Vanderbilt Journal of Transnational Law

Volume 32
Issue 2 *March 1999*

Article 5

1999

Where's the Beef? Mad Cows and the Blight of the SPS Agreement

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I. INTRODUCTION

The policies of a nation are seldom as susceptible to criticism from other nations as those policies that attempt to regulate international commerce. Indeed, even the internal regulations of one country can often have pervasive effects well beyond its own borders. In the wake of the "Mad Cow" scare, the European Union (EU) proposed a ban on any use of animal remains believed to have a specific risk of harboring Bovine Spongiform Encephalopathy (hereinafter BSE),[1] which will become effective

1. Specifically, the head and spine of cattle, sheep, and goats over twelve months old and the spleen of all sheep and goats. *See EU BSE Moves Threat to $100M US Tallow Exports*, MARKETLETTER, Aug. 18, 1997, *available in* 1997 WL 11871062.

January 1, 2000.[2] This ban is justified by the EU as prudent in response to public health needs.[3]

The ban is absolute and extends to foreign imports which contain any materials at high risk of carrying BSE.[4] One such use of the animal remains is the production of tallow, or animal fat, by boiling whole animal carcasses.[5] This is a common practice in U.S. slaughterhouses which claim the ban is unfair because it forces them to change their production methods,[6] particularly since there is no conclusive evidence that BSE exists in the domestic U.S. cattle market from which these producers draw their supplies.[7] Tallow derivatives are used in an estimated eighty percent of pharmaceuticals and in cosmetics and lubricants.[8] Additionally, the ban reaches cattle byproducts such as gelatin and gelatin-based cosmetics.[9] Collectively, this ban potentially affects up to $4.5 billion in U.S. pharmaceuticals exports which use tallow derivatives as key ingredients.[10]

The United States has threatened to submit a complaint to the World Trade Organization (WTO) if it is not exempted from the ban.[11] The ban is questionable under the GATT Sanitary and Phytosanitary Standards Agreement from the Uruguay Rounds

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2. The ban, set for January 1, 1999, was recently delayed one year by EU ministers amid concerns of the impact on the pharmaceuticals and cosmetics trade. *See EU Delays Animal Parts Ban*, AP Online, Dec. 15, 1998, *available in* 1998 WL 23511491. In fact, the ban has been delayed several times to date amid similar concerns and pressures. *See generally* Curt Anderson, *Stick to Scientific Evidence in Trade Disputes, Glickman Urges Europe*, COM. APPEAL, Jan. 8, 1998, at B7, *available in* 1998 WL 3659179.

3. Recent studies have shown a link between BSE and brain disorders in humans. *See, e.g., Coping with BSE*, ECONOMIST, Mar. 14, 1998, at 15.

4. *See* Neil Buckley, *Talks on BSE Threat to Drugs*, FIN. TIMES (London), Sept. 9, 1997, at 8, *available in* 1997 WL 11055529. These high risk materials are labeled "specified risk materials" (hereinafter SRMs). *See EC Compromise on Imports of US Made Gelatin*, Chemical Business NewsBase, Dec. 23, 1997, *available in* 1997 WL 16040885. SRMs are thought to possess contaminants which may cause BSE which has been linked to Creutzfield-Jakob disease—the human form of Mad Cow disease. *See id.*

5. *See* Buckley, *Talks on BSE*, *supra* note 4, at 8.

6. *See* Neil Buckley, *EU Urged to Exempt Drugs from BSE Rules*, FIN. TIMES (London), Sept. 9, 1997, at 8, *available in* 1997 WL 11052281. It is likely the EU would exempt tallow "prepared" according to EU standards and shown to be similarly "BSE free," but the current U.S. practices are unacceptable to the EU and the new ones are prohibitively expensive for U.S. producers to implement. *Id.*

7. *See* Anderson, *supra* note 2, at B7.

8. *See* Jonathan Stearns, *EU to Reconsider Exemptions for U.S., Partners on Meat Rules*, WALL ST. J. EUR., Oct. 14, 1997, *available in* 1997 WL-WSJE 12213506.

9. *See* Anderson, *supra* note 2, at B7.

10. *See E.U. Scientists Meet to Consider U.S. Tallow Ban Appeal*, Dow Jones Int'l News, Sept. 8, 1997, *available in* WESTLAW, DJINSPLUS Database.

11. *See id.*

(SPS Agreement).[12] The SPS Agreement allows a WTO member to choose the level of regulatory protectionism it wants to employ to preserve "public health" and to protect the environment from "risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs."[13] However, the Agreement established a framework within which the decision is to be made. This framework specifically outlines the need for "scientific" considerations to be made in the "risk assessment" phase of the regulatory process when a measure, such as the current EU proposal, is on the table.[14] These considerations are primarily to ensure that bona fide health regulations are passed, not "protectionist" devices under the pretext of "public health."[15] But the statute has been plagued by several interpretational difficulties by the Member States.[16]

The most glaring examples of these interpretational problems have arisen in the hormone dispute[17] over a ban by the EC (now the EU) of the administration of certain hormones (excepting those for medical purposes) to cattle, and also the marketing and slaughtering of cattle given the hormones, or selling or processing the meat or meat products derived from such cattle.[18] The United States argued the hormones were "scientifically" proven safe if used correctly and brought its complaint to the WTO for resolution.[19] Both sides were split (among other things) as to: (1) the meaning of "scientific justification," (2) what "based on" international standards means when choosing a level of protection, (3) the role of the Precautionary Principle, and (4) the

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12. *See* Michele D. Carter, *Selling Science Under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy*, 6 MINN. J. GLOBAL TRADE 625, 625-26 (1997).

13. *Id.* at 631-33.

14. *Id.* at 633.

15. *Id.* at 633-34.

