Selling Science Under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy

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The controversy over the European Community's ban on the use of growth hormones in beef production has been raging for more than a decade. Early in 1996, the United States revived the debate when it filed a complaint against the European Community (EC) with the World Trade Organization (WTO). The new debate looks much like the old, but with an added twist: the United States claims the ban lacks scientific basis, is rooted in protectionism, and violates the Sanitary and Phytosanitary Measures passed during the Uruguay Round negotiations in 1994.[1] The European Community maintains the ban is permissible under the relevant GATT provisions,[2] because the absolute safety of hormones has not been scientifically shown[3] and the ban was instituted for safety reasons.[4] In late 1996, the United States and the European Community submitted the first round of briefs to the Dispute Panel assembled to rule on the controversy.[5] The Panel's decision is expected in May 1997.[6]

This Note will examine the hormones dispute within the framework of the SPS Agreement by exploring the need for

1. First Submission of the United States (Public Version) ¶ 5, WTO Dispute Settlement Panel, *European Communities - Measures Concerning Meat and Meat Products,* (Aug. 28, 1996) [hereinafter U.S. Submission].

2. The EC claims, specifically, that the hormone ban does not violate Article III:4, Article I:1, and the SPS Agreement of GATT 94. First Written Submission of the European Community to the Panel on European Community (Public Version) ¶¶ 146-250, WTO Dispute Settlement Panel, *Measures Concerning Meat and Meat Products (Hormones)* (Sept. 20, 1996) [hereinafter EC Submission].

3. EC Submission, *supra* note 2, ¶ 36.

4. EC Submission, *supra* note 2, ¶ 29.

5. The U.S. Submission was submitted August 28, 1996. The EC submitted its brief September 20, 1996. *See* U.S. Submission, *supra* note 1, and EC Submission, *supra* note 2.

6. Telephone Interview with Kris Wilkus, Publicity Dept., U.S. Trade Rep. (Feb. 10, 1997).

"sound science," as well as the role consumer preference plays in regulatory determinations. Part I briefly outlines the history of the hormones dispute and the present state of the controversy. Part II examines what constitutes a "sound" scientific basis for health regulations under the SPS Agreement. It also identifies other factors which may be taken into account when health standards are determined. Part III analyzes the hormone ban in terms of the factors discussed in Part II, and incorporates the role consumer preference plays in the hormone debate. This Note concludes that the ban not only imposes an impermissible barrier to international trade, but also fails to accomplish the European Community's stated goals.

I. A BRIEF HISTORY OF THE HORMONES DISPUTE

A. BEGINNINGS OF THE CONTROVERSY

In January 1989, the European Community instituted a blanket ban on beef treated with particular growth hormones.[7] The hormones at issue are three naturally occurring hormones and three synthetic versions of those hormones.[8] The three "natural" hormones - those produced by animals - are oestradiol, testosterone, and progesterone.[9] The three synthetic hormones, which are designed to mimic the action of the natural hormones, are trenbolone acetate (TBA), zeranol, and melengestrol acetate (MGA).[10]

Due to public fears over the use of hormones, the European Parliament had been planning a ban on growth hormones for several years.[11] Europeans first became concerned over hormone use in the early 1980s, when a synthetic hormone known as diethylstilbestrol (DES) was found in baby food made from veal.[12] Cases of children born with birth defects due to exposure

7. Council Directive 85/649, arts. 5 & 6(1), 1985 O.J. (L 382) 229-30. For a complete analysis of the 1989 ban, *see* Adrian Halpern, Comment, *The U.S. - E.C. Hormone Beef Controversy and the Standards Code: Implications for the Application of Health Regulations to Agricultural Trade*, 14 N.C. J. INT'L L. & COM. REG. 135 (1989); Michael B. Froman, *The United States-European Community Hormone Treated Beef Conflict*, 30 HARV. INT'L L.J. 549 (1989); *see also* Holley, *Europeans Say No to Pumped-Up Beef*, SAN DIEGO UNION-TRIB., Dec. 28, 1988, at B6; Janice Castro, *Why the Beef Over Hormones?*, TIME, Jan. 16, 1989, at 44.

8. EC Submission, *supra* note 2, ¶¶ 65-66.

9. *Id.*

10. *Id.*

11. *See, e.g.*, Timothy Aeppel, *Europeans Not Cowed by U.S. Threat*, CHRISTIAN SCI. MONITOR, Jan. 10, 1989, at 6.

12. Castro, *supra* note 7.

to DES were reported all over Europe.[13] After the DES scandal, a huge consumer crusade erupted throughout Europe against natural and artificial hormones.[14] Consumer advocates led a campaign to ban the use of hormones in Europe.[15] According to one report, the European Community considered that a ban on all hormones, rather than just DES, made sense because the test for DES alone was very expensive.[16] However, unlike DES, none of the hormones at issue in the current controversy has been shown to pose any threat to human or animal health.[17]

In the absence of evidence suggesting untoward effects on human health, American farmers have continued to use these hormones to reduce production costs and increase the nation's food supply. For nearly thirty years, American cattle feeders have promoted weight gain in cattle by giving them natural and synthetic hormone implants.[18] The hormones are implanted behind the ears of the cattle, and are time-released to give out the hormones during key growth stages.[19] The hormones may eliminate as many as twenty-one days of feeding time at a substantial savings to the cattle feeders.[20]

In contrast to American confidence in hormones, the European Community claimed the ban was necessary to protect public health.[21] In citing consumer anxiety over the safety of beef treated with hormones,[22] the European Community implicitly equated consumer *fears* over hormone safety with actual public health needs. In contrast, the United States asserted that the ban lacked any scientific basis[23] and was motivated largely by

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13. *Id.* DES has also been linked to cancer. *Id.*

14. Aeppel, *supra* note 11.

15. *Brie and Hormones*, THE ECONOMIST, Jan. 7, 1989, at 21.

16. *A Short History of Hormones*, THE ECONOMIST, Jan. 7, 1989, at 22. At the time the ban was instituted, each test for DES alone cost $300. *Id.*

17. U.S. Submission, *supra* note 1, ¶¶ 65-84; *see also infra* notes 66-70 and accompanying text.

18. Castro, *supra* note 7.

19. *Id.*

20. *Id.*

21. EC Submission, *supra* note 2, ¶ 54.

> When adopting the challenged measures in 1981 and in 1988, the EC clearly stated that it did so for the purpose of protecting human and animal health. The EC legislator [sic] was of the same conviction in April 1996 when it decided to maintain and re-enact these measures. This is beyond doubt.

Id.

22. Castro, *supra* note 7.

23. *Senators Urge Interim Curbs on Beef Imports from EC in Response to EC Ban on Hormone Use*, 5 Int'l Trade Rep. (BNA) No. 43, at 1447 (Nov. 2, 1988) [hereinafter *Senators Urge Interim Curbs*]. *But see* Jagdish N. Bhagwati,

protectionism.[24] The United States responded to the ban by imposing prohibitive duties on over $100 million of Common Market agricultural products to compensate for the decline in beef exports caused by the ban.[25]

In addition, the United States brought a complaint against the European Community under the Standards Code[26] of the General Agreement on Tariffs and Trade (hereinafter GATT),[27] alleging that the ban was an unnecessary obstacle to trade.[28] The Standards Code was designed to ensure that newly imposed technical regulations or standards did not create such barriers to trade.[29] The United States claimed that the ban's lack of scientific justification illegally circumvented the Standards Code, thus warranting the creation of a dispute settlement panel.[30]

The Standards Code, unfortunately, does not create a clear mechanism for resolving such disputes;[31] enforcement of the Code depends primarily on the "moral suasion of the Code's free trade ethic and the desire of signatories to avoid diplomatic con-

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Hormones and Trade Wars, N.Y. TIMES, Jan. 9, 1989, at A17 (asserting that the U.S. is acting in a ludicrous fashion by making war over the issue of scientific evidence; the ban is prompted by social concerns and falls well within their rights under the GATT).

24. *See, e.g., Senators Urge Interim Curbs*, *supra* note 23 (U.S. Senators claim the ban is an "obvious trade barrier hiding behind the veil of 'food safety'"); Michael B. Smith, *Trade and the Environment: GATT, Trade, and the Environment*, 23 ENVTL. L. 533, 536-37 (asserting that the EC knew when it instituted the ban that the hormones posed no threat to human health and that the ban was instead motivated by a desire to protect their domestic beef market and appease the politically powerful "Green" party).

25. *U.S., EC Hold First Meeting of Task Force Created to Resolve EC Hormone Ban Dispute*, 6 Int'l Trade Rep. (BNA) No. 10, at 303 (Mar. 8, 1989). The U.S. imposed sanctions on EC agricultural exports such as fruit juices, coffee extracts, and pork shoulders. *Id.*

26. Agreement on Technical Barriers to Trade, *opened for signature* Apr. 12, 1979, 31 U.S.T. 405 [hereinafter Standards Code]. The Standards Code was adopted during the Tokyo Round of GATT negotiations.

