risks, it might have decided to do so by applying the standards adopted by Codex. However, the risks associated with consumption of hormone-treated meat that were recognized by the Scientific Conference and are supported by scientific evidence indicate that the limitations established by Codex and the FDA cannot provide absolute protection against such risks. The EU has chosen to achieve a higher level of protection than those standards would achieve, i.e., a zero-risk level of protection. Therefore, it has used a measure that is intended to achieve that level of protection -- a total ban on trade in hormone-treated meat.

The SPS Agreement is not intended to require "the upward or downward harmonisation of technical regulations or standards as a result of international standardisation activities."⁷⁰ Therefore, as the United States has recognized, the choice of a measure that is different from international standards "does not in itself, create any adverse presumption concerning that measure."⁷¹ To this end, the Agreement explicitly recognizes the right of countries to

70. Letter from Peter D. Sutherland, GATT Director-General, to Ambassador John Schmidt, Chief US Negotiator, Dec. 15, 1993.

71. US Administrative Statement at 92.

introduce or maintain [SPS] measures which result in a higher level of [SPS] protection than would be achieved by measures based on the relevant international standards . . . if there is a scientific justification, or as a consequence of the level of protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 16 through 23.⁷²

The SPS Agreement explains that there is a scientific justification for adopting a measure resulting in a higher level of protection than afforded by international standards if

on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of protection.⁷³

Thus, under the requirements of the SPS Agreement, the first step in analyzing an SPS measure that provides a higher level of protection than international standards is to evaluate the available scientific information through a risk assessment.⁷⁴ If the scientific evidence shows that a risk exists, the country may implement measures necessary to achieve its chosen level of protection against that risk.

1. The Use of Growth Hormones in Livestock Presents a Real Health Risk Justifying Protective Measures

Under the SPS Agreement, risk assessment is "the evaluation of the potential adverse effects on human . . . health arising

72. SPS Agreement, Art. 3(3).

73. Id., Art. 3(3) n.2.

74. The only "relevant provisions of [the SPS] Agreement" that apply to the examination and evaluation of scientific evidence are Article 5, paragraphs 1-7, which set forth the requirements for risk assessment.

from the presence of additives, contaminants [or] toxins . . . in food."⁷⁵

The United States contends that "presumably, the level of any risk, if one could have been identified, would have been related to the level of residue" of hormones in meat.⁷⁶ However, the SPS Agreement does not make any distinction based on levels of risk. The Agreement's focus on assessing the risk of the "presence" of additives, instead of a certain amount or concentration of additives, makes clear that risk assessment is intended to determine whether such risk exists at any amount or concentration. Therefore, the determination that a particular additive constitutes a risk does not depend on the amount of the additive required to cause harm or the amount of harm likely to be caused.

The United States position in its submission is inconsistent with its own previously stated position:

Importantly, "risk assessment" as used in the Agreement is not limited to quantitative risk assessment, which is a particular type of risk assessment used to evaluate the potential for carcinogenesis.⁷⁷

The USTR reiterated this point while defending the Delaney Clause as a measure that satisfies the requirements of the SPS

75. SPS Agreement, Annex A, para. 4.

76. US Submission, para. 127.

77. US Statement of Administrative Action at 95. See also id. at 92 (risk assessment means evaluating "whether a particular substance or product, including a process or production method, poses any risk to human, animal, or plant life or health" (emphasis added)).

agreement. Under the Delaney Clause, the United States prohibits residues in processed foods of additives that concentrate in such foods and that have been "found to induce cancer when ingested by man or animal."⁷⁸ Although the USTR recognized that "some scientists might argue that small amounts of [certain chemicals banned under the clause] pose very little cancer risk," it stated that the Delaney Clause is nevertheless

completely consistent with the SPS Agreement. Congress' decision that U.S. consumers should not be subjected to any risk from cancer-causing chemicals in foods is a value judgment that is fully protected under the Uruguay Round [SPS] Agreement.⁷⁹

Determining that a risk exists also does not require proving that the substance or process in question will cause harm. This is clear from the definition of "risk" -- "exposure to the chance of injury or loss."⁸⁰ Therefore, the possibility that a substance or process may cause harm is sufficient to permit a country to institute measures to protect against that risk. The United States has agreed with this interpretation: "The determination that a particular substance poses a risk of cancer is a scientific determination, based on an evaluation of the potential for a substance to induce cancer."⁸¹ In other words, with respect

78. 21 U.S.C. § 348(c).

79. USTR Report on Food Safety and the Uruguay Round 4 (emphasis in original). See also id. Executive Summary at i.

80. Random House Dictionary of the English Language 1660 (2d ed. unabridged 1987) (emphasis added).

81. US Statement of Administrative Action at 95 (emphasis added).

to hormone-treated meat, the EU may choose a level of protection and implement measures to achieve that level of protection unless there is absolutely no possibility that the use of such hormones could be a risk to human health.

Defining risk assessment in this manner is consistent with the precautionary principle. If SPS measures could only be instituted to protect against risks that were absolutely certain to occur or that would occur only upon exposure to a certain amount of a substance, nations would not be able to implement protective measures where there was conflicting or incomplete scientific evidence of possible harm.

In assessing risk, the SPS Agreement requires countries to take into account

available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.⁸²

Contrary to the United States' assertion,⁸³ consideration of these factors demonstrates that the EU's ban is based on an assessment of risk and is supported by scientific evidence that the use of growth hormones in meat animals constitutes a risk to human health.

a. Meat From Animals Treated with Growth Hormones Contains Residues of those Hormones

82. SPS Agreement, Art. 5(2).

83. See US Submission, paras. 5, 102-110.

As the following evidence demonstrates, the use of each of the growth-promoting hormones approved by Codex and the FDA results in residues of these hormones in meat from the animals in which they are used. These residues are greater than the amounts that naturally occur in such meat.