16. *See* WTO Secretariat, *EC Measures Concerning Meat and Meat Products (Hormones)*, Complaint by Canada, Report of the Panel, WT/DS48/R/CAN Parts III-IV (Aug. 18, 1997), *available at* <http://www.wto.org/wto/ddf/ep/public.htm> [hereinafter Canada Panel Report].

17. This dispute arguably was the impetus for the adoption of the SPS Agreement. The Agreement was viewed as a mechanism for resolving such international trade disputes and evading damaging trade wars that often adversely affect the world economy. *See infra* notes 37-43 and accompanying text. *See also* <http://www.wto.org/wto/goods/spsund.htm>.

18. *See* John R. Schmertz and Mike Meier, *WTO Panel Decision Holds that European Communities' Ban on Meat from Animals Treated with Growth Hormones Violated International Trading Rules*, 3 INT'L. L. UPDATE, 120, 121 (1997), *available in* WESTLAW, TP-ALL Database.

19. *See id.* at 121.

precise contours of a "risk assessment" in the context of the SPS Agreement.[20]

For better or for worse, the recent resolution (and appellate decision) of the Beef Hormones Dispute by WTO dispute resolution panels shed some much needed light on a statutory text wrought with ambiguities. The decisions are likely to greatly influence the outcome of the SRM dispute should the United States formally go before the WTO. Since this is the first case interpreting the SPS Agreement, the decision is the first step in the development of what will inevitably become the "common law" of science in the realm of world trade disputes.[21]

Unfortunately, the decisions are likely more harmful than beneficial to the necessary goal of harmonizing the needs of international trade and public health and welfare. First, the decision announced a limited applicability of the Precautionary Principle under the Agreement even though the Precautionary Principle is not yet an accepted norm of international law.[22] The dispute resolution panel also emphasized that considerations other than empirical science may be accounted for during risk assessment.[23] The natural inference from this holding is that social, political, and economic values outside of the realm of science have a role under the Agreement.[24]

These holdings seem to undermine the true purpose of the statute—making science a more prevalent factor in international trade regulation for public health.[25] As a result, as long as the EU conforms to the Agreement's demands for risk assessment—demands which now seemingly permit social influences as part of the equation—the proposed ban may be acceptable regardless of any political or social motivations behind it.

While social influences and public anxiety are, by their nature, a necessary element of any public policy consideration, more neutral influences such as science should be more heavily weighted where the ramifications of the regulation extend beyond the borders of that particular country. This is not only to protect the needs of the world economy in efficient international trade,

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20. *See generally* WTO Secretariat, *EC Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997), *available at* <http://www.wto.org/wto/ddf/ep/public.htm> [hereinafter U.S. Panel Report].

21. *See* Jeffrey Atik, *Science and International Regulatory Convergence*, 17 NW. J. INT'L L. & BUS. 736, 755 (1997) (discussing the potential impact of panel decisions on the regulatory decisions of the WTO Members).

22. *See infra* notes 92-93 and accompanying text.

23. *See infra* notes 122-24 and accompanying text.

24. Indeed, it is likely that such considerations may underlie the holdings of the panels themselves.

25. *See* Atik, *supra* note 21, at 740.

but also to protect the interests of those foreign, yet similarly affected, peoples to whom the state owes no political accountability. Thus, a country should be limited in the range of discretion it has to choose the "level of protection" it deems necessary, as under the SPS agreement, in order to protect public health by the regulation of drugs and foodstuffs. Placing restrictions on the global market is not the proper means for regaining "consumer confidence" (a stated goal of the EC in proposing the ban[26]) in what is largely an intrastate issue.

Accordingly, and opposed to the view of the appellate panel, the WTO should demand adherence to acceptable international regulatory standards, thereby giving every nation a voice in the approval of the ban. If a Member is unhappy with the international standards it can lobby the other Members to conform their views to its own, thereby utilizing the inherent structural protections of the WTO. Furthermore, Members will find it in their best interests to treat other Members fairly, and they would not likely want to establish unfavorable precedents that could ultimately work against them.

Demanding adherence to the international standards will also help ensure uniformity[27] by inhibiting the opportunity for a country to adversely effect international trade, whether consciously or unconsciously, by establishing trade regulations which, in light of the international standards, are neither necessary nor proper in relation to the actual threat posed.

Finally, the Agreement's strong emphasis on eliminating "protectionism" tends to overshadow the fact that there are other evils, with potentially more egregious effects, that may arise from giving countries too much discretion in risk management. As with the proposed tallow ban, a Member State's regulation, even with presumably proper[28] motives, can harmfully effect international trade while still adhering to the form of the current SPS Agreement.[29]

This Note will first outline the SPS Agreement itself—specifically, Part II attempts to present the relevant articles in a manner providing the necessary background for understanding the WTO dispute panel and Appellate Body decisions. Next, Part

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26. Tara Parker-Pope & Julie Wolf, *EU Agrees to Ban Exports of British Beef*, WALL ST. J., Mar. 26, 1996, at A14 (quoting EU Agriculture Commissioner Franz Fischler on the need for the ban to bolster confidence in the beef market). While this was before the proposal to ban imports, it clearly shows the initial impetus for action.

27. Uniformity is a primary goal of modern trade accords.

28. "Proper" means that there are no protectionist motives.

29. As the Agreement is apparently understood by the WTO Appellate Body for the Hormone Dispute.

III discuss and critique, the dispute panel and Appellate Body decisions, specifically, noting the shortcomings of these decisions in the context of the SPS Agreement and its utility as a precedent of international dispute resolution in the area of international regulation of drugs and feedstuffs. Next, I will addresses the likely effect of these decisions upon a possible WTO resolution of the SRM dispute (should it proceed that far). Finally, Part V offers conclusions and recommendations to help guide future decisions to be more pragmatic and to better promote the goals of the SPS Agreement.