27. General Agreement on Tariffs and Trade, *opened for signature* Oct. 30, 1947, 61 Stat. pts. 5, 6, T.I.A.S. No. 1700, current version at 55 U.N.T.S. 187 [hereinafter GATT].

28. Halpern, *supra* note 7, at 135. In July 1987, the United States invoked the Standards Code, using its dispute resolution settlement procedures to urge creation of a technical group to study the scientific validity of the hormone ban. *Id.* at 142. The EC wanted a panel established to determine whether it was circumventing the Standards Code itself, rather than a panel to examine scientific justifications of the ban. *Id.* at 142-43. Two years later, dispute settlement talks continued with little progress. *Id.* at 143.

29. Standards Code, *supra* note 26, pmbl.

30. Halpern, *supra* note 7, at 142.

31. *See id.* at 140-42 (discussing the dispute resolution mechanism of the Standards Code).

flict."[32] The Standards Code has also been deemed inadequate to deal with sanitary and phytosanitary measures.[33] According to one author, the Standards Code has "no clear link to international organizations like the Codex Alimentarius Commission, no coverage of processes and production methods of subfederal governments, an ineffective dispute settlement system and few signatories."[34] Indeed, no dispute was ever resolved under the Standard Code's dispute resolution mechanism, although the European Community's hormone ban easily fell within its authority.[35] As a result, the hormone controversy has remained unresolved for over a decade.

B. THE URUGUAY ROUND AND THE SPS AGREEMENT

The passage of new Sanitary and Phytosanitary measures (SPS Agreement)[36] during the Uruguay Round of trade negotia-

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32. *Id.* at 142.

33. Marsha Echols, *Sanitary and Phytosanitary Measures, in* THE WORLD TRADE ORGANIZATION 193 (Terence P. Stewart ed., 1996). One might argue, however, that the Standards Code did *not* cover the hormone ban, because it exempted "process and production methods" from its purview. Whether the Standards Code applies to the hormone ban depends on whether it is categorized as a process restriction or a product restriction.

34. *Id.*

35. *Id.*

36. Agreement on the Application of Sanitary and Phytosanitary Measures, Dec. 15, 1993, GATT Doc. MTN/FA II-AIA-4 [hereinafter SPS Agreement]. American agricultural interests eagerly anticipated the Uruguay Round negotiations, particularly the SPS Agreement. *USDA Report: Uruguay Round Will Raise Farm Exports and Income, Create Jobs*, U.S. Newswire, Mar. 17, 1994; *see also Implementation of the Uruguay Round as it Affects United States Agriculture: Hearing before the Senate Committee on Agriculture, Nutrition, and Forestry*, 103d Cong., 2nd sess., at 21-22 (1994) (statement of Michael Espy, U.S. Secretary of Agriculture) [hereinafter *Hearing*]. In Senate hearings regarding the Uruguay Round, U.S. Agriculture Secretary Espy stated:

> [I]n the area of S & P requirements, the Uruguay Round agreement ensures that any trade restrictive measure taken by an importing country for the purpose of protecting human, animal, or plant health *must be based on principles of sound science*. . . . We believe that these provisions will discourage countries from using unjustified health-related measures as disguised barriers to trade.

Id. (emphasis added). Then U.S. Trade Representative Kantor added:

> The S & P Agreement provides safeguards against blatant trade protectionism in the guise of a health regulation. Our trading partners have repeatedly sought to exclude perfectly safe U.S. products from their markets by citing false 'health' pretexts.
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> For example, a determination that a particular food additive poses a health risk is made on *scientific* grounds.

Id. at 69 (statement of Ambassador Michael Kantor, U.S. Trade Representative) (emphasis in original).

tions[37] significantly changed the locus of the growth hormone dispute. The new measures were motivated in large part by the stalemate resulting from the continued ban on hormones.[38] The new SPS Agreement was designed to expand the meaning of GATT Article XX(b)[39] pertaining to measures affecting plant, animal, and human life or health, and Article XX(g)[40] concerning exhaustible natural resources.[41] Compared to Article XX, the new measures include more technical and scientific requirements for product prohibitions claimed to be necessary for health or environmental reasons.[42]

Article 2 of the SPS Agreement gives Members[43] the right "to take sanitary and phytosanitary measures *necessary for the protection of human, animal or plant life or health*," as long as such measures are not inconsistent with the provisions of the SPS Agreement.[44] The Article further explains that Members must ensure that any sanitary measure taken "is *applied only to the extent necessary* to protect human, animal or plant life or health, is *based on scientific principles* and is *not maintained without sufficient scientific evidence*."[45] Finally, Article 2 prohibits Members from applying a sanitary measure in any manner

37. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 9 (1994) [hereinafter Uruguay Round].

38. *See, e.g.* David A. Wirth, *Symposium: The Role of Science in the Uruguay Round and NAFTA Trade Disciplines,* 27 CORNELL INT'L L.J. 817, 824-25 (1994) (asserting that the motivation for the separation of the SPS measures from the Standards Code was the U.S.-EU hormone dispute); 19 U.S.C. § 2901(b)(7)(c) (identifying as a principle negotiating objective of the U.S. in the Uruguay Round "eliminating and reducing substantial[ly] . . . unjustified phytosanitary and sanitary restrictions").

39. GATT, *supra* note 27, art. XX. Article XX is designed to provide Members with the ability to circumvent the general GATT prohibition of international trade restrictions, provided the particular measure falls within an explicit article XX exception.

40. *Id.*

41. For a thorough analysis of the SPS Agreement's affect on health regulations under GATT, see Julie Cromer, *Recent Developments: Sanitary and Phytosanitary Measures: What They Could Mean for Health and Safety Regulations Under GATT,* 36 HARV. INT'L L.J. 557 (1995); *see also* C. FORD RUNGE, THE LIVESTOCK SECTOR AND THE ENVIRONMENT: BASIC ISSUES AND IMPLICATIONS FOR TRADE, A BACKGROUND STUDY PREPARED FOR THE FOOD AND AGRICULTURE ORGANIZATION 69 (1994).

42. SPS Agreement, *supra* note 36, art. 2.

43. The term "Members" refers to countries who are parties to the GATT and, therefore, the SPS Agreement.

44. SPS Agreement, *supra* note 36, art. 2:1 (emphasis added).

45. *Id.* art. 2:2 (emphasis added).

"which would constitute a disguised restriction on international trade."[46]

Annex A to the SPS Agreement defines a "sanitary or phytosanitary measure" as one which is designed to "protect human or animal life or health . . . from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs."[47] The SPS Agreement includes as a sanitary or phytosanitary measure:

> all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.[48]

The Agreement also provides Members with the power to impose "provisional measures" in cases where scientific data is "insufficient" to justify regulations based solely on current scientific knowledge.[49] Members are obligated to seek out additional scientific evidence and to re-evaluate their health measures when

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46. *Id.* art. 2:3.

47. *Id.* Annex A, ¶ 1. The complete definition of "sanitary or phytosanitary measure" is any measure applied:

> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
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> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
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> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Id.

48. *Id.*

49. *Id.* art. 5:7. The full text is as follows:

> In cases *where relevant scientific evidence is insufficient*, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, *Members shall seek to obtain the* additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

Id. (emphasis added).

further evidence is discovered.[50] Under the SPS Agreement, health regulations which create trade barriers must pass a stricter level of scrutiny before being allowed to impose such barriers.[51]

The inclusion of an agreement on sanitary and phytosanitary measures in the Uruguay Round Agreements was intended to provide a mechanism by which countries could impose bona fide health-related measures while preventing the imposition of such measures for protectionist, rather than health, reasons.[52] A Member may adopt measures more stringent than those called for by international standards, so long as those measures have a "scientific justification."[53] The SPS Agreement elaborates on the meaning of "scientific justification" by explaining that "there is a scientific justification 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."[54]

The SPS Agreement allows each Member to choose its own level of sanitary protection.[55] It notes that "many Members. . . refer to this concept as the 'acceptable level of risk'" and defines the appropriate level of protection as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life

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50. *Id.*

51. *See* Cromer, *supra* note 41, at 561-62.

52. Echols, *supra* note 33, at 192.

53. SPS Agreement, *supra* note 36, art. 3:3. A good U.S. analogue comes from Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2790 (1993). The case dealt at great length with the admissibility and validity of scientific evidence. The *Daubert* Court concluded that considerations involved in determining whether a methodology is scientifically valid include

> whether the theory or technique in question can be (or has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community.

Id. at 2790. The Court also explored the meaning of scientific knowledge: "The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Id.* at 2795. The *Dauber* Court found that, "in order to qualify as 'scientific knowledge', an inference or assertion must be derived by the scientific method. . . . [and] supported by appropriate validation — i.e. 'good grounds', based on what is known." *Id.* at 2795.