Estradiol-17 β

A Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives found that the use of estradiol-17 β as a growth promoter in livestock increases the natural level of that hormone in edible animal tissues to two to five times the levels at which it is naturally found.⁸⁴

A study submitted to the FDA indicated that the administration of Synovex-S, a combination of estradiol and progesterone that is approved for use in the United States, resulted in estradiol-17 β residues that were six to 23 times as great as those naturally occurring in animal tissue.⁸⁵ Moreover, the use of a second Synovex-S implant, which is also approved by the FDA, nearly doubled the estradiol-17 β residues in fat and muscle of the treated animals.⁸⁶ The use of Revalor-H, an FDA-

84. FAO/WHO Expert Committee, 32d Report at 18.

85. Freedom of Information Summary for Synovex-S (Estradiol Benzoate/Progesterone), NADA No. 009-576 at 3, FDA Center for Veterinary Medicine (Aug. 19, 1994).

86. Id. at 4.

approved combination of estradiol and TBA, also results in residues of estradiol that are greater than those naturally occurring in animal tissue.⁸⁷

Progesterone

The FAO/WHO Expert Committee found that there is as much as twice the amount of progesterone residue in the edible tissues of progesterone-treated animals as in the tissues of untreated animals.⁸⁸ The same is true when progesterone and estradiol-17 β are administered in combination.⁸⁹

Testosterone

The FAO/WHO Expert Committee found that administration of testosterone in combination with estradiol-17 β results in testosterone residues from two to 13 times the normal amounts in the edible animal tissues.⁹⁰ Studies submitted to FDA indicated that implantation in steers of a combination of estradiol and testosterone resulted in testosterone residues in edible tissues

87. Freedom of Information Summary for Revalor-H (Trenbolone Acetate and Estradiol), NADA No. 140-992 at 6, FDA Center for Veterinary Medicine (Dec. 13, 1994). See also Epstein Aff., para. 3(a).

88. FAO/WHO Expert Committee, 32d Report at 20.

89. Id. at 21.

90. Id. at 22.

that were as much as 30 times higher than normal background levels.⁹¹

Trenbolone Acetate (TBA)

The FAO/WHO Expert Committee found that residues of TBOH, a carcinogenic metabolite of TBA, occur in the edible tissues of animals treated with TBA.⁹² Studies submitted to the FDA indicated the same.⁹³ TBOH does not occur naturally in animal or human tissues.⁹⁴

Zeranol

The FAO/WHO Expert Committee found that treatment with zeranol results in residues in the edible tissues of the treated animals.⁹⁵ Zeranol does not occur naturally in animal or human tissues.⁹⁶

Melengestrol Acetate (MGA)

91. Freedom of Information Summary for Synovex-H, NADA No. 11-427, FDA Center for Veterinary Medicine (undated). See also Epstein Aff., para. 3(b).

92. FAO/WHO Expert Committee, 32d Report, at 23-24.

93. Freedom of Information Summary for Finaplix (Trenbolone Acetate), NADA No. 138-612 at 13, FDA Center for Veterinary Medicine (approved July 2, 1986); Freedom of Information Summary for Revalor-S (Trenbolone Acetate and Estradiol), NADA No. 140-897 at 5, FDA Center for Veterinary Medicine (Nov. 27, 1991).

94. See Epstein Aff., para. 3(c).

95. FAO/WHO Expert Committee, 32d Report at 26.

96. Id. at 23. See also Epstein Aff., para. 3(d).

Studies submitted to the FDA indicate that edible tissue from animals treated with MGA contain residues of that hormone.⁹⁷ MGA does not occur naturally in animal or human tissues.⁹⁸

b. Consumption of Growth Hormones Presents a Risk to Human Health

The evidence described in this section demonstrates that growth promoting hormones, including all of the hormones approved for use by the FDA and Codex, are known to cause cancer in humans and laboratory animals. As explained below, this risk is exacerbated by the fact that these hormones are frequently administered improperly, increasing their concentration in meat. Moreover, there is not a practical method of testing meat before it is sold or consumed to ensure that it does not contain residues of hormonal additives. There is therefore more than sufficient risk of harm to human health to justify SPS measures to protect against those risks.

(1) Hormones Approved by the Codex Alimentarius Commission and FDA Constitute a Risk to Human Health

Estradiol-17 β

The International Agency for Research on Cancer (IARC) has determined that exposure to sex hormones causes cancer. The IARC

97. Freedom of Information Summary for MGA 100/200 Premix, MGA 500 Liquid Premix (Melengestrol Acetate), NADA Nos. 034-254 and 039-402, FDA Center for Veterinary Medicine (June 29, 1994).

98. See also Epstein Aff., para. 3(e).

has determined that exposure to estrogenic hormones, including estradiol-17 β ,⁹⁹ causes human cancer.¹⁰⁰ As the IARC stated:

The administration of oestrogens (including [DES]) to adult women is causally associated with an increased incidence of endometrial cancer. There is also a possibility that the risk of breast cancer is increased by such therapy.¹⁰¹

These effects are increased both with exposure to larger doses of estrogens and with increased duration of exposure to small doses.¹⁰² Exposure to estradiol-17 β has been found to cause mammary, pituitary, uterine, cervical, vaginal, testicular, lymphoid, kidney and bone tumors in experimental animals.¹⁰³

The FAO/WHO Expert Committee on Food Additives also found that high levels of estradiol-17 β "can increase the incidence of tumours in experimental animals."¹⁰⁴ Estradiol-17 β was found to

99. The IARC concluded that the carcinogenic potential of estradiol-17 β is comparable to that of DES and that the carcinogenic properties of DES are due to its estrogenic activity (*i.e.*, the same activity caused by exposure to estradiol-17 β). See 21 IARC Monographs 131. This finding is significant because DES is a potent carcinogen that causes vaginal cancer and serious reproductive problems in the daughters of women to whom it has been administered during pregnancy. The IARC has unequivocally concluded that DES causes cancer. IARC Monographs, Supp. 7 at 273. In fact, the carcinogenic effect of DES caused the FDA to ban its use in livestock production.