II. THE SPS AGREEMENT

The Sanitary and Phytosanitary Standards (SPS) Agreement of the Uruguay Round augments the content of GATT Article XX(b) and (g) relating to "measures affecting, plant, animal, and human life or health" and the environment.[30] Prior to the SPS Agreement, GATT scrutiny of discriminatory regulations under the guise of public health was far less rigorous.[31] The SPS Agreement was intended to make "science" a more prevalent factor in the affected areas because of the potential for "protectionist" regulatory devices under the guise of "public health" or "safety".[32] Indeed, as one commentator has noted, "the presence and integrity of scientific support is a principal touchstone for determining the legitimacy of many national regulatory efforts aimed at assuring . . . public health."[33] Additionally, the Agreement was intended to aid developing countries which may have economic or political difficulties in complying with SPS measures of other more developed nations.[34]

The preamble sets forth several goals of the Agreement. Specifically, the Agreement encourages the adoption of those

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30. Carter, *supra* note 12, at 630 (citing General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-3, 55 U.N.T.S. 188).

31. *See* Julie Cromer, *Sanitary and Phytosanitary Measures: What They Could Mean for Health and Safety Regulations Under GATT*, 36 HARV. INT'L L.J. 557, 558 (1995).

32. *See* Carter, *supra* note 12, at 630-31. More specifically, the agreement prohibits measures "which would constitute a disguised restriction on international trade." GATT Secretariat, *Agreement on the Application of Sanitary and Phytosanitary Measures*, MTN/FA II-A1A-4, art. 2.3 (Dec. 15, 1993), *available at* <http://www.wto.org/wto/goods/spsagr.htm> [hereinafter SPS Agreement].

33. David Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT'L L.J. 817, 818 (1994).

34. *See* SPS Agreement, *supra* note 32, at pmbl.

regulations necessary to protect human health.[35] Furthermore, the Agreement promotes harmonization of sanitary and phytosanitary measures between Members based upon internationally accepted norms, but qualifies this by noting that Members should maintain discretion to set their own appropriate levels of SPS protection.[36] Finally, the Agreement seeks to eliminate SPS measures which would result in a "disguised restriction on international trade."[37]

Article 2 sets out the basic rights and obligations of the Members.[38] Article 2 gives Members the ability "to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health" that are likewise consistent with the rest of the SPS Agreement.[39] A Member's SPS measures must be uniformly applied and may not arbitrarily discriminate between Members where similar conditions exist.[40] In other words, protectionism is not a permissible justification for an SPS measure.[41] The Agreement mandates that an SPS measure is to be "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."[42] Additionally, these measures may not be applied in a manner "which would constitute a disguised restriction on international trade."[43]

The SPS Agreement also gives Members a powerful discretionary device in the "risk management" or public policy

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35. *Id.* However, the Agreement does little to define what is necessary to protect human health in this context. This will become relevant in the ultimate task of risk management. The Agreement avoids adopting a particular cost, benefit or risk management methodology. For example, how much weight should be accorded economic injury to other Members where a measure's benefit is slim, but arguably necessary to protect a human life? In other words, is it appropriate to regulate in a discriminatory manner if only one life in a million will be protected by the regulation? One in ten million? These unresolved issues leave considerable discretion with the Members in setting their own levels of SPS protection.

36. *Id.* The Agreement specifically alludes to recommendations of relevant international organizations for guidance in this task, including the Codex Alimentarius Commission, the International Office of Epizootics, and the "international and regional organizations operating within the framework of the International Plant Protection Convention." *Id.*

37. *Id.*

38. *See generally id.* at art. 2.

39. *Id.* at art. 2.1. The Agreement specifically defines an SPS measure as one applied "to protect animal or plant life or health . . . from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms." *Id.* at Annex A, para. 1(a).

40. *See id.* at art 2.3.

41. *See id.*

42. *Id.* at art. 2.2.

43. *Id.* at art. 2.3.

application of the Agreement.[44] A Member has a duty under Article 3 to harmonize its SPS measures with international recommendations or guidelines.[45] While a Member is encouraged to base its measures on internationally accepted standards,[46] a Member may nonetheless impose measures more stringent than those applied by current international standards where such measures have "scientific justification."[47] The Agreement specifically defines "scientific justification" as existing 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]."[48] Those measures which do conform to international guidelines are presumptively valid.[49]

Furthermore, Members are permitted, during "risk assessment," to choose their own "acceptable level of risk" when adopting health related measures.[50] More specifically, that level of risk should be "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."[51]

However, each member must additionally consider "the objective of minimizing negative trade effects."[52] To this end, the Agreement states that "Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."[53] "[A]

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44. While the term "risk management" is not express in the Agreement, its import is nonetheless assumed for any rational application of an accord which regulates public policy. *See* Wirth, *supra* note 33, at 837.

45. *See* SPS Agreement, *supra* note 32, at art. 3.1. The extent of this duty and what it means to "base" an SPS measure upon international norms is currently a subject of intense debate. *See* discussion *infra* Part III.E.

46. *See* SPS Agreement, *supra* note 32, at art. 3.1.

47. *Id.* at art. 3.3. This measure seems to controvert the goal of harmonization.

48. *Id.* at art 3.3 n.2.

49. *See id.* at art. 3.2.

50. *See id.* at Annex A, para. 5. But the SPS Agreement asserts that Member assessments should "*tak[e] into account* risk assessment techniques developed by the relevant international organizations." *Id.* at art. 5.1 (emphasis added).

51. *Id.* at Annex A, para. 5.

52. *Id.* at art. 5.4. In doing so Members are required to assess relevant economic effects of the entry or establishment of a disease, its control costs and "the relative cost-effectiveness of alternative approaches" to minimizing the risks of the entry or establishment of such diseases. *Id.* at art. 5.3.