54. SPS Agreement, *supra* note 36, art. 3:3 & n.2 (emphasis added).

55. *Id.* Annex A, ¶ 5.

within its territory."[56] Each Member may choose the "appropriate" level of protection, provided it also considers "the objective of minimizing negative trade effects."[57] Article 5.5 allows the Member to impose levels of protection higher than accepted standards, but establishes that "the objective of obtaining consistency in the application of . . . appropriate level[s] of sanitary or phytosanitary protection" must be followed when creating the higher levels.[58] National measures which conform to international standards, such as those established by the Codex Alimentarius Commission, are presumptively valid.[59]

The SPS Agreement also governs risk assessment, which requires a country to evaluate the possibility of health risks as related to the proposed sanitary measure to be applied.[60] "Risk assessment" is:

> the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary . . . measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives . . . in food . . . .[61]

Once the risk is evaluated, the Member must choose the level of protection it deems necessary to avoid that risk. Article 5:5 of the SPS Agreement contains crucial language about higher levels of risk avoidance. The Article allows Members to promulgate higher levels of protection than those accepted internationally, but contains significant caveats. First, the Member must avoid "arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."[62] Second, Members must work with a Committee on Sanitary and Phytosanitary Measures,[63] to develop implementation guidelines, while taking into account "all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves."[64] In short, Article 5:5 mandates that a Member be consistent

56. *Id.*
57. *Id.* art. 5:4.
58. *Id.* art. 5:5.
59. Wirth, *supra* note 38, at 825.
60. SPS Agreement, *supra* note 36, Annex A, ¶ 4.
61. *Id.*
62. *Id.* art. 5:5.
63. *Id.* art. 12:1. The Committee is intended to provide a "regular forum for consultations" related to SPS measures. *Id.*
64. SPS Agreement, *supra* note 36, art. 5:5.

when establishing health regulations, rather than tailoring regulations to accommodate needs, such as economic protection, which are unrelated to health.

A final distinction of the SPS Agreement is that, unlike the earlier Standards Code, the SPS Agreement provides for dispute resolution[65] through the World Trade Organization (WTO).[66] Due in part to its experience with the hormones controversy, the United States was influential in creating an effective enforcement system for solving trade disputes.[67] The Dispute Settlement Understanding of the WTO outlines the procedures for resolving conflict between Members,[68] including a fourteen month timetable within which DSU proceedings are to be completed.[69]

C. THE NEW DISPUTE

Recent scientific studies of the growth hormones at issue indicate that they are safe when used responsibly.[70] The EC's Commissioner of Agriculture convened a scientific conference in

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65. *Id.* art. 11. The Dispute Settlement Understanding (DSU) of the Uruguay Round was highly anticipated in American agricultural circles. *See Hearing*, *supra* note 36, at 59 (statement of Mickey Kantor) ("The new system is a significant improvement on the existing practice. In short, it will work and it will work fast.").

66. Agreement Establishing the World Trade Organization, *opened for signature* Apr. 15, 1994, 33 I.L.M. 1144 [hereinafter WTO Agreement]. For an explanation of the relationship between GATT and the WTO, *see* William J. Davey, *The WTO/GATT World Trading System: An Overview*, *in* 1 HANDBOOK OF WTO/GATT DISPUTE SETTLEMENT (Pierre Pescatore et al. eds., 1996). For a thorough explanation of the WTO's role in dispute resolution in GATT, *see* Richard O. Cunningham & Clint N. Smith, *Section 301 and Dispute Settlement in the World Trade Organization*, *in* THE WORLD TRADE ORGANIZATION 584-89 (Terence P. Stewart ed., 1996); Steven P. Croley & John H. Jackson, *WTO Dispute Procedures, Standard of Review, and Deference to National Governments*, 90 AM. J. INT'L L. 193 (1996).

67. Richard O. Cunningham, *Dispute Settlement in the WTO: Did We Get What the United States [Wanted], or Did We Give Up the Only Remedy That Really Worked?*, *in* 1996 THE GATT, THE WTO AND THE URUGUAY ROUND AGREEMENTS ACT: UNDERSTANDING THE FUNDAMENTAL CHANGES 547 (Practicing Law Inst. ed., 1996) [hereinafter Cunningham, UNDERSTANDING THE FUNDAMENTAL CHANGES].

68. Understanding on Rules and Procedures Governing the Settlement of Disputes, WTO Agreement, *supra* note 66, Annex 2 [hereinafter DSU]. DSU Article 3:3 provides that "the prompt settlement" of situations when a Member considers it is being harmed by the actions of another Member "is essential to the effective functioning of the General Agreement." *Id.*

69. Cunningham, UNDERSTANDING THE FUNDAMENTAL CHANGES, supra note 67, at 557. For a detailed explanation of the DSU timetable, see *id.* at 557-59; *see also infra* note 82 and accompanying text.

70. *See infra* notes 73, 74.

Brussels to study growth hormones in late 1995.[71] The conference was comprised of scientists chosen by an independent scientific committee.[72] Participants in the conference determined that the hormones at issue do not pose a risk to human health.[73] Significantly, the Codex Alimentarius Commission, the joint FAO/WHO body responsible for international food standards, also adopted the recommendations of the scientific panel and approved the use of growth hormones.[74]

These scientific studies were instituted in part because of the growing illegal use of hormones throughout Europe.[75] The ban has not succeeded in completely stamping out hormone use in Europe.[76] An international survey and scientific testing of meat purchased throughout Europe found evidence of a wide variety of illegal hormones in the meat.[77] To retain control over its lucrative business, the strong black market for hormones has turned to violence.[78] The violence, which involves threats, beatings, and even murder of those attempting to stop illegal hormone use, has resulted in calls for tougher controls on the use of hormones within the European Community.[79]

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71. *EU Looks to Conference to Justify Continued Ban on Growth Hormones*, 12 Int'l Trade Rep. (BNA) No. 38, at 1626 (Sept. 27, 1995). The Commissioner, Franz Fischler, said that the EU needed to develop a long-term policy on the use of hormones which is grounded in "well-founded scientific discussion." *Id.* Sixty-five observers, made up of consumers, farmers and industry members, were present at the conference. *Id.* Political representatives from EC member states also attended. *Id.*

72. *Id.*

73. *European Conference Says Hormones for Growth Safe in Meat Production*, 12 Int'l Trade Rep. (BNA) No. 48, at 2005 (Dec. 6, 1995); *see also EU Official Signals Continuation of Ban on Hormone-Treated Meat*, INSIDE U.S. TRADE, Dec. 8, 1995, at 8 [hereinafter *EU Official*] (noting that the Conference concluded that the hormones [excluding MGA] "have no human health risk when used under prescribed conditions").

74. *UN Food Standards Body Approves Use of Growth-Promoting Hormones in Meat Products*, FAO Press Release (July, 13, 1996) <http://www.fao.org/waicent/ois/press_ne/presseng/H48F.HTM>. The Commission confirmed that all Codex decisions on food safety must be based on sound scientific analysis and evidence. *Id.*

75. *See* Peter Blackburn, *EU Meat Hormone Rules to be Reviewed in Brussels*, Reuters World Service, Nov. 28, 1995, *available in* LEXIS, World Library, TXTEE file (noting that the scientific conference on growth hormones was held amid mounting public concern over illegal usage and black market trade).

76. *Meat and Livestock: Consumers Associations Launch Attack on Growth Hormones*, EUR. REP., Dec. 21, 1994, § 2003.

77. *Id.*

78. Katherine Butler, *Why the Mafia is Into Your Beef: The EU Ban on Growth Hormones for Cows has Created a Lucrative Black Market*, THE INDEP., Mar. 19, 1996, at 13.

79. *Id.*

In light of the recent scientific findings on hormone safety, the United States called for new negotiations on the hormone ban, hoping to benefit from the heightened scrutiny such bans receive under the SPS Agreement.[80] The United States argued that these scientific studies point to what it has been claiming all along — that growth hormones, when used properly, pose no threat to human health.[81] The United States forced negotiations with the European Community when it filed a complaint with the WTO in January 1996.[82] After the two parties failed to come to an agreement over the ban,[83] the United States requested a panel be created to investigate the issue.[84] Despite the American pressure, the European Parliament and the Euro-

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80. Mark Felsenthal, *Kantor Backs Glickman Proposal for WTO Action on EU Beef Hormone Ban*, 13 Int'l Trade Rep. (BNA) No. 3, at 78 (Jan. 17, 1996). In a written statement, Agriculture Secretary Dan Glickman said, "The evidence is overwhelming that proper use of these hormones poses no danger to human health, and the WTO sanitary and phytosanitary agreement ensures that the principles of sound science must prevail in matters such as this." *Id.* U.S. Ambassador to the EU Stuart Eizenstat stated:

> If there is no scientific basis for the ban . . . it is an unnecessary trade barrier. This is a very dangerous precedent that the U.S. feels very strongly about. If the EU can get away with this ban on what has been judged to be unscientific grounds, then what [will] stop numerous other countries from imposing bans for pseudo-scientific reasons.

Joe Kirwin, *U.S. Files WTO Complaint Against EU Ban on Meat Imports with Hormones*, 13 Int'l Trade Rep. (BNA) No. 5, at 160 (Jan. 31, 1996).