100. IARC Monographs, Supp. 7, Preamble and p. 280.

101. 21 IARC Monographs 133.

102. IARC Monographs, Supp. 7 at 280.

103. IARC Monographs, Supp. 7 at 284.

104. FAO/WHO Expert Committee, 32d Report at 18.

increase the incidence of certain brain tumours in experimental mice.¹⁰⁵

Exposure to an excess of estrogen has also been tied to male reproductive disorders. A recent report from the US National Institute of Environmental Health Sciences states:

The male reproductive system is very sensitive to the influence of an excess of estrogen; therefore, estrogen-like effects in the environment are a primary suspect for causing the increased reproductive disorders of men and wildlife animals.¹⁰⁶

Progesterone

The IARC has concluded that progesterone, which studies have shown to increase the incidence of ovarian, uterine and mammary tumors in mice, may cause cancer in laboratory animals.¹⁰⁷ The FAO/WHO Expert Committee on Food Additives found that progesterone increased the incidence of tumors of the mammary gland, ovary, uterus and vagina in laboratory animals.¹⁰⁸

The IARC has also stated that there is evidence that low doses of progesterone administered over long periods act in combination with carcinogenic agents, such as some viruses or chemicals, to enhance tumour developments. In part, therefore, long-term administration

105. Id. at 27. See also Epstein Aff., para. 1(a).

106. Jorma Toppari et al., Male Reproductive Health and Environmental Xenoestrogens, 104 Env'l Health Perspectives Supp. 4, p. 760 (Nat'l Inst. of Env'l Health Sci. Aug. 1996).

107. IARC Monographs, Supp. 7 at 296.

108. FAO/WHO Expert Committee, 32d Report at 20.

of synthetic progestins may produce a comparable hazard by increasing the incidence of tumours due to other agents.¹⁰⁹

Testosterone

The IARC has determined that testosterone is "probably carcinogenic to humans."¹¹⁰ This is based in part on the IARC's findings that "testosterone may be involved in the genesis of [prostatic] tumours" in humans¹¹¹ and that there is "sufficient evidence for the carcinogenicity of testosterone in mice and rats."¹¹²

The FAO/WHO Expert Committee on Food Additives found that high doses of testosterone caused a "surprisingly high" incidence of uterine tumors and an increased level of prostatic tumors in experimental animals.¹¹³

Trenbolone Acetate (TBA)

The FAO/WHO Expert Committee on Food Additives found that long-term feeding of TBA to rats and mice caused liver hyperplasia and an increase in tumors.¹¹⁴ Studies considered by

109. 21 IARC Monographs at 132. See also Epstein Aff., para. 1(c).

110. IARC Monographs, Supp. 7 at 96 (identifying testosterone and other androgenic steroids as Group 2A carcinogens).

111. Id. at 96.

112. 21 IARC Monographs 132; IARC Monographs, Supp. 7 at 97.

113. FAO/WHO Expert Committee, 32d Report at 22. See also Epstein Aff., para. 1(b).

114. FAO/WHO Expert Committee, 32d Report at 24.

the FDA indicated that long-term consumption of TBA caused "significant increases in hepatic proliferative lesions (neoplasia and hyperplasia) in male and female [mice] -- and an increased incidence of pancreatic islet tumors" in rats.¹¹⁵ In addition, when TBA was administered to two successive generations of mice, it was found to "have an emasculating effect" on male mice and to cause female mice to develop male characteristics.¹¹⁶

Zeranol

The IARC has noted that zearalenone, which is produced when zeranol is consumed,¹¹⁷ has a carcinogenic effect in experimental animals.¹¹⁸ The IARC found that the inclusion of zearalenone in the diet of such animals caused effects including

atrophy of the seminal vesicles and testes, squamous metaplasia of the prostate gland, osteopetrosis, myelofibrosis of the bone marrow, cytoplasmic vacuolization of the adrenal glands, hyperkeratosis of the vagina and endometrial hyperplasia, . . . pseudopregnancy [and] infertility.¹¹⁹

In addition, consumption of zearalenone by pregnant animals caused a reduction in fetal weight and an increased prevalence of skeletal problems and incidence of stillbirths.¹²⁰

115. Freedom of Information Summary for Finaplix (Trenbolone Acetate), NADA No. 138-612 at 5, 7, 8-10, FDA Center for Veterinary Medicine (approved July 2, 1986).

116. Id. at 6-7. See also Epstein Aff., para. 2(a).

117. Epstein Aff., para. 2(b).

118. 56 IARC Monographs 431; 31 IARC Monographs 287.

119. 56 IARC Monographs 417.

120. Id. at 421-22.

The FAO/WHO Expert Committee on Food Additives found that zeranol caused brain tumors in laboratory mice.¹²¹

Melengestrol Acetate (MGA)

Melengestrol Acetate (MGA) is a growth hormone that the FDA has approved for use as a feed additive in livestock. Codex has not considered the safety of this hormone. Documents submitted to FDA by the manufacturer of MGA indicate that the hormone causes a "significant increase" in rapidly invasive breast cancers in experimental animals and induces liver and pituitary tumors in male rodents.¹²²

As these facts make clear, the hormones that have been approved for use by the FDA and Codex constitute a risk to consumers.