53. *Id.* at art. 5.6.

measure is not more trade restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."[54] Additionally, where scientific evidence is unclear, "a [m]ember may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information."[55] However, in such circumstances the Members must try to gather additional scientific evidence to perform a more accurate risk assessment.[56] Additionally, the Member must review the SPS measure within a reasonable period to assure its effectiveness and continued necessity.[57]

Finally, a Member must base its SPS measure upon a risk assessment under Article 5.[58] Such assessment must consider the risks to human or animal life or health and take into account relevant risk assessment techniques promulgated by the appropriate international organizations.[59] The risk assessment must also take into account all relevant scientific evidence—including relevant processes and production methods, and sampling and testing methods.[60] Additionally, Members must consider "the exceptional character of human health risks to which people voluntarily expose themselves."[61]

While a step in the right direction, the Agreement is ambiguous on its face about several pertinent issues related to the effective enforcement and interpretation of the Agreement. For instance, what is a "substantially" less trade restrictive measure? What does it mean to "base" a measure on international standards? Is the Precautionary Principle a "relevant international standard" upon which to base a decision as to the "acceptable level of risk" of a particular member? Should an economic cost/benefit paradigm, as to the probability and magnitude of the threat posed, be considered in the risk assessment? Does risk management in the context of the Agreement require adherence to the findings of the risk assessment? As is usually the case in statutory interpretation, many such inevitable ambiguities will likely be resolved by the

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54. *Id.* at art 5.6 n.3.
55. *Id.* at art. 5.7. This provision seemingly adopts the Precautionary Principle.
56. *See id.*
57. *See id.*
58. *See id.* at art. 5.1.
59. *See id.*
60. *See id.* at art. 5.2.
61. *Id.* at art. 5.5.

judiciary, or, as here, by the eventual body of WTO dispute resolution opinions.

III. THE BEGINNINGS OF THE "COMMON LAW": THE RESOLUTION OF THE HORMONES DISPUTE

The decision of the dispute resolution panel of the WTO regarding the Hormones Dispute and the subsequent appellate decision, while unsatisfying in several regards,[62] offer the first explanation of some of the troubling ambiguities in the SPS Agreement and likely set precedent for future decisions.

A. *The Role of the Precautionary Principle*

The use of the Precautionary Principle[63] in the regulatory process is gaining acceptance on the international level where countries face risk assessment decisions in the face of substantial scientific uncertainties or where public health is potentially implicated.[64] The Precautionary Principle "counsels governmental authorities to err on the side of environmental [or public health] protection in formulating public policy in contexts characterized by conditions of scientific uncertainty."[65] The EU's precautionary approach during the Hormone Dispute specifically promoted "the attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies."[66] Those who support the Precautionary Principle tend to endorse precautionary measures in the face of any risk to the environment or public health without further engaging in an evaluation of the seriousness of the actual risk.[67] Indeed, they cite the difficulty of establishing scientific "certainty" on a

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62. *See* discussion *infra* Part V.

63. Although this is called the Precautionary Principle, several authors maintain that it should be the Precautionary "Approach" because there is not a specific, uniform formation of the approach to merit labeling as a "principle" per se. *See, e.g.,* Carter, *supra* note 12, at 643-44; Wirth, *supra* note 33, at 838.

64. *See* Wirth, *supra* note 33, at 838.

65. *Id.*

66. Carter, *supra* note 12, at 642 n.122 (quoting *EC Measures Concerning Meat and Meat Products (Hormones),* Submission of the European Community to the Panel on European Community 124 (Sept. 20, 1996)).

67. *See, e.g., id.* at 640-41 (stating that the EC's ban is based more on precaution than on scientific evidence).

particular biological health threat as justification for erring on the side of caution.[68]

Furthermore, this approach is seemingly endorsed by the very terms of the SPS Agreement which permits Members to choose their own level of sanitary or phytosanitary measures.[69] This right is "qualified" by the need for a "scientific justification,"[70] but the Agreement, in a footnote, defines "scientific justification" as being based on "an examination and evaluation of available scientific information."[71] This definition seemingly endorses a precautionary approach as it does not require "conclusive" scientific justification for a particular measure, but only a risk assessment based upon current science. Indeed, even what "science" means in the context of the Agreement is a subject of debate. At least one author argues that "science is not fixed," but rather is subject to opinion potentially as varying as the geographic and cultural centers from which the opinion could emanate.[72] Thus, because the Agreement does not require a threshold of scientific certainty of any potential risk, but rather only consideration of science, the Agreement seems to support the adoption of a precautionary measure in the face of any amount of risk.

Those who oppose the Precautionary Principle tend to focus on the adverse implications of overly cautious regulation in the absence of conclusive scientific evidence of the actual risk.[73] These countries generally tend to endorse a "wait and see" philosophy which endorses "scientific certainty as a precondition to adopting policy responses."[74] Furthermore, these countries specifically reject the influence of "consumer anxieties rather than any actual adverse effects on human health" when conducting risk assessments of a particular health threat.[75] Thus, the adoption or acceptance of the Precautionary Principle, in the context of the SPS Agreement, would allow for potentially more trade-restrictive regulations than are necessary for the

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68. *See* Wirth, *supra* note 33, at 837-38 (stating that the precautionary principle rejects the "wait and see" approach that emphasizes "a high degree of scientific certainty as a precondition to adopting policy response").

69. *See* SPS Agreement, *supra* note 32, at art. 3.3 (stating that Members can choose higher measures than those recommended by relevant international standards "if there is a scientific justification").

70. *Id.*

71. *Id.* at art. 3.3 n.2.

72. *See* Atik, *supra* note 21, at 749.