81. *European Conference Says Hormones for Growth Safe in Meat Production*, *supra* note 73, at 2005. The preliminary results of the conference were released December 1, 1995. According to the Commission, "the accumulation of experience and published data on the use of natural and sex hormones and related compounds . . . has shown no evidence of human health risk arising from their use, where these substances are used under prescribed conditions." *Id.*

82. Kirwin, *supra* note 80, at 160. Under WTO rules, the EU had 30 days to meet with U.S. representatives to discuss the complaint. DSU, *supra* note 68, art. 4:3. The joint U.S.-EU consultations had 60 days to produce an agreement. *Id.* art. 4:7. When consultations are unsuccessful, WTO rules allow the parties to request a dispute settlement panel to decide on the issue. *Id.* Panels are allowed nine months to issue a final report. *Id.* art. 12:9. Generally, appellate rulings must come within 60 days of receipt of the panel report. *Id.* art. 17:5.

83. *Dispute Settlement Panel to Look at EU Hormone Ban*, 13 Int'l Trade Rep. (BNA) No. 21, at 845 (May 22, 1996).

84. *Id.* The European Union blocked the U.S. request for a panel earlier in May, but under WTO rules could not do so a second time. *Id.* The European Union in turn demanded that a WTO panel investigate the United States' $100 million retaliatory tariffs on EU agricultural products. *EU Puts on Hold Request for WTO Panel After U.S. Lifts Punitive Beef Sanctions*, 13 Int'l Trade Rep. (BNA) No. 29, at 1180 (July 17, 1996). The EU request for a panel was viewed largely as a tactical response to the U.S. complaints. *Id.* As a result, the United States lifted its $100 million in duties on products coming from the European Union. *Id.*

pean Union's Council of Agricultural Ministers voted in January 1996 to maintain the hormone ban.[85] Due to the new, stricter standard for health-related regulations required by the SPS Agreement, as well as the positive scientific findings on growth hormones, American agricultural and trade interests are confident that the current arguments against the hormone ban are more convincing than those proffered in 1989.[86]

1. U.S. Position

In its Panel Submission, the United States argues that the European Community ban on growth hormones lacks any scientific justification—a basic requirement of any such regulation under the SPS Agreement. The United States claims that the European Community failed to adequately perform the required assessment of the dangers posed by growth hormones before implementing the ban. Moreover, the United States alleges that the ban stems not from legitimate health concerns but from a desire to protect the Community's domestic cattle industry. As such, the ban is wholly impermissible under the provisions of GATT 94, especially the SPS Agreement.[87] Finally, the United States concludes the ban constitutes a disguised restriction on international trade.

Because it is not supported by sufficient scientific evidence, the United States claims the hormone ban violates Article 2.2 of

85. Kirwin, *supra* note 80.

86. Felsenthal, *supra* note 80; *EU Looks to Conference to Justify Continued Ban on Growth Hormones, supra* note 71, at 1626 (regarding new WTO requirements, the EU Commissioner of Agriculture said, "These [provisions] . . . may only exist on the basis of danger to human or animal health and on scientific grounds. [Consequently, the EU faces] enormous problems, because we simply don't want to consume these products, but that does not release us from the . . . requirement to come up with a scientific argument.").

Other nations are watching the proceedings with great interest. Australia and New Zealand each joined the U.S. as interested parties in its complaint against the ban. *EU Policy on U.S. Meat Imports Seen in Conflict with Stand on U.K. Imports,* 13 Int'l Trade Rep. (BNA) No. 7, at 241 (Feb. 14, 1996). In September 1996, the Canadian government requested that the WTO establish a panel to investigate the Canadian opposition to the EU hormone ban. *Canada Demands Own WTO Beef Hormone Panel*, EUR. REP., Oct. 2, 1996, § 2162. Canada, like Australia and New Zealand, is also supporting the U.S. action as an interested third party. *Id.*

87. U.S. Submission, *supra* note 1, ¶ 85. The U.S. claims the ban is inconsistent with several provisions of the WTO Agreement, in particular the SPS Agreement, and Articles I, III, and XX of GATT 94. *Id.* ¶ 179-212. The U.S. also asserts that, if the SPS Agreement didn't apply, the ban would violate the Agreement on Technical Barriers to Trade (TBT Agreement). *Id.* ¶ 85. This Note will address only the American allegations under the SPS Agreement.

the SPS Agreement.[88] Additionally, the United States maintains the ban cannot be justified as a "provisional" measure because enough evidence is available to actually determine whether the hormones are safe.[89] To support its charges, the United States emphasizes the findings of the 1995 Conference, which concluded hormones pose no health risk.[90] The United States also relies on the Codex Alimentarius Commission's review of growth hormones and its conclusion that they are safe for use in cattle.[91]

Moreover, the United States rejects the European Community's claim that the ban is justified under an appropriate risk assessment.[92] Under the SPS Agreement, Members must ensure that their sanitary or phytosanitary measures are "based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."[93] The United States alleges that the requirement of risk assessment "serves a very basic and obvious, yet important, purpose[:]" if a substance poses no risk, a sanitary or phytosanitary measure cannot be said to be necessary to protect against that risk.[94] The United States asserts that the European Community has failed to perform any risk assessment with which it could justify the hormone ban.[95] Indeed, according to the United States, the "remarkable characteristic" of the pub-

88. *Id.* ¶ 112. The U.S. claims it violates Article 2.2 of the SPS Agreement. *See supra* note 45 and accompanying text. The U.S. cites the EC's referral of the matter to the Scientific Working Group and the 1995 Conference to support its contention and asserts that in both instances the scientists involved concluded there is no scientific evidence supporting the ban. U.S. Submission, *supra* note 1, ¶ 113.

89. *Id.* ¶ 118-21; *see also supra* note 49. The U.S. says the hormones have been thoroughly tested, examined, and reviewed. It further alleges the scientific community has conducted thorough risk assessments and has concluded that the "hormones do not pose any identified risk to human life or health when used in accordance with good animal husbandry practices." U.S. Submission, *supra* note 1, ¶ 119.

90. U.S. Submission, *supra* note 1, ¶ 68; *see supra* note 73 and accompanying text.

91. U.S. Submission, *supra* note 1, ¶69; *see supra* note 74 and accompanying text.

92. U.S. Submission, *supra* note 1, ¶ 102-110.

93. SPS Agreement, *supra* note 36, art. 5:1.

94. U.S. Submission, *supra* note 1, ¶ 103.

95. *Id.* The United States claims that the EC has not even relied on the risk assessments performed by others. *Id.* ¶ 104. Allegedly, the conference relied upon by the EC did not actually appear to do risk assessments; it merely "discussed the safety assessment" of the hormones. *Id.* ¶ 108 & n.72.

lic debate over these hormones is that the risk is usually described in terms of *consumer anxieties* rather than any actual adverse effects on human health.[96] The SPS Agreement, by its terms, demands something more than "consumer anxieties" to justify a sanitary or phytosanitary measure.

The United States also claims that, in addition to its lack of a scientific basis, the ban is a disguised restriction on international trade, which violates Article 2.3 of the SPS Agreement.[97] The factors used by the United States to determine that the ban is a disguised restriction on trade include the EC's failure to conduct risk assessment, the lack of scientific evidence to support the ban, and the EC's alleged concession that its measure is designed to remove competitive advantages accruing to imports.[98] From the American standpoint, these factors are the "essence" of a disguised restriction on international trade.[99] Ultimately, the criteria for determining whether the ban is a disguised restriction on trade is similar to that used to measure the ban's failure to have a scientific basis.[100]

According to the United States, the hormone ban is not only more extensive than is necessary to protect health, it is more trade-restrictive than what would be required to achieve the appropriate level of sanitary protection.[101] Additionally, the United States asserts that the ban lacks specificity—in other words the ban is not intended to achieve any particular level of sanitary protection from any identified risk.[102] Presumably, if a level of risk could be identified, it would relate to the level of hormone residue remaining in the meat.[103] However, the United States claims that, instead of addressing any level of hormone residue in the meat, the EC ban regulates meat based on the production method used.[104]

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96. *Id.* ¶ 104 (emphasis added).
97. *Id.* ¶ 137.
98. *Id.*
99. *Id.*
100. *Id.* ¶ 140.
101. *Id.* ¶ 122.
102. *Id.* ¶ 127.
103. *Id.* The amount of a growth hormone that is present in meat is measured in terms of the residue level of the hormone. In determining the permissible residue level under veterinary standards, the Codex Alimentarius and other organizations calculate Maximum Residue Levels (MRL's). Because all meat contains *some* hormones, whether artificially injected or naturally occurring, MRL's may be used to ensure that levels of hormone residue remain below a threshold that is generally recognized as being "safe." Meat from a wide variety of production methods may pass or fail these threshold tests.
104. *Id.*

To bolster its claims, the United States provides several examples of the ban's inconsistency. For instance, the EC continues to allow human consumption of domestically produced meat from animals administered with the banned hormones for *therapeutic* purposes.[105] The EC also allows consumption of meat from animals with higher levels of endogenous hormones (those occurring naturally) than the levels found in meat administered with the same hormones for growth promotion.[106] Additionally, the EC permits consumption of other food products—such as milk, butter, and eggs—which contain far higher levels of endogenous hormone residues than those found in the growth-enhanced animals.[107] From the American standpoint, the European Community is permitting limitless human consumption of endogenous hormones while simultaneously banning imported meat from animals that have been given scientifically safe hormones for growth purposes.[108]

The legal meaning of this inconsistency can be found in Article 5:5 of the SPS Agreement. The Article provides that higher measures of protection may be implemented, but *only if* the higher level of protection is consistent with other levels within the Member country.[109] The EC's failure to monitor the levels of naturally occurring hormones demonstrates an inconsistency within its regulations and is consequently suspect under the Article 5:5 provisions. Although the United States does not make this argument directly, the inconsistency of the EC's regulation adds a further level of doubt regarding its validity.