Effects of Hormones on Infants and Neonates

The carcinogenic effects just described are magnified with respect to infants and newborns, who have been shown to be more

121. FAO/WHO Expert Committee, 32d Report at 27; see also Epstein Aff., para. 2(b). The FAO/WHO Committee noted, however, that estradiol-17 β caused an even greater increase in brain tumors than did zeranol. FAO/WHO Expert Committee, 32d Report at 27. This finding appears inconsistent with Codex's conclusion that a minimum residue limit is necessary for zeranol but not for estradiol-17 β .

122. Goyings et al, MGA Tolerance Studies with ICR and C3HAn/f Mice, Report No. 610-9610-LSG-71-7 (Upjohn Co. June 7, 1972); Memorandum, J.H. Mark, Acting Directory of Bureau of Veterinary Medicine to Tuco Products Co., Division of Upjohn Co., Nov. 28, 1967. See also Epstein Aff., para. 2(c).

susceptible than adults to a wide range of carcinogens.¹²³

Substantial scientific evidence demonstrates that neonatal rodents are more sensitive than adult rodents to the carcinogenic effects of natural and synthetic hormones, both individually and in combination.¹²⁴ For example, the IARC noted that "neonatal exposure of mice to progesterone plus estradiol-17 β resulted in an increased incidence of mammary tumors."¹²⁵

Hormone Combinations

Growth-promoting hormones are commonly administered to livestock in combination. For example, each of the commonly-used, FDA-approved implants Revalor-S, Revalor-H and Synovex-S contains a combination of two different hormones.¹²⁶

123. See Perinatal and Multigeneration Carcinogenesis, IARC Scientific Pub. No. 96 (L. Tomatis & H. Yamasaki eds. 1989); Natural Resources Defense Council, Intolerable Risks: Pesticides in Our Children's Food, Feb. 27, 1989. See also, Epstein Aff., para. 1(d).

124. See, e.g., H.A. Bern et al., Use of the Neonatal mouse in Studying Long-term Effects of Early Exposure to Hormones and Other Agents, J. Toxicol. Env'l Health Supp. 1 at 103-116 (1976); T. Mori et al., Long-term Effects of Neonatal Steroid Exposure on Mammary Gland Development and Tumorigenesis in Mice, 57 J. Nat'l Cancer Inst. 1057-1062 (1976); H.A. Bern & L.A. Jones, Long-Term Effects of Neonatal Treatment with Progesterone Alone, and in Combination with Estrogen, on the Mammary Gland and Reproductive Tract of Female Balb/cfC3H Mice, 37 Cancer Res. 67-75 (1977); IARC Monographs Supp. 7 at 272-308 (1987).

125. IARC Monographs Supp. 7 at 303.

126. FDA Freedom of Information Summaries for Revalor-S (NADA No. 140-897 (Nov. 27, 1991)), Revalor-H (NADA No. 140-992 (Dec. 13, 1994)), Synovex-S (NADA No. 009-576 (Aug. 19, 1994)).

The IARC has noted that exposure to estrogens combined with either progestins or androgens (such as testosterone) can cause "[m]asculinization of the external genitalia in female fetuses" and that combining synthetic progestins with estrogens "seems to enhance [the progestins'] carcinogenic potential."¹²⁷ The IARC has also concluded that oral contraceptives that use a combination of hormones cause cancer in humans.¹²⁸ As noted above, the IARC has recognized the carcinogenic effects in mice of neonatal exposure to a combination of progesterone and oestradiol-17 β .¹²⁹

(2) Non-approved Hormones

Numerous non-approved hormones are sold on the black markets for use in meat production.¹³⁰ One such hormone is DES, which, as described above, was once considered safe for use both as a growth-promoter and by pregnant women. Another category of non-

127. 21 IARC Monographs 65, 132.

128. IARC Monographs Supp. 7 at 297.

The EU Scientific Conference qualified its final conclusions with the caveat that there was not sufficient evidence concerning the effect on humans of combinations of hormones and therefore there is "need for further study of the effects of growth-promoters administered in combination; the presence of one [hormone] may disturb the metabolism of others." EU Scientific Conference Report at 4.

129. IARC Monographs Supp. 7 at 303.

130. Brie and Hormones, The Economist, Jan. 7, 1989 at 22; EU Scientific Conference Report at 7.

approved hormones are β_2 -agonists,¹³¹ with respect to which the EU Scientific conference found that

[t]here is currently substantial concern about the potential risks to consumer-health at the high doses [of β_2 -agonists] necessary for growth promotion, since [β_2 -agonists] are pharmacologically potent substances. Since 1990, there have been at least five cases of mass intoxications after consumption of liver and meat containing high levels of [one of these substances].

Acute toxic effects observed in animals and man include muscle tremor, tachycardia, palpitations and nervousness. . . . The clinical consequences for consumers continuously exposed to residues of potentially highly active β_2 -agonists are still unclear. The use of highly active β_2 -agonists as growth promoters is not appropriate because of the potential hazard for human and animal health.¹³²

Other studies have demonstrated the risks associated with β_2 -agonists. A report prepared by the FDA stated that " β_2 -agonists have been associated with the induction of . . . benign tumours in rats."¹³³ Moreover,

there have been reports of acute poisoning in humans following consumption of liver containing residues of the beta-agonist, clenbuterol. The largest confirmed outbreak of this type of poisoning occurred in Spain between March

131. These hormones are quite likely to be used as growth promoters, given the EU Scientific Conference's finding that there "seems no doubt that the hormones called β_2 -agonists bring about a marked increase of the proportion of lean meat to fat as well as improved efficiency of food conversion." Report of the EU Scientific Conference at 6. An FDA report also stated that "the growth promoting action of [beta-agonists] has been well demonstrated in several species." M. Miller & J. Leighton, Risk Assessment Strategies for Hormones and Hormone-Like Substances (US FDA 1995).