73. *See* Carter, *supra* note 12, at 638-39 (stating that restriction is based on "consumer anxieties" rather than science and that "the ban is a disguised restriction on international trade").

74. Wirth, *supra* note 33, at 838.

75. Carter, *supra* note 12, at 639.

protection of human health.[76] This would defeat the stated goal of the SPS Agreement of minimizing the negative regulatory effects on international trade.[77]

The goals of protecting public health and minimizing the adverse impact of sanitary and phytosanitary regulations on international trade, within the context of the SPS Agreement, are frequently contradictory in nature, and present a formidable obstacle in the path of any attempt at harmonization.

In its resolution of the Hormones Dispute, the WTO dispute resolution panel specifically held that the Precautionary Principle "would not override the explicit wording of Articles 5.1 and 5.2 [of the SPS Agreement]," but that the principle was, at the same time, "incorporated and given a specific meaning in Article 5.7."[78]

Article 5.1 maintains that "[m]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human . . . health, taking into account risk assessment techniques developed by the relevant international organizations."[79] Article 5.2 commands that "[i]n the assessment of risks, Members shall take into account available scientific evidence; relevant processes . . . [and] relevant inspection, sampling and testing methods."[80] Finally, Article 5.7 suggests that "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."[81] Article 5.7 goes on to encourage Members to actively seek additional measures for a more "objective assessment of risk."[82]

Thus, a finding by the Panel that a Member did not base its sanitary or phytosanitary measure on a "risk assessment," in the context of the SPS Agreement, cannot be overridden by the fact that the member was adopting a Precautionary Approach in the

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76. *See, e.g., id.* (citing *EC Measures Concerning Meat and Meat Products (Hormones)*, Submission by the United States 122 (Aug.28, 1996)).

77. *See* SPS Agreement, *supra* note 32, at pmbl. (stating that measures should not be "a disguised restriction on international trade").

78. WTO Secretariat, *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body WT/DS26/AB/R, WT/DS48/AB/R para. 120 (Jan. 16, 1998) (discussing the findings of the initial dispute panel) [hereinafter Appellate Report].

79. SPS Agreement, *supra* note 32, at art. 5.1.

80. *Id.* at art. 5.2.

81. *Id.* at art. 5.7.

82. *Id.* Presumably, this indicates that a Member may not be able to sustain an overly cautionary measure once more scientific evidence of the actual risk is available.

application of the measure.[83] The basis of the Panel's holding is that "the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in" the Agreement.[84] Thus, to the extent a Member has an obligation to perform a "risk assessment," a Member cannot bypass this obligation in reliance on its own precautionary regulatory policy.

The EU submitted that the Precautionary Principle is, "a general customary rule of international law" or "a general principle of law" in accordance with the provisions of Article 5.2 of the Agreement.[85] In relation to Articles 5.1 and 5.2 of the Agreement, the EU maintained that applying the Precautionary Principle means that "it is not necessary for all scientists around the world to agree on the "possibility and magnitude" of the risk, nor for all or most of the WTO Members to perceive and evaluate the risk in the same way."[86] The EU argued that the Agreement incorporates such an approach because it does not "prescribe a particular type of risk assessment and [does] not prevent Members from being cautious in their risk assessment exercise."[87]

On the contrary, the United States does not consider the Precautionary Principle to be "customary international law" and suggested that it is indeed more of an "approach" than a "principle."[88] However, the United States did recognize that the Precautionary Approach is an "emerging principle of law" which may someday be a "general principle[ ] of law recognized by civilized nations."[89]

Unfortunately, the Dispute Resolution Panel (and the Appellate Body)[90] deftly was able to avoid making a definitive finding on the issue by the mere technicality, as noted above, that the EU failed to perform a "risk assessment" as obligated under

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83. *See* Appellate Report, *supra* note 78, at para. 120 (citing U.S. Panel Report, *supra* note 20, at para. 8.158).

84. *Id.* at para. 124.

85. *Id.* at para. 121 (citing EC's appellant's submission, para. 91).

86. *Id.* (citing EC's appellant's submission, para. 88).

87. *Id.* (citing EC's appellant's submission, para. 94).

88. *See id.* at para. 122.

89. *Id.* (citing United States" appellee's submission, para. 92). A cynical view of this pundit would suggest, however, that this was merely a strategic "out" the U.S. employed to enable it to credibly adopt the counter view should the tables turn in a future dispute.

90. The Appellate Body was a panel formed by the WTO to hear the appeals from the Hormone Dispute resolution. *See* SPS Agreement, *supra* note 32, at 11 (providing that disputes shall be settled in accordance with the procedures outlined in Articles XXII and XXIII of the General Agreement on Tariffs and Trade (1994) and applied by the Dispute Settlement Understanding).

the Agreement in Articles 5.1 and 5.2.[91] This sleight of hand conveniently left the door open for a Member to once again defend an SPS measure on the ground of the Precautionary Principle.

However, in what is arguably dicta, and in a subsequent footnote, the Appellate Body seemed to indicate its view that the Precautionary Principle was not yet an accepted principle of "general" or "customary international law."[92] Indeed, the Appellate Body specifically noted that the "Precautionary Principle, at least outside the field of international environmental law, still awaits authoritative formulation."[93]

Furthermore, the Panel likewise did not outline the precise role of the Precautionary Principle in Article 5.7 because the EU did not seek to defend the Hormones Ban under that provision.[94] However, the Appellate Body, in a finding that will undoubtedly confuse the issue even more, confirmed that the Precautionary Principle nonetheless "finds reflection in Article 5.7," and that there was "no need to assume that Article 5.7 exhausts the relevance of a precautionary principle."[95]

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91. *See* Appellate Report, *supra* note 78, at paras. 123, 250.

92. *See* Appellate Report, *supra* note 78, at para. 123 & n.92 (citing authors who do not believe that the Precautionary Principle has yet reached the status of a principle of international law).