2. *EC Position*

The European Community's position could not be further from that of the United States. In justifying the ban, the EC relies heavily upon its belief that the scientific evidence about growth hormones is uncertain. To further its argument that hormones are unsafe, the EC asserts that the controls necessary to ensure the safe administration of hormones are not in place in American feedlots. The EC also cites reasons for the ban unrelated to scientific criteria; namely, the Community's historical use of the "precautionary principle" and the proposed "fourth

105. U.S. Submission, *supra* note 1, ¶ 128 (emphasis added).
106. *Id.*
107. *Id.* ¶ 129.
108. *Id.*
109. SPS Agreement, *supra* note 36, art. 5:5.

hurdle"[110] of scientific inquiry. The EC claims it approaches the evaluation of risks differently than the United States does, citing its longstanding policy of precaution. The EC also strongly rejects the American contention that the ban is based on protectionism rather than health needs.[111]

The EC soundly rejects the American assertion that the scientific data on hormones is conclusive. To support its position, the European Community cites historical instances where scientific investigation initially deemed a particular substance "safe," and the substance was later found to pose serious health risks.[112] The EC specifically notes two contemporary examples of health hazards once thought safe: the E.Coli virus and bovine spongiform encephalopathy (BSE).[113] Significantly, with regard to BSE, the EC has taken strong measures to prevent British cattle discovered carrying the disease from reaching other European consumers.[114] The EC's swift reaction to the BSE scare, however, does not support its position on hormones; the danger posed by BSE was far more real than any present dangers associated with properly-used growth hormones.

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110. For general discussion of this concept, *see* Ronald Bailey, *The Fourth Hurdle,* FORBES, Apr. 2, 1990, at 166.

111. The EC maintains that an "objective observer of the historical events . . . [of the hormone ban] would readily admit that the aim and purpose of the EC measures is to protect human and animal health . . . ." EC Submission, *supra* note 2, ¶ 29. *But see EU Official, supra* note 73, at 8 (reporting EU claims that lifting the ban would "create an over-supply of meat, which could drive rural beef suppliers out of business" and that the EU does not need U.S. beef imports, as it is not short of meat).

112. EC Submission, *supra* note 2, ¶¶ 114-22. The EC refers to cyclamates, saccharin, phenformin, and pesticides to illustrate its point.

113. *Id.* ¶ 126. With regard to E.Coli, the EC adopted rules of meat hygiene in 1964, embracing the precautionary approach; at that time, the United States allegedly criticized the measures as overly-done and unnecessary. *Id.* ¶ 128. The United States government did not completely ignore the dangers of E.Coli; it simply did not follow the approach taken by the EC. The United States assumed consumer protection could be assured by testing end-products for the virus. *Id.* However, subsequent outbreaks of E.Coli caused the United States to review, and alter, its testing methods. *Id.*

As for BSE, commonly known as "mad cow disease," the EC claims that the link between BSE and Creutzfeldt-Jakob disease, a fatal human condition, is nearly certain. *Id.* ¶ 129. Therefore, the EC asserts its precautions were the wise approach to dealing with the disease. *Id.* ¶¶ 129-30.

114. *See, e.g., Britain: Burnt by the Steak (Effects of Mad Cow Disease on the British Beef Industry),* THE ECONOMIST, Apr. 6, 1996, at 57. The EU imposed a worldwide ban on British beef, citing the potentially deadly link between BSE in cattle and cases of Creutzfeldt-Jakob disease in humans. *Id.* However, no concrete link between the two has yet been established. *See, e.g.,* Bruce Wallace, *Panic on the Hoof: Fears of 'Mad Cow Disease' Lead to a Worldwide Ban on British Beef,* MACLEAN'S, Apr. 8, 1996, at 26.

The EC's Panel Submission focuses on the need for strict adherence with veterinary practices in order to ensure safe usage of growth hormones. It maintains that hormone safety cannot be assured without such strict controls.[115] The EC acknowledges that all countries, including the United States, regulate the use of growth hormones in farm animals.[116] The difference, according to the EC, is the extent to which their use is regulated.

In the EC's view, the United States does not impose sufficiently strict controls on the use of hormones.[117] Hormones used as growth promoters are available over the counter in the United States.[118] Even though the Food and Drug Administration imposes conditions on their use, there are no "effective, official" controls in place to ensure that hormones are used properly.[119] In contrast, the EC strictly limits use of the hormones; it allows three hormones to be used only for therapeutic or zootechnical purposes, and bans three hormones altogether.[120] This, according to the EC, demonstrates the dissimilar approaches of the two countries.[121]

The EC considers the difference in regulation to be a reflection of the different levels of consumer protection adopted by each country.[122] The EC opines that, in instances where the safety of a product is in question, the United States gives the benefit of doubt to the producer; the United States will not protect consumers unless there is clear and weighty evidence of harm.[123] The European Community, in turn, allegedly places more emphasis on the needs of the consumer whenever safety is an issue.[124] The EC, however, does not illustrate its point by giving any examples of lax American regulation of hormone use.

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115. EC Submission, *supra* note 2, ¶ 105. The EC asserts that, with regard to growth hormones, the following conditions are necessary to safeguard public health: the administration must be an implant in an animal's ear; the animal must be identified to allow for controlled withdrawal; administration must be done by a veterinarian; hormones must be on approved EC list; and hormones must have been shown to be effective and safe. *Id.*

116. EC Submission, *supra* note 2, ¶ 123.

117. *Id.* ¶ 124.

118. *Id.*

119. *Id.*

120. *Id.* ¶ 123.

121. *Id.* ¶ 124.

122. *Id.* The EC's precautionary approach places "the attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies." *Id.*

123. *Id.*

124. *Id.*

The EC's Submission also focuses heavily on the concept of "risk." The EC makes several claims about the risks hormones pose, including their alleged carcinogenic effects.[125] The EC notes that administered hormones also pose health risks due to the presence of metabolites — substances remaining after a drug is metabolized into the body.[126] Another alleged risk is the use of hormone cocktails, which are potent combinations of different hormones that sometimes use very dangerous and universally banned substances such as DES.[127] A related concern is the potential danger of multiple hormone exposures to humans.[128] The EC states that, because the effects of long-term exposure are unknown, preventing such exposure is consistent with the "'precautionary' principle . . . at the heart of the policy followed by the EC" on such matters.[129]

The EC explains how it has adopted the precautionary principle in its approach to growth hormones and many other health-related issues.[130] The "precautionary principle" advises governmental authorities to err on the side of environmental and health protection when formulating public policy whenever the context is characterized by uncertain scientific conditions.[131] The Uruguay Round has been interpreted as endorsing the application of the precautionary principle as an "element of the in-

125. EC Submission, *supra* note 2, ¶ 76-79. The report the EC cites acknowledges that the carcinogenic potential of hormones is "unlikely." *Id.* ¶ 78.

126. *Id.* ¶ 82. Anabolic steroids (growth hormones) have a large variety of metabolites. *Id.* The EC argues that the toxicity of the growth hormones' metabolites is unknown, and could be potentially very harmful. *Id.*

127. *Id.* ¶ 88. The EC asserts that illegal mixtures of drugs can result in unknown levels of hormone residues in foods, which may constitute a risk for the consumer. *Id.* ¶ 89. It does not explain, however, how its blanket ban on hormones prevents their illegal introduction into the European market. For information on DES, see *supra* notes 12-16 and accompanying text.

128. EC Submission, *supra* note 2, ¶ 93-95.

129. *Id.* ¶ 96.

130. The precautionary principle can be found in resolutions of the European Parliament. EC Submission, *supra* note 2, ¶ 125. The principle is inscribed in the EC Treaty of Rome, Article 130R, which pertains to the protection of the environment. It reads in part,

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken. . . . Environmental protection requirements must be integrated into the definition and implementation of other Community policies.

Treaty Establishing the European Economic Community, Mar. 25, 1957, art. 130R, 298 U.N.T.S. 11 [hereinafter Treaty of Rome or EC Treaty].