132. EU Scientific Conference Report at 16.

133. Miller & Leighton at 13.

and July of 1990, and involved 135 people. Adverse clinical effects of muscle tremors, tachycardia, palpitations, nervousness, cephalgia and myalgia, occurred 30 min to 6 h post consumption of beef liver and lasted for about 40 h. . . . Another report implicated clenbuterol residues in an acute poisoning episode in France which affected 22 people who consumed beef liver containing 375 - 500 ppb of clenbuterol.¹³⁴

(3) The Conclusions of the EU Scientific Conference, Codex and the FDA Concerning the Safety of Growth Hormones Are Based on Mistaken Assumptions

The agencies that have approved the use of growth-promoting hormones in meat animals have done so on the basis of several mistaken assumptions.

Two of these mistakes concern the conclusion that "[t]he daily production of sex hormones by humans is much higher than the amounts possibly consumed from meat, even in the most sensitive humans (prepubertal children and menopausal women)" and, therefore, that consumption of meat with residues of natural sex hormones could not harm humans.¹³⁵ The first mistake concerning this conclusion is that it does not take into account the effects of such consumption on the naturally occurring hormone levels in the body. Scientific evidence indicates that consumption of meat products containing residues of specific growth hormones increases the levels of those hormones in the body of the consumer.¹³⁶ Such increases in naturally occurring

134. Id.

135. EU Scientific Conference Report at 15.

136. Epstein Aff., para. 5(a).

hormones disturbs the complex patterns of normal hormonal balance in the body, which in turn poses carcinogenic hazards.¹³⁷

The second mistake concerning the relationship between the level of hormone residues in meat and the amount of hormones in humans is that prepubertal children and menopausal women are not the segments of the human population that are most sensitive to the incremental effects of the consumption of hormone-treated meat. Rather, infants produce the lowest amount of natural hormones.¹³⁸ As noted above, infants are particularly sensitive to the carcinogenic effects of hormones.

A third error made by agencies that have approved the use of growth hormones in meat production is that they have analyzed the effects of individual hormones in isolation. As noted above, growth hormones are frequently administered in combination and such combinations have been demonstrated to have carcinogenic effects. Moreover, evidence that xenobiotic pesticides induce synergistic estrogenic effects that are approximately 1000 times greater than individual exposure to those pesticides makes it likely that the consumption of combinations of growth hormones has a similarly extreme effect.¹³⁹ These effects may be further exacerbated by the interaction of growth hormones with xenoestrogenic pesticides and other industrial chemical

137. Id.

138. Id., para. 5(b).

139. Id., para. 5(d).

contaminants in meat products, which have been shown to have serious effects on humans, including increasing reproductive disorders in men.¹⁴⁰

Because of the increased risk associated with such possible synergistic effects, the EU Scientific Conference qualified its conclusion concerning the risk of consumption of hormone residues by "emphasi[zing] the need for further study of the effects of growth-promoters administered in combination; the presence of one may disturb the metabolism of others."¹⁴¹ The Conference also noted the need for further research into the "pharmacodynamic and pharmacokinetic interactions of combinations of growth promoters and other concomitantly used xenobiotics."¹⁴² Despite its recognition of the possible relevance of such considerations, the EU Scientific Conference nevertheless reached conclusions without obtaining scientific evidence on this point. Likewise, neither Codex nor the FDA has considered the possibly serious consequences of exposure to growth hormone residues in combination with residues of other growth hormones or contaminants.

140. Id., para. 5(e); Jorma Toppari et al., Male Reproductive Health and Environmental Xenoestrogens, 104 Env'l Health Perspectives Supp. 4, p. 760 (Nat'l Inst. of Env'l Health Sci. Aug. 1996).

141. EU Scientific Conference Report at 4.

142. Id. at 24.

The United States has stated that there is evidence that the use of estradiol-17 β , progesterone, testosterone, trenbolone acetate (TBA), zeranol and melengestrol acetate (MGA) present no risk to humans at the levels found in hormone-treated meat. However, the existence of scientific evidence suggesting that there is no risk does not negate the legitimacy of an SPS measure as long as other scientific evidence indicates that a risk exists. The United States' own position concerning conflicting evidence of risk supports this interpretation:

It is clear that the requirement in the [SPS] Agreement that measures be based on scientific principles and not be maintained "without sufficient scientific evidence" would not authorize a dispute settlement panel to substitute its scientific judgment for that of the government maintaining the [SPS] measure. For example, by requiring measures to be based on scientific principles (rather than, for instance, requiring measures to be based on the "best" science) and not to be maintained without sufficient scientific evidence (rather than, for instance, requiring an examination of the "weight of the evidence"), the [SPS] Agreement recognizes the fact that scientific certainty is rare and many scientific determinations require judgments between differing scientific views. The [SPS] Agreement preserves the ability of governments to make such judgments.¹⁴³

Because there is evidence that these hormones may cause serious health problems such as cancer, the EU is justified in implementing measures to protect against this risk.

c. Misuse of Growth Hormones Presents a Risk to Human Health

143. US Statement of Administrative Action at 90, 95 (emphasis in original). See also USTR Report on Food Safety at ii; id. at 15 ("[D]ispute settlement panels will not be responsible for choosing among competing scientific views, but will only determine whether a particular SPS measure has a scientific basis" (emphasis added)).