93. *Id.* at para. 123. The Appellate body specifically noted that the "status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges." *Id.* at para. 123 n.92. The Appellate Report suggests J. Cameron, *The Status of the Precautionary Principle in International Law, in* INTERPRETING THE PRECAUTIONARY PRINCIPLE (J. Cameron and T. O"Riordan, eds. 1994); 1 P. SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW (1985) for a more intensive look at the status of the Precautionary Principle in international law and the law generally. *See id.* The Appellate Report asserts that these books suggest that while the Precautionary Principle is still evolving, there is sufficient state practice to support the view that it is a customary principle of international national law. *See id.* In contrast the Appellate Report cites P. BIRNIE & A. BOYLE, INTERNATIONAL LAW AND THE ENVIRONMENT (1992); L. Gundling, *The Status in International Law of the Precautionary Principle*, 1,2,3 INT"L J. OF ESTUARINE AND COASTAL L. 25 (1990) for arguments that due to a great variety of interpretations of the Principle, it has not yet attained the status of a general principle of international law. *See id.* Additionally, the Appellate Body noted that the International Court of Justice has not yet recognized the precautionary principle as a new norm or standard in the field of environmental protection. *See id.* at para. 123 n.93 (citing Case Concerning the Gabcikovo-Nagymaros Project (Hung. v. Slovk.), 1997 I.C.J. 111-14, (Sept. 25)).

94. *See id.* at para. 120 (citing U.S. Panel Report, *supra* note 20, at para. 8.157).

95. *See id.* at para. 124. Furthermore, the Appellate Body recognized that the Precautionary Principle is reflected in the preamble and in Article 3.3, which explicitly permit Members to establish their own appropriate level of sanitary protection, which may be higher than implied existing international standards or guidelines imply. *See id.*

Additionally, specifically addressing the obligations of Articles 5.1 and 5.2, the Appellate Body held that a panel charged with determining whether "sufficient scientific justification" exists to set a level of sanitary protection more stringent than accepted international norms should "bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[96] This statement impliedly concedes that the Precautionary Principle may play a viable role in the "risk management" task associated with the implementation of an SPS measure.[97] However, it remains unclear what formulation of the Precautionary Principle the Appellate Body is implicitly recognizing, because the Appellate Body simultaneously maintains that there is no authoritative formulation of the Precautionary Principle as a general rule of law.[98] This inconsistency will doubtlessly and needlessly confuse a Member trying to conform to its obligations under the Agreement.

B. *Risk Assessment Under the SPS Agreement*

The SPS Agreement specifically defines "risk assessment":

> 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 [SPS] 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, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.[99]

The Panel interpreted the above definition as a two-step process that "should (i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat or meat products . . . . and (ii) if any such adverse effects exist, evaluate the potential or probability of occurrence of these effects."[100] Though specifically addressing the Hormones Controversy, the conceptual framework would clearly be applicable to any case where a substance and its specified use are called into question in the application of an SPS measure.

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96. *Id.*

97. This assumes that a "risk assessment," as defined by the Agreement, was undertaken prior to the policy implementation. *See* SPS Agreement, *supra* note 32, at Annex A, para. 4 for the definition of "risk assessment."

98. *See* Carter, *supra* note 12, at 641.

99. SPS Agreement, *supra* note 32, at Annex A, para. 4.

100. U.S. Panel Report, *supra* note 20, at para. 8.44 (emphasis omitted).

While not explicitly rejecting the Panel's two pronged analysis, the Appellate Body did object to the Panel's use of "probability" as an alternative term for "potential."[101] The Appellate Body held that "[t]he ordinary meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability" . . . [which] implies a higher degree or a threshold of potentiality or possibility."[102] The Appellate Body objected to the introduction of a "quantitative dimension to the notion of risk."[103]

In the application of its "probability" standard, the Panel made a subjective decision that a risk of harm to human health of approximately one in a million is not a "scientifically identified risk."[104] Thus, the Panel implicitly held that a certain magnitude or threshold level of risk must be demonstrated in a risk assessment for an SPS measure based thereon to be otherwise consistent with Article 5.1 of the Agreement.[105]

Quite to the contrary, the Appellate Body specifically rejected the imposition of a quantitative assessment of risk into the terms of the SPS Agreement.[106] Rather, a panel will be "authorized only to determine whether a given SPS measure is "based on" a risk assessment."[107]

Additionally, the Appellate Body discussed the scope of what was permissible to consider while carrying out a risk assessment. It considered relevant the fact that the listing in Article 5.2 begins with evaluation of "available scientific evidence": "[A] risk assessment . . . is a scientific process aimed at establishing the scientific basis for the sanitary measures a Member intends to take."[108] However, it did not agree with the Panel as to the limiting effect of this characterization—that this necessarily excluded from the scope of a risk assessment matters not capable of quantitative analysis by empirical methods commonly used in the physical sciences.[109] Instead, the Appellate Body argued that several Article 5.2 factors, such as "relevant processes and

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101. *See* Appellate Report, *supra* note 78, at para. 184. Observe that the term "probability" was not included in the Agreement's definition of "risk assessment."

102. *Id.*

103. *Id.*

104. *See id.* at para. 185 (citing U.S. Panel Report, *supra* note 20, at Annex, para. 819).

105. *See id.* at para. 186.

106. *See id.*

107. *Id.* See discussion of "based on" in the context of the Agreement, *infra* Parts III.D-E.

108. Appellate Report *supra* note 78, at para.187 (citing with approval, U.S. Panel Report, *supra* note 20, at para. 8.107).