131. *See, e.g.*, Wirth, *supra* note 38, at 838. There is no universal formulation of the precautionary principle. *Id.* at 838-39.

ternational trade regime."[132] The precautionary approach has become increasingly accepted on the international level due to the uncertainty of conditions when regulatory requirements are made.[133]

In addition to the precautionary approach, the EC also emphasizes that the European Parliament was discussing the need for a "fourth hurdle" as early as 1988.[134] Before being approved within the European Community, new veterinary drugs must meet three criteria: safety, efficacy, and quality.[135] Arguments have been made that a fourth factor — socioeconomic and environmental impact — should be included in the evaluation of new veterinary drugs.[136] According to the EC, the Statements of

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132. *Id.* at 839. The author interprets the SPS Agreement's provision allowing each Member's right to establish its own level of protection as exemplifying the precautionary approach. *Id.*

133. *Id.* at 838.

134. EC Submission, *supra* note 2, ¶ 43.

135. *Id.*; *see also, e.g., Threat of EC/US Trade War as FDA Approves BST*, AGRA EUR., Nov. 12, 1993, at E/2-3. This report acknowledges that, regarding Bovine Somatotropin, a drug which enhances the milk-yield of dairy cattle, "On a scientific level, the EC is in agreement with the US authorities that the substance is safe. . . . The EC, which overruled scientific evidence in favour of socio-economic arguments in the case of BST, has been looking to extend regulations on safety, efficacy and quality to include a fourth, socio-economic factor." *Id.* at E/3. The EC placed a moratorium on the use of BST in 1989. William VanDaele, *BST & the EEC: Politics vs. Science,* BIO/TECHNOLOGY, Feb. 1992, at 148.

This approach is directly contrary to the American approach to BST. *See, e.g.* Stauber v. Shalala, 895 F.Supp. 1178 (W.D. Wis. 1995). In *Stauber*, consumers of commercially sold dairy products brought suit against the Secretary of Health and Human Services and the Commissioner of Food and Drug Administration challenging defendant's approval of recombinant bovine somatotropin (rbST, a.k.a. BST), a milk-production-enhancing, synthetic version of the naturally-produced BST. *Id.* The plaintiffs wanted all milk products derived from rbST-treated cows to be labelled as such, and offered in support of their argument "widespread consumer desire" for mandatory labelling. *Id.* at 1193. The *Stauber* court soundly rejected the consumer preference argument:

> [P]laintiffs are incorrect in their assertion that by itself consumer opinion could suffice to require labelling. The FDA does consider consumer opinion relevant when determining whether a label is required . . . but a factual predicate to the requirement of labelling is a determination that a product differs materially from the type of product it purports to be. . . . If . . . the product does not differ in any significant way from what it purports to be, then *it would be misbranding to* label the product as different, even if consumers misperceived the product as different. In the absence of evidence of a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.

Id. at 1193 (emphasis added).

136. EC Submission, *supra* note 2, ¶ 43; *see also Mac Sharry Backs 'Fourth Hurdle' for Licensing of BST*, AGRA EUR., May 18, 1990, at E/2-3. Sharry, who

Principle adopted by the Codex Alimentarius Commission in 1995 recognize that other "legitimate" factors relevant for the health protection of consumers may be considered in determining health standards. In the EC's opinion, a "legitimate" factor includes consumer anxieties.[137] Although the EC has given much attention to these arguments for a fourth hurdle, nothing formal regarding a fourth hurdle has ever been codified into EC law.[138]

II. SCIENCE, SAFETY, AND SANITARY MEASURES

The European Community has essentially four arguments with which to support a continued ban on growth hormones. The EC argues that the scientific data on the safety of growth hormones is not, contrary to the United States' assumption, adequate to warrant lifting the ban. Second, the EC maintains that, despite recent scientific studies which may suggest that some growth hormones pose no health threat to humans, the lack of adequate control over hormones within the American market renders them unsafe. Third, the EC contends that it has assessed the risks associated with growth hormones, and has concluded from such assessment that the hormones are unsafe. Finally, the EC's claims that, because it has historically employed a higher level of protection for its consumers, the present ban is in keeping with those higher standards and does not violate the SPS Agreement.

A. HOW PRECISE IS SCIENCE UNDER THE SPS AGREEMENT?

Because of the SPS Agreement's structure and emphasis on scientific validity, scientific tests are at the core of the trade disciplines established in it.[139] Reliance on "available scientific evidence,"[140] "relevant scientific evidence,"[141] "sufficient scientific

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was the EC Agriculture Commissioner, stated, in his recommendation that the EC instigate a definitive ban on BST:

> There have to be serious doubts about introducing major productivity enhancing products that could seriously aggravate the socio-economic situation in the member states and which might have destabilising effects on the Community market. New technologies may well open up new vistas on the productivity front. But if the public reaction is likely to be one of rejection, or even revulsion in some cases, it would be counterproductive to go down that road.

Id. at E/3.

137. EC Submission, *supra* note 2, ¶ 134.

138. *Id.* ¶ 43.

139. Wirth, *supra* note 38, at 825.

140. SPS Agreement, *supra* note 36, art. 5:2.

evidence,"[142] "scientific justification,"[143] and basis on "scientific principles,"[144] are all mandated by the SPS Agreement. However, it is not at all clear what would be adequate scientific findings for the purposes of the Agreement.[145]

Similarly, the SPS Agreement does not explain what would suffice as an adequate scientific justification upon which to base health regulations. If "science" is taken at its plain meaning,[146] the studies which have been conducted on the growth hormones at issue in this case should be enough to validate their safety.[147] Yet, as is apparent by the hormone dispute, what constitutes scientific "proof" is subject to different interpretations.

The language of the SPS Agreement is also ambiguous with regard to "appropriate levels" of regulation.[148] It provides no clear definition of what is "appropriate."[149] The Agreement is designed to ensure that Members have autonomy to promulgate regulations, but appears to leave open the question of how much flexibility a Member has to determine its own "appropriate" level of regulations. The wording of the Agreement is uncomfortably circular: the appropriate level of protection allowed each Member under Annex A is the level of protection deemed appropriate by that Member.[150]

One way to resolve this difficulty—to give this term some content—is to focus on the parallel provisions within the SPS Agreement, particularly the trade barrier references. The Agreement is replete with language admonishing Members

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141. *Id.* art. 5:7.

142. *Id.* art. 2:2.

143. *Id.* art. 3:3.

144. *Id.* art. 2:2.

145. *See* Daubert v. Merrell Dow Pharmaceuticals, *supra* note 53, for a U.S. debate on the meaning of scientific validity and its legal significance.

146. The term "science" is defined as: "a branch of knowledge requiring systematic study and method. . ."; the term "scientific" is defined as: "using careful and systematic study, observations, and tests of conclusions." OXFORD AMERICAN DICTIONARY 811 (Heald Colleges ed. 1980).

147. *See supra* notes 73, 74 and accompanying text.

148. SPS Agreement, *supra* note 36, art. 5:1.

149. The term "appropriate" is found in Articles 5:4, 5:5, and 5:6 of the SPS Agreement. No explanation beyond the term's plain meaning is given. "Appropriate" is commonly defined as "suitable or proper." OXFORD AMERICAN DICTIONARY 39 (Heald Colleges ed. 1980).

150. SPS Agreement, *supra* note 36, Annex A, ¶ 5. Annex A of the SPS Agreement defines the "appropriate level of sanitary or phytosanitary protection" as "[t]he level of protection *deemed appropriate* by a Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." *Id.* (emphasis added).

against impermissibly restricting international trade.[151] A more definitive way to approach the unclear language of the SPS Agreement is to focus on the consistency requirement of Article 5:5.[152] This Article demands that any health-related measures which go beyond those accepted internationally must be consistent with other regulations promulgated by the Member.[153] This requirement—that regulations be consistently applied—may flesh out the opaque nature of the Agreement's language. For example, the EC's failure to monitor hormone residue levels stemming from endogenous hormones is inconsistent with its position that hormones may pose a health threat. This lack of consistency runs counter to the ban's legitimacy. Similarly, the EC's failure to adequately monitor illegal hormone use within its own market is also a glaring inconsistency under Article 5:5.

In addition to claims of inconsistent application of the SPS, the United States also argues that the EC fails to consider appropriate scientific evidence. According to the United States, the SPS Agreement allows only currently available data to be taken into account when determining appropriate regulations.[154] Because the great amount of evidence available on the hormones at issue suggests their safety, the United States claims the ban violates the SPS Agreement.[155]

The EC, however, claims it has the right to use factors other than pure "science" to determine the appropriate level of protection it wishes to give its citizens.[156] Under the EC's interpretation, a Member may always claim that there is insufficient evidence for a careful decision to be made regarding the safety of a given substance. If this rationale were followed, a Member could impose any regulation it liked and insulate the regulation against SPS attacks by perpetually calling for more testing. Such an interpretation would thwart the purpose of the SPS Agreement.