Scientists have determined that it is common for there to be high concentrations of hormone residue in meat "due to the widespread illegal use of multiple ear and, worse still, of muscle implants."¹⁴⁴ The EU's Scientific Conference found that

some producers apparently use injections, rather than implants, of steroid hormones, which is an impediment to their detection at slaughter and potentially allows the sale of meat containing very [high] concentrations of hormones.¹⁴⁵

FDA documents show that in the United States in 1986,

as many as half of all cattle sampled in feedlots as large as 600 animals were found to have hormones illegally implanted in muscle rather than the ear skein, to induce further increased growth.¹⁴⁶

These common abuses of growth hormones can result in extremely high hormone concentrations in meat.¹⁴⁷ As the IARC has recognized, the risks from consuming growth hormones that are described above are much greater when the concentration of the hormones is increased.¹⁴⁸ This increased risk makes protection against exposure to these hormones even more important.

144. S. Epstein, How Safe Is Hormone Beef, June 17, 1996.

145. Report of the Scientific Conference at 7. See also id. at 15 ("[i]ntramuscular injection of [growth-promoting hormones] could result in high residue concentration at injections sites in edible tissue).

146. Epstein, The Chemical Jungle at 279.

147. See EU Scientific Conference Report at 15 ("Intramuscular injection of these substances could result in high residue concentration at injection sites in edible tissue"); Epstein Aff., para. 4.

148. See IARC Monographs, Supp. 7 at 280 (carcinogenic effects of estrogen exposure are increased as doses increase).

Moreover, routine monitoring cannot identify meat that has been affected by intramuscular injection of growth hormones.

d. Obstacles to Protecting Against Harm from the Consumption of Growth Hormones

Protecting consumers against the risks associated with growth hormones is complicated by the lack of adequate methods for monitoring the presence of such hormones and the common practice of mixing the hormones administered to livestock.

Identifying the presence of growth hormones in meat is an extremely complicated process that is impractical in the market context. There are no available practical methods for detecting natural or synthetic growth hormones such as those approved for use in the United States.¹⁴⁹ The excess of these hormones over normal background levels, whether due to overapplication of the hormones or intramuscular implantation, can only be identified by using highly specialized tests that are not suited for routine monitoring of meat samples intended for the market.¹⁵⁰

The Joint FAO/WHO Expert Committee on Food Additives has recognized this, stating that although

most methods of analysis for estradiol-17 β . . . may be satisfactory for measuring estradiol-17 β levels in

149. Epstein Aff., para. 3.

150. *Id.* Such tests include radio-immune assays and gas chromatography, both of which require complex preparations and the use of sophisticated and expensive laboratory equipment. Conversation with Samuel S. Epstein, M.D. Because of the complexity and cost of such experiments, these methods are not technically or economically feasible for routinely monitoring the presence of hormones in meat intended for the market.

experimental situations, improvements would be needed if routine analytical methods for the control of residues were required.¹⁵¹

The FDA has also recognized the absence of practical monitoring methods. Although FDA approval of veterinary drugs requires that there be a practical basis for monitoring for the presence of such drugs, the FDA has waived this requirement with respect to growth hormones and has relied instead on the complicated, time-consuming laboratory tests undertaken by the manufacturers of the hormones.¹⁵²

The absence of practical testing methods may explain the fact that the United States apparently does not monitor for the presence of growth hormones in meat, despite the FDA's admission that elevated levels of these hormones could have "adverse effects." In 1993, the US Department of Agriculture's Food Safety and Inspection Service (FSIS) monitored meat for residues of animal drugs and pesticide compounds, but, with the exception of MGA, did not monitor at all for the presence of residues of growth hormones.¹⁵³

151. FAO/WHO Expert Committee, 32d Report at 19.

152. Epstein Aff., para. 3.

153. See Domestic Residue Data Book National Residue Program 1993 (FSIS Dec. 1993).

Even if it had monitored for the presence of growth hormones, the FSIS's monitoring program is of marginal value in preventing exposure to harmful residues. In 1993, the FSIS monitored 39,128 samples, representing 0.005% of the 129.8 million head of livestock and seven billion birds raised in the United States. Id., Summary. With respect to MGA, the FSIS

The common practice of mixing growth hormones used with livestock increases the difficulty of protecting consumers against the risks associated with these hormones. As the EU's Scientific Conference noted, there is

evidence from many European countries and from elsewhere for the illegal use of growth-promoting substances, often in the form of mixtures of recognised substances or of others which are not at present approved for use in any countries. These practices will not always be detected by standardised screening techniques.¹⁵⁴

In light of this evidence, the Conference concluded that

[i]t might be more difficult to control use of prohibited growth promoting substances in a situation where certain substances are permitted because veterinary inspection to identify animals treated with prohibited substances might be more difficult.¹⁵⁵

Thus, despite the numerous clearly identified risks associated with the consumption of growth hormones, as well as the insufficient evidence to analyze many other possible risks, there are no practical methods for protecting consumers from unwittingly eating meat that has been raised using such hormones.

The evidence described above demonstrates that the use of growth hormones in livestock results in residues of those hormones in meat. In addition, there is evidence that consumption of such residues -- whether of those hormones approved for use in the United States or other hormones -- at any

monitored only 22 samples, of which one, or 4.5% tested positive. Id., Appendix.

154. Report of the Scientific Conference at 7.

155. Id. at 23.

level may pose a risk of harm to human health. This risk is exacerbated by the fact that common misuse of growth hormones results in elevated hormone concentrations in meat, which in turn increases the risk of harm to human health. These risks are sufficient to support the EU's decision to protect against them completely through measures that achieve zero risk from hormone residues that differ from those naturally occurring in meat.