109. *See id.*

production methods" and "relevant inspection, sampling and testing methods" by their very nature were not susceptible of investigation according to common laboratory methods associated with the physical sciences.[110] Furthermore, they held that the list of factors under Article 5.2 was not "intended to be a closed list."[111] In other words, what matters is not only risk ascertainable by common laboratory methods, but risk tangible in the "real world" and its "actual potential for adverse effects on human health in the real world where people live and work and die."[112]

Here, as with the Precautionary Principle, the Appellate Body unfortunately restrained itself from creating any enforceable boundary to the list of appropriate factors for consideration in a risk assessment under Article 5.2, instead only further befuddling the issue with its broad notions of "real world" effect. Thus, the role of these "unquantifiable real world effects"—most notably "consumer anxiety"—in the context of the Agreement remains uncertain.

C. *Social Policy and Risk Management Under the SPS Agreement*

Article 2.2 of the SPS Agreement sets forth the basic risk management obligation: "Members shall ensure that any sanitary or phytosanitary measure 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, except as provided in [Article 5.7]."[113] The Agreement defines risk assessment as "the evaluation of the potential for adverse effects on human or animal health . . . ."[114]

The Panel held that Article 2.2 informs Article 5.1[115] which obliges Members to "ensure that their [SPS] measures are based on an assessment . . . of the risks to human, animal or plant life or health."[116] Furthermore, the Panel found that "risk management" and "risk assessment" were thereby two distinct processes in the context of the Agreement.[117] "Risk Management" was a "policy exercise involving social value judgments made by political bodies," while a "risk assessment" was a "scientific examination of data and factual studies."[118]

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110. *Id.*
111. *Id.*
112. *Id.*
113. SPS Agreement, *supra* note 32, at art. 2.2.
114. *Id.* at Annex A, para. 4.
115. *See* Appellate Report, *supra* note 78, at para. 193.
116. *Id.* at art 5.1.
117. *See* U.S. Panel Report, *supra* note 20, at paras. 8.37-8.38, 8.41.
118. *Id.* at para. 8.40.

More specifically, the Panel held that the risk assessment obligations under Article 5.2 (relating to "relevant inspection, sampling and testing methods") do not permit the assessment of factors such as "control" (ensuring the observance of good practice) which seem primarily related to the economic or social incidence related to a substance or its particular use rather than the risks specific to the substance itself.[119] Therefore, a Member was not to consider "non-scientific" data in the course of risk assessment—a risk assessment which the risk management decision must be based upon.[120]

However, the Appellate Body disagreed with this interpretation. The Appellate Body noted that the "term "risk management" is not to be found in either Article 5 or in any other provision of the SPS Agreement."[121] Thus, the Appellate Body refused to accept the Panel's more restrictive notion of "risk assessment," rather endorsing a more general view of risk assessment which need not be informed by merely scientific data.[122] The Appellate Body relied directly upon the text of the Agreement that states that "control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification."[123] This definition thereby informs Article 5.2 which maintains that in addition to "available scientific evidence," a risk assessment should take into account "relevant inspection, sampling and testing methods."[124] Moreover, the Appellate Body concluded that the list of relevant factors was not meant to be exhaustive.[125]

The natural implication of these determinations is that a Member has leeway to consider relevant social policies in addition to "science" in the assessment of risks. The precise parameters of what may be considered "relevant social policies" remain unclear. Furthermore, since Article 5.1 indicates that a Member may consider Article 5.7 where "insufficient relevant scientific data exists,"[126] the Precautionary Principle, by implication, conceivably may play a role in "risk management" under the Agreement. But, once again, the extent to which a Member may justify its SPS measures by invoking the Principle is an issue left unresolved by the Appellate Body.

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119. *Id.* at para. 8.92.
120. *Id.*
121. *See* Appellate Report, *supra* note 78, at para. 181.
122. *See id.*
123. *Id.* at para. 205 (quoting SPS Agreement, *supra* note 32, at Annex C n.7) (emphasis in Appellate Report).
124. *Id.*
125. *See id.* at para. 187.
126. SPS Agreement, *supra* note 32, at arts. 5.1, 5.7.

D. *When is an SPS Measure "Based On" a Risk Assessment?*

Article 5.1 of the SPS Agreement states that "Members shall ensure that their [SPS] measures are *based on an assessment*, as appropriate to the circumstances, of the risks to human, animal or plant life or health."[127] The question that immediately begs resolution is whether "basing" a measure on a risk assessment implies a minimal procedural requirement.

The Panel held that a party, in defending a measure under Article 5.2, needs to "submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as *based on* a risk assessment."[128] Thus, even where a party conducts a risk assessment, failure to provide evidence that they took account of the assessment will condemn the measure for failure to conform to the obligations of Article 5.2.

However, the Appellate Body rejected the subjectivity inherent in the "taking into account" standard in favor of a more objective manner of satisfying the minimal procedural requirement:[129] "We believe that "based on" is appropriately taken to refer to a certain objective relationship between two elements, that is to say, to an objective situation that persists and is observable between an SPS measure and a risk assessment."[130] In other words, there is no additional procedural burden upon a Member defending an SPS measure to show evidence that they took account of a risk assessment.

Additionally, the Panel articulated the "substantive requirements" necessary for an SPS measure to be "based on" a risk assessment. The Panel identified two distinct inquiries which comprise this substantive requirement. First, identifying the scientific conclusions reached in the risk assessment and the scientific conclusions implicit in the SPS measure; and second, examining those scientific conclusions to determine whether or not one set of conclusions matches, i.e., conforms with, the second set of conclusions.[131] Thus, the substantive task of the

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127. *Id.* at art. 5.1 (emphasis added).

128. U.S. Panel Report, *supra* note 20, at para. 8.59.

129. The Appellate Body was concerned that the subjectivity of the "minimal procedural requirement" suggested by the "taking into account" standard could potentially lead to the exclusion of available scientific evidence that "rationally supports the SPS measure being examined." Appellate Report, *supra* note 78, at para. 190.