The two conflicting interpretations of the SPS Agreement cannot be immediately reconciled with each other. The SPS Agreement, however, suggests an answer to this riddle in Article 5:5. This provision does not allow a Member to promulgate regulations that are either inconsistent with its overall policy in a

151. *See id.* pmbl., arts. 2:3, 5:4, 5:5, 5:6; *see also* text accompanying *supra* notes 97-100 for the American position on disguised trade restrictions.
152. SPS Agreement, *supra* note 36, art. 5:5.
153. *Id.*
154. U.S. Submission, *supra* note 1, ¶ 5-6.
155. *Id.* ¶ 6.
156. *See* EC Submission, *supra* note 2, ¶ 43.

given area or that are inconsistently applied. The language of Article 5.5 does not allow a Member to impose "arbitrary or unjustifiable distinctions" between the regulatory standards applied to different situations.[157]

Under the guidelines of the SPS Agreement, if a Member's rules comply with internationally-accepted standards, they are presumptively valid.[158] It follows that if the Codex Alimentarius Commission found that the presence of growth hormones in meat pose no significant risk to human health,[159] the American method of using growth hormones in meat production is acceptable under the SPS Agreement. By extension, the EC's ban on hormones would be invalid. The SPS Agreement, however, allows Members to promulgate regulations which are stricter than the international standards.[160] The Agreement stresses that such regulations are valid only if they have taken into account the "available scientific information" and have determined that international standards are not sufficient to achieve the appropriate level of protection.[161] The EC has not done this.

B. THE ASSESSMENT OF RISKS

The SPS Agreement also addresses the concept of "risk assessment."[162] Choosing the acceptable level of risk would appear to be at the discretion of each Member, so long as it does not unduly interfere with international trade. This language has been deemed to add another level of interpretational difficulty to the SPS Agreement.[163] One author maintains that this passage "links a party's appropriate level of sanitary or phytosanitary protection with the concepts of 'scientific justification' and 'available scientific information.'"[164] This suggests that there are "scientific constraints on the choice of the appropriate level of protection, [which is] a risk management decision that reflects social value choices distinct from the scientific process of risk assessment."[165] Under this rationale, factors other than strict scientific data should properly be used in risk deter-

157. SPS Agreement, *supra* note 36, art. 5:5.
158. *Id.* art. 3:2.
159. *See supra* notes 73, 74 and accompanying text.
160. SPS Agreement, *supra* note 36, art. 3:3.
161. *Id.*
162. *Id.* Annex A, ¶¶ 4-5.
163. *See* Wirth, *supra* note 38, at 827.
164. *Id.*
165. *Id.*

minations.[166] It is not clear, however, how this analysis fits into the overall goal of the SPS Agreement, which is to lessen the burdens on international trade created by those health regulations not based on scientific evidence.[167]

The EC maintains that there is simply not enough scientific data with which to judge the safety of growth hormones on a risk assessment basis.[168] It is true that there is no accepted level of "certainty" with regard to scientific data.[169] While this fact could support the EC's contention, it directly conflicts with the stated goal of the SPS Agreement. Moreover, in order to regulate confidently, Members must be given a baseline level of certainty which can be used to justify health-related regulations. But, this baseline level does not need to be constructed as an "all or nothing" dichotomy; Article 5:5 indicates that such an interpretation is not necessary. A baseline level of certainty needs to be in place, but does not need to be the last word with regard to scientific data. Under Article 5:5, a Member may promulgate regulations more strict than available scientific data would require. In order to comply with the terms of Article 5:5, however, such regulations must be applied *consistently*. The EC's failure to be consistent in applying the growth hormone ban has fatally harmed its position.

C. VIABILITY OF THE PRECAUTIONARY PRINCIPLE

To support its claims of the benefits of the precautionary system, the EC cites examples of the E.Coli bacterium and the BSE outbreak.[170] The European Community claims that United States' treatment (or lack of treatment) of E.Coli is similar to its current regulation of growth hormones.[171] Since it is now clear that E.Coli is a danger to human health, the EC feels its precautionary approach should also be justified with respect to growth hormones. The EC's case for BSE is not as persuasive. Scientific experts are still unsure whether the outbreak of "mad cow

166. *Id.*
167. *See, e.g.*, Cromer, *supra* note 41, at 557.
168. *See supra* notes 112-14 and accompanying text.
169. *See* Wirth, *supra* note 38, at 840. Wirth maintains that scientific uncertainty requires "the exercise of judgment and discretion, both scientific and regulatory." *Id.* In the face of uncertain scientific data, the precautionary approach — and its increasing acceptance as a norm in international trade agreements — supports the validity of applying conservative assumptions in the absence of empirical data. *Id.*
170. *See supra* note 113 and accompanying text.
171. *Id.*

disease" has anything to do with the new form of Creutzfeldt-Jakob disease.[172] While BSE precautions may not be as clearly justified as the measures taken against E.Coli, the EC's precautions are not entirely inappropriate. The EC claims that, although it was criticized by some for taking such precautionary measures where the infected cows were concerned, it was very fortunate to have done so, in order to prevent the spread of such a serious disease.[173]

While both of the diseases cited by the EC are serious, the evidence regarding growth hormones simply does not merit the same kind of precautionary measures. These hormones occur naturally, and are found in cattle consumed by Europeans every day.[174] No scientific evidence has yet to surface which supports any claim of harm to consumers from hormones.[175] Without such evidence, the EC cannot justify its ban on the supposed health risks related to hormone consumption. The comparison between demonstrably dangerous viruses and the growth hormones at issue in this case is a disingenuous attempt to justify the current ban — an attempt that is not merited by the evidence.

The EC has also repeatedly stressed in its arguments that its past use of precautionary restrictions validates the hormone ban.[176] In its arguments, the EC cites examples of instances when such a precautionary approach has been used successfully.[177] It also notes instances where available scientific data deemed a substance "safe," with dire consequences.[178] However, the EC has never codified the precautionary principle into laws governing the approval of new substances.[179] The EC cites examples of the United States' failure to proceed cautiously with respect to new substances that were not safe, such as cyclamates, saccharin, phenformin, and pesticides.[180] These sub-

172. *Id.*
173. *See* EC Submission, *supra* note 2, ¶ 130.
174. *See supra* notes 105-08 and accompanying text.
175. *See supra* notes 122, 130-31 and accompanying text.
176. *See supra* notes 113-14.
177. *Id.*
178. *See supra* note 112 and accompanying text.
179. In 1988, the precautionary principle was discussed in the "Collins" Report, which concerned the approval of veterinary medicines and specifically included discussion of growth hormones. Interestingly, the principle was *not* included in the final version of the report. EC Submission, *supra* note 2, ¶ 43. The EC has incorporated the precautionary principle in its environmental regulations, specifically in Article 130R of the EC Treaty.
180. EC Submission, *supra* note 2, ¶¶ 118-22.

stances have all been found to be extremely dangerous to human and animal health.[181] The EC contends that science has its limits. Although it acknowledges the "crucial role science plays in regulating the use of toxic substances and drugs,"[182] the EC maintains that scientific certainty in a regulatory process is currently an "illusory" goal.[183]

While the EC willingly admits that "no products would probably be approved if a showing of absolute safety" was required,[184] it claims that the strict level of precaution it imposes with regard to hormone use is necessary for the protection of human health.[185] Yet it does not explain what level of safety would merit approval of growth hormones in its beef. It also fails to respond to the American allegations that the EC does allow the consumption of beef treated with growth hormones for therapeutic and zootechnical reasons. Additionally, the EC does not appear to be concerned by high levels of endogenous hormones in beef bound for EC consumers.[186] The apparent inconsistencies of the EC's actions, which once again conflict with the language of Article 5:5 of the SPS Agreement, considerably undermine its position.

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181. *Id.*

182. *Id.* ¶ 115.

183. *Id.*

184. EC Submission, *supra* note 2, ¶ 117. An interesting case example involves an American company which organized in 1990 to export high-quality, hormone-free beef to the United Kingdom. RUNGE, *supra* note 41, at 75-76 (citing personal communications with D. Simon); L. Kotschwar, D. Simon, and E.W.F. Peterson, *Laws Governing the Use of Technical Standards as Barriers to Trade: The Case of Trade in Livestock Products,* AGRIBUSINESS, Jan. 1993, at 91-101. Landmark Meats, U.S., organized the processing and exportation of hormone-free beef, in compliance with the hormone ban. RUNGE, *supra* note 41, at 75. The sampling procedures introduced by the EU to detect hormone residues were kept secret from the meat exporters, which made compliance with the procedures more difficult, thereby raising costs of shipments. *Id.* An EC veterinarian even visited the American feedlots involved in the hormone-free exports, and found Landmark Meats and other producers met the EU requirements. *Id.* Even so, in December, 1990, the American company's certification to export hormone-free beef was revoked. *Id.* Landmark Meats alleged the EC was exceedingly reluctant to establish criteria and explain the steps required to comply with its technical standards, because it did not want American imports to compete with its domestic beef surplus. RUNGE, *supra* note 41, at 80 (citing personal communications with D. Simon).