2. Uncertainties Concerning the Risk from Consuming Growth Hormones Support Provisional Health-Protective Measures

The SPS Agreement allows countries to adopt provisional SPS measures "where relevant scientific evidence is insufficient."¹⁵⁶

As the United States has put it, this means that "a country may choose to err on the side of caution when the science is inconclusive."¹⁵⁷

The EU's Scientific Conference identified numerous areas in which the scientific evidence concerning the risk to human health from the consumption of growth hormones is inconclusive. For example, the Conference qualified all of its conclusions with the statement that there is very little scientific evidence concerning the actual effect of growth hormones on humans:

[M]ost studies of growth-promoting substances . . . rely on studies with laboratory animals, where it is common practice to determine a level of administration of the substance concerned below which no untoward effects can be found; this is called the No Observable Effect Level (Noel). . . . [W]hen the Noel is defined by animal experiments alone,

156. SPS Agreement, Art. 5(7).

157. USTR Report on Food Safety at 5.

directly extrapolating it to people . . . would take no account of the unknown physiological differences of the responses of people and the species of the laboratory animals.¹⁵⁸

Codex has itself noted the uncertainty inherent in assessing risks to human health:

Human data of insufficient extent may be considered in the setting of [a Codex Acceptable Daily Intake] on the basis that extrapolation of data from animal studies will contain greater uncertainty.¹⁵⁹

158. Report of EU Scientific Conference at 3-4.

159. FAO/WHO, Food Standards Programme, Codex Alimentarius Commission, Risk Assessment Procedures used by the Codex Alimentarius Commission and its Subsidiary Advisory Bodies (1993).

In light of the uncertainties concerning the similarities and differences between laboratory animals and humans, humans, scientists, including those involved in the EU Scientific Conference, routinely apply a 100-fold safety factor in attempting to convert the results of experiments with animals into results that are relevant to humans. See EU Scientific Conference Report at 3-4. However, even the choice of the safety factor is permeated with uncertainty, as expressed by scientists at the FDA:

[T]he margin of safety is a reasonable approach to the matter, but its acceptance should not fool researchers and/or the public into believing that there is any experimental or theoretical basis for its existence.

R. McColl, Biological Safety Factors in Toxicological Risk Assessment, in A report produced for the Environmental Health Directorate Health Protection Branch Health and Welfare Canada at 8 (March 1989). Codex concurs:

Uncertainty in the safety evaluation process is primarily addressed through the use of safety factors. Their respective values are arbitrary and have no measured biological significance, however, their appropriateness is somewhat borne out by experience.

FAO/WHO, Food Standards Programme, Risk Assessment Procedures Used by the Codex Alimentarius Commission, and its Subsidiary and Advisory Bodies 11 (June - July 1993).

Finally, the IARC has noted that

Epidemiological studies to evaluate possible carcinogenic effects of administered oestrogens and progestins in humans suffer from two major difficulties. Firstly, the interval between the commencement of administration and the possible appearance of cancer may be long. Secondly, to detect a small or moderate change in risk, observations on large numbers of subjects are required.¹⁶⁰

An additional shortcoming of scientific evidence concerning the risk of consuming growth hormones was expressed by the EU Scientific Conference's Working Group on the Assessment of Health Risk, which found that "[t]he [acceptable daily intake (ADI)] model has been developed to establish safe levels of exposure to a single compound, whereas in practice humans are exposed to mixtures of chemicals. That circumstance needs further attention."¹⁶¹ As noted above,¹⁶² the Conference qualified its final conclusions with the caveat that there needs to be further study concerning the effects on humans of combinations of growth hormones.

Another area of insufficient scientific evidence concerns the effect of consumption of growth hormones on human DNA. The EU Scientific Conference stated that its conclusions concerning the Acceptable Daily Intake (ADI) amounts for growth promoting hormones did not take into account the potential for long-term damage to human DNA because

160. 21 IARC Monographs 133.

161. Report of EU Scientific Conference at 14.

162. See supra note 128.

[t]he ADI concept is not appropriate in the risk-assessment of hazards involving long-term damage to human DNA (otherwise called "genotoxic" hazards), perhaps leading to cancers of various kinds.

. . .
The ADI model does not predict quantitative risks and is not applicable to genotoxic (damaging to DNA) carcinogens, for which presumably no threshold levels can be established. These substances need a quantitative risk assessment, based on their modes of toxic action.¹⁶³

When, as here, the scientific evidence concerning risk is inconclusive, the SPS Agreement permits a country to implement precautionary protective measures as long as the country seeks to obtain additional information and review the SPS measures within a reasonable time.¹⁶⁴ The EU Scientific Conference did this by identifying "a number of priority areas where further research should be undertaken and where actions should be initiated" with respect to the assessment of the risk to human life and health from consumption of hormone-treated foods.¹⁶⁵

While the EU gathers the information necessary to fill the gaps in the existing scientific evidence concerning the risk from consumption of hormone-treated meat, paragraph 22 of the SPS Agreement permits it to implement precautionary measures to protect against this risk.

163. Report of EU Scientific Conference at 4, 14.

164. SPS Agreement, Art. 5(7).

165. Report of EU Scientific Conference at 24-25.

E. The EU's Ban on Trade in Hormone-Treated Meat Is Not More Trade Restrictive than Required to Achieve the EU's Zero Risk Level of Protection

By claiming that the EU must accept meat raised using the growth hormones approved for use in the United States, the United States is in essence arguing that the means that the EU has chosen to achieve its chosen level of protection are broader than necessary to do so. As the preceding discussion demonstrates, the United States has no other ground for challenging the EU ban than to argue that the ban is more restrictive than necessary to achieve the EU's zero-risk level of protection. The ban is not discriminatory. It is intended to protect against a risk that is supported by scientific evidence. The United States cannot ask the WTO panel to substitute its judgment for the EU's concerning the weight of the evidence of risk or the appropriate level of protection against that risk. Therefore, the United States is arguing that the EU can achieve its zero risk level of protection while at the same time permitting the importation of animals and meat treated with hormones approved for use by the United States.