185. *See supra* note 112 and accompanying text.

186. U.S. Submission, *supra* note 1, ¶ 128-29.

III. CONSUMER PREFERENCE AS A COMPONENT OF CONSUMER PROTECTION

Along with its claim that hormones have not been proven to be safe, the EC has justified its ban on the needs and demands of EC consumers. Scholars note that there is no way to infer regulatory outcomes solely on the basis of scientific data, because most regulations are implicitly or explicitly designed to respond to social, economic, or political contexts.[187] Scientific analysis may provide assistance in achieving a public health goal, but the *choice* of that goal reflects societal values where science provides little, if any, guidance.[188] In other words, science may inform the regulatory process but cannot, by itself, determine the result.[189] According to this school of thought, science does not play a crucial role in determining health goals until *after* such goals have been determined by a society.

This analysis illuminates the current hormone debate. It is generally acknowledged that consumer concerns over the safety of growth hormones encouraged the public campaign in favor of the hormone ban.[190] But how significant a role consumer concerns should play in allowing a country to impose a ban that restricts international trade remains an open question. For the United States, the answer is clear: no ban should be upheld unless it is based on scientific evidence.[191] The European Community, however, places strong emphasis on the preferences and needs of its consumers, arguing that such concerns must play a key role in health regulations. According to the EC, an important aspect of its political system is the voice it allows its citizens in matters of scientific question.[192]

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187. *See, e.g.*, Wirth, *supra* note 38, at 833.

188. *Id.*

189. *Id.* Wirth uses the example of a risk assessment helping set the standard designed to limit the probability that an individual will develop cancer after a lifetime of exposure to a particular chemical to no more than one chance in a million. However, the choice of a one-in-a-million goal, rather than a zero, or one-in-a-thousand goal, is one of public policy.

190. *See supra* text accompanying notes 14-15.

191. U.S. Submission, *supra* note 1, ¶ 5.

192. Yet the notion of "consumer preference" may be resting with very fickle consumers. A British butcher recently lamented on the fluctuating moods of consumers and the fate of British cattle after the BSE scare:

> Two weeks ago, all you ever heard was how you should boycott lamb because they were mistreated on the way to market, and how American beef was bad because it is loaded with growth hormones. . . . Then the papers are full of BSE and suddenly nobody wants to buy British beef. Do you think anybody gives a damn about growth hormones

A. THE FOURTH HURDLE

The idea of a fourth hurdle — the addition of a socio-economic factor to the other requirements needed for drug approval — has emerged as a way of codifying consumer preference and including it in EC law.[193] What is not clear in the present hormone debate, however, is whether factors other than consumer preference are the driving force behind the ban. It is apparent that consumer anxiety was a factor in the initial implementation of the hormone ban. Yet, the United States alleges that additional support for the ban came from the EC's concern that domestic producers would suffer economically if the ban affected only EC producers.[194] In order to protect the domestic beef market, the EC imposed the hormone ban on *all* producers, rather than just those within the EC's borders.

Use of an economic factor in the calculation of health regulations is not permissible under the SPS Agreement.[195] Without scientific substantiation, arguments for a fourth hurdle carry very little weight. It is unclear whether consumer anxiety could ever be an acceptable justification for health regulations under current GATT provisions.[196]

The legitimacy of consumer preferences must also be evaluated in light of their potential implications on international trade. The EC should explore any alternatives to the blanket ban on growth hormones which would assuage consumer fears while avoiding dramatic trade restrictions. For instance, the EC could concentrate its efforts on the safe administration of hormones, implementing stricter controls and testing procedures to ensure that safe use occurs. To accomplish this objective, the EC could work with, rather than against, the American cattle

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now? And if they start incinerating thousands of animals, watch everyone panic about what might be getting into the atmosphere.

Wallace, *supra* note 114.

193. *See supra* notes 134-39 and accompanying text.

194. *See* U.S. Submission, *supra* note 1, ¶ 33.

195. No provision of the SPS Agreement permits any basis other than a scientific one (such as economic considerations) for sanitary and phytosanitary measures. For a classic statement of the principle in American law, see Baldwin v. G.A.F. Seelig, 294 U.S. 511 (1935) ("Neither the power to tax nor the police power may be used by the state of destination with the aim and effect of establishing an economic barrier against competition with the products of another state or the labor of its residents. Restrictions so contrived are an unreasonable clog upon the mobility of commerce."). *Id.* at 527.

196. The GATT provision which would most likely come into play when consumer needs are argued as justification for a regulatory measure is Article XX. For further explanation, see *supra* notes 39-41.

industry. Such a project would not only avoid the current trade impasse, but would also ensure that EC consumers are not eating beef treated with illegal—and potentially very dangerous—hormones.

The EC has also rejected an offer by the United States to label all American meat. This solution would allow consumers the choice whether or not to purchase meat produced with growth hormones. Had the EC truly contemplated consumer needs and preferences when it decided how to deal with growth hormones, this option would satisfy their alleged objectives. Without citing any reasons, however, the EC did not accept the American offer.

If the EC is allowed to justify the hormone ban on consumer preference alone, without the requirement of hard scientific evidence, it could employ the "fourth hurdle" concept whenever it chooses to assist its own producers or give in to the demands of a small group of interested citizens. If such actions are permitted by GATT, the consequences could reach far beyond the borders of the European Community. Numerous nations could use similarly vague "consumer preference" arguments to justify regulations that lack scientific merit. Such justifications would render the SPS Agreement without meaning.

B. UNINTENDED CONSEQUENCES OF THE HORMONE BAN

An additional argument against the hormone ban falls completely outside the purview of the SPS Agreement. Namely, the alleged objective of the hormone ban is undermined by the dangers caused by unmonitored illegal hormone use within the European Community. The EC claims that its ban on growth hormones prevents such hormones from reaching the citizens of the Community. Many recent reports, however, have noted the presence of a growing black market in illegal hormones throughout the EC.[197] Therefore hormones are still being used throughout Europe, but they are not subject to regulation because they are purchased and administered illegally.[198] Indeed, due to the European government's frequent failure to detect hormones in meat, European consumers do not actually know if the meat they are consuming is truly hormone free.

The EC did not adequately address such problems in its submission to the Panel. It admitted that the 1995 EC Scientific

197. *See supra* notes 76-78 and accompanying text.
198. *See supra* notes 76-78 and accompanying text.

Conference reported evidence that illegal hormones were used in cattle production worldwide.[199] The EC recognized that the use of such illegal hormones, which often are found in hormone "cocktails,"[200] is practiced because they achieve higher growth rates than those obtained through individual hormones.[201] The EC acknowledged the significant danger such cocktails pose, because they often include universally banned substances.[202] It did not, however, admit to the presence of such cocktails in its own market. It simply stated that "[f]rom the information the EC possesses it would appear that the use of cocktails *in the US* is not subject to strict control, since they seem to be freely available on sale in the market."[203] The EC failed to mention that, despite the fact it has made all use of growth hormones illegal in its own countries, it does not have adequate control over the introduction of illegal hormones into its own beef production.

The EC cannot ignore the reality that hormones are used by EC producers, perhaps in larger numbers than in American beef. Since growth hormones have been detected in Community beef despite the ban, it appears the ban on imported beef treated with growth hormones is not the most effective way to prevent hormone-treated beef from reaching EC consumers. Once the EC found hormone cocktails were dangerous, it concluded that the "existing international rules do not deal adequately with this potential source of risk."[204] If this is an accurate statement of the EC's position, the EC must acknowledge that the current ban also fails to adequately deal with the presence of illegal and potentially dangerous hormones within its own borders.

CONCLUSION

The Panel decision regarding the ban on growth hormones has great implications for future health-related regulations promulgated under the guise of sanitary and phytosanitary measures. The SPS Agreement's emphasis on scientific evidence suggests that such evidence must be the sole criterion for determining the safety of health regulations. Although the idea of a precautionary principle has a role when determining the legality of health regulations, it must be implemented in a way

199. EC Submission, *supra* note 2, ¶ 88.
200. *See supra* note 127 and accompanying text.
201. EC Submission, *supra* note 2, ¶ 88.
202. *Id.*
203. *Id.* ¶ 91 (emphasis added). The EC did not identify the sources of its information.
204. *Id.* ¶ 92.

that does not restrict the trade of products deemed "safe" by approved scientific standards. Similarly, consumer preference may be a factor, but it must not dictate health regulations if such regulations lack scientific support.

The only way to ensure that restrictions on trade are not disguised as health regulations is to subject such regulations to vigorous scientific analysis. If a Member wishes to use a precautionary approach, it must do so in a manner that does not unduly restrict international trade in products that pose no threat to human health. Additionally, the EC must focus its health risk determinations on actual products, rather than on the processes used to create products. In the future, whenever any Member seeks to implement a health regulation, it must do so consistently, on the basis of scientific evidence, and without reference to bald consumer anxiety.