The SPS agreement explains that a measure is not more trade restrictive than required

unless there is another measure, reasonably taking into account technical and economic feasibility, that achieves the appropriate level of protection and is significantly less restrictive to trade.¹⁶⁶

During the negotiation of the SPS Agreement, the Director-General of the GATT indicated that the WTO members

166. SPS Agreement, Art. 5(6) n.3.

felt it was obvious from other provisions of the Agreement that the Agreement does not concern itself with insignificant trade effects nor could a measure be considered more trade restrictive than necessary in the absence of a reasonably available alternative.¹⁶⁷

GATT dispute panels that have interpreting the necessity requirement of Article XX have reached the same conclusion. In the Thai cigarette case, the panel concluded that a measure is

"necessary" in terms of Article XX(b) only if there [are] no alternative measures consistent with the General Agreement, or less inconsistent with it, which [the country] could reasonably be expected to employ to achieve its health policy objectives.¹⁶⁸

Another panel interpreted the same requirement in the context of another GATT exception (Article XX(d) for measures "necessary" to secure compliance with other laws) not to require a country to change its substantive law or its desired level of enforcement of that law. Rather, where a country can reasonably secure that level of enforcement through other means consistent with GATT, it must do so.¹⁶⁹

The SPS Agreement places the burden on the United States to demonstrate that another measure is reasonably available, taking into account technical and economic factors, that achieves the EU's zero-risk level of protection and is significantly less

167. Letter from Peter D. Sutherland, GATT Director-General, to Ambassador John Schmidt, Chief US Negotiator, Dec. 15, 1993.

168. Thailand -- Restrictions on Importation of and Internal Taxes on Cigarettes, 37th Supplement BISD 200, ¶ 73 (adopted 1990).

169. United States -- Section 337 of the Tariff Act of 1930, 36th Supp. BISD 345, 393, ¶ 5.26 (adopted Nov. 7, 1989).

restrictive to trade. By stating that "a measure is not more trade restrictive than required unless there is another measure" that achieves the chosen level of protection and is less restrictive,¹⁷⁰ the Agreement creates a presumption that the measure in question is the least trade restrictive measure that will achieve the chosen level of protection. This presumption can be rebutted by showing the existence of "another measure" that is less trade restrictive. The burden is thus on the challenging country to show the existence of such a measure. To require the country that has implemented the measure to prove that there are no less restrictive measures would be to require it to prove an unlimited number of negatives -- it would have to show that it had considered every possible alternative and that none of them could achieve the chosen level of protection.

The United States has proposed no alternative measure that would achieve the EU's level of protection. Rather, the United States has argued that the EU ban is more restrictive than necessary because it "is not intended to achieve any particular level of sanitary protection from any identified risk."¹⁷¹ As set forth above, however, the EU's ban is intended to achieve a zero risk level of protection from the risk of possible harm to human health resulting from hormone residues in meat.

170. SPS Agreement, Art. 5(6) n.3 (emphasis added).

171. US Submission, para. 127.

There are no reasonably available alternative measures that would achieve the EU's zero risk level of protection. Permitting trade in meat treated with the hormones approved for use in the United States would not achieve that protection because of the scientific evidence, described above, that those hormones may harm human health.

In addition, the EU Scientific Conference and others have noted that the common misuse of hormones increases the risks associated with consuming hormone-treated meat and makes it more difficult to prevent the use of other hormones, such as β_2 -agonists.¹⁷² Because there is no reasonably available means of monitoring for the presence of hormones in meat, banning the use of all growth hormones and trade in meat treated with such hormones is the only reasonable means of protecting against the misuse of growth hormones.

Therefore, because there are no alternative measures that would effectively achieve the EU's zero risk level of protection against the risks associated with consumption of hormone-treated meat, the EU ban is a legitimate sanitary measure that is permitted under GATT and customary international law.

CONCLUSION

Customary international law and GATT both strongly protect each country's right and responsibility to make the political judgments necessary to determine the appropriate level of

172. See supra p. 55.

protection against a given risk. The precautionary principle allows a country to determine that it will protect against possible risks to human health even if no conclusive or overwhelming evidence is available as to whether the activity actually causes that harm. GATT permits measures legitimately intended to achieve the chosen level of protection as long as they do not discriminate against foreign products and are not more restrictive of trade than necessary. The SPS agreement sets forth standards for determining whether health-protective measures are legitimate and may be implemented despite any incidental effect on international trade.

The EU's ban on trade in hormone-treated meat is not discriminatory because it applies equally to domestic and foreign meat products. The EU has legitimately chosen zero risk as its appropriate level of protection against the risks associated with the consumption of hormone-treated meat. This choice is supported by a substantial body of scientific evidence indicating that the use of growth hormones in meat animals results in hormone residues in meat and that consumption of such residues may cause cancer in humans.

Because international law respects a scientifically-supported choice of an appropriate level of protection, the only challenge available to the United States is that the EU's ban is more restrictive than necessary to achieve the EU's chosen zero-risk level of protection. The United States has failed to

suggest any less-restrictive measure that would achieve this level of protection.

For these reasons, the EU ban satisfies the requirements of the SPS Agreement. Any other conclusion would be inconsistent with the customary international legal norm of the precautionary principle and would impermissibly restrict the EU's right to protect consumers from the risks associated with the consumption of hormone-treated meat. The WTO panel must therefore uphold the ban.

SIERRA CLUB LEGAL DEFENSE FUND

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