130. *Id.* at para. 189.

131. *See* U.S. Panel Report, *supra* note 20, at para. 8.63 (discussing specifically the inquiry to be made about the EC measures concerning the use of growth hormones in meat).

Member is to ensure at least some conformity of the scientific conclusions implicit in the SPS measures to the scientific conclusions reached in the risk assessments submitted as justification for the particular measure.

The Appellate Body essentially endorsed the approach of the Panel in this regard, but in a passage of paramount importance, the Body indicated that conformity of the scientific conclusions implicit in the risk assessment and the SPS measure itself does not alone outweigh the relevance of other policy considerations implicit in risk management.[132] The specific standard adopted by the Appellate Body is as follows:

> We believe that Article 5.1, when contextually read as it should be, in conjunction with and informed by Article 2.2 of the *SPS Agreement*, requires that the results of the risk assessment must sufficiently warrant—that is to say, reasonably support—the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a *rational relationship between the measure and the risk assessment.*[133]

Such a deferential standard seems to leave great discretion with the Members to base the SPS measures primarily on non-scientific social or policy choices needing only a rational relation to the scientific conclusions implicit in the risk assessment itself—a risk assessment which, as defined by the Appellate Body itself, may include assessment of non-quantifiable factors not grounded in the customary physical sciences.[134] Such a result seems incongruous with the primary aim of the Agreement in making science a more relevant consideration in international regulatory decisionmaking. This holding of the Appellate Body seemingly leads to the circular result that a Member seeking to justify an SPS measure need only show that its measure was rationally related to a risk assessment whose implicit scientific conclusion need not even be based in "science" as generally understood—that is to say the quantifiable physical sciences. Accordingly, "science" is lost in the mix and the SPS measure may be justified without ever showing a truly "scientific justification."

Furthermore, the Appellate Body held that Article 5.1 "does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community."[135] The Appellate Body noted that often there are divergent views on any particular issue within the relevant

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132. *See* Appellate Report, *supra* note 78, at para. 193.
133. *Id.* (emphasis added)
134. *See id.* at para. 253(j)
135. *Id.* at para.194.

scientific community which itself may indicate "scientific uncertainty."[136] The opinion recognized that while governments often tend to base legislative measures and administrative regulations on the predominant or "mainstream" scientific opinions, a government may act responsibly and "in good faith" on the basis of a contradictory opinion from an equally qualified or respected source.[137] Therefore, the fact that a Member may not be basing its SPS measure upon mainstream scientific opinion does not, by itself, signal failure to comply with the substantive procedural requirements of Article 5.2. The opinion further suggested that the "reasonable relationship," in this context, is even more apparent where the risk involved is "life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety."[138]

Thus, the opinion of the Appellate Body seems to impart considerable autonomy to a Member in both objectively and subjectively "basing" their SPS measures on a risk assessment. The objective requirement is satisfied by a showing that an objective situation persists and is identifiable in both the measure and the risk assessment. The subjective element is satisfied by showing a rational relationship between the measure and the risk assessment—a risk assessment which need not adopt the mainstream scientific opinion on the issue. This creates an environment where a Member could fabricate a satisfactory response to these "minimal" procedural requirements which is merely a pretext for a disguised restriction on international trade, yet still have "based" their measure on a "risk assessment" in the context of the Agreement.

E. *When is an SPS Measure "Based On" an International Standard?*

Article 3.1 of the SPS Agreement provides "[t]o harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall *base* their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided

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136. *Id.* However, the Appellate Body did not indicate the threshold of uncertainty necessary for a Member to apply for protection under Article 5.7, which implicitly adopts the Precautionary Principle. This could ultimately become an important issue which future panels must confront.

137. *Id.* This implicitly suggests that there must nonetheless be some sort of subjective determination of what may be considered "qualified and respected sources."

138. *Id.*

for in this Agreement, and in particular in paragraph 3."[139] The Panel viewed "based on" international standards as equating to "conforming to" international standards.[140] The Panel found that considering whether a particular SPS measure is "based on" an international standard requires an account of the level of sanitary protection the measure achieves.[141] This level of sanitary protection should then be compared to the level of protection implicit in the international standards, recommendations, or guidelines.[142] If a sanitary measure is to be found to be "based on" the international standard, in conformance with a Member's obligations under Article 3.1, it must reflect the "same" level of protection implicit in the international norms.[143] Thus, where the international standard reflects a different level of sanitary protection, the Member's measure will not be "based on" the international standard for the purposes of the Agreement.[144]

However, the Appellate Body did not accept this interpretation. As a matter of strict textual interpretation, the Appellate Body noted that the plain meaning of "based on" is quite different than the ordinary understanding of "conform to":[145]

> A thing is commonly said to be "based on" another thing when the former "stands" or is "founded" or "built" upon or "is supported by" the latter. In contrast, much more is required before one thing may be regarded as "conform[ing] to" another: the former must "comply with", "yield or show compliance" with the latter. The reference of "conform to" is to "correspondence in form or manner", to "compliance with" or "acquiescence", to "follow[ing] in form or nature".[146]

Thus, while conformity with an international standard assures that the sanitary measure will be "based on" that standard, a measure may nonetheless be "based on" the international standard yet not be in "conformity" with every element of the international standard.[147] As the Appellate Body apparently reads the Agreement, the international standards are more in the line of recommendations which a Member need only consider as a guide rather than adopt or be "based on" as a model.

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139. SPS Agreement, *supra* note 32, at art. 3.1 (emphasis added).
140. *See* U.S. Panel Report, *supra* note 20, at para. 8.18.
141. *See id.*
142. *See id.*
143. *See id.*
144. *See id.*
145. *See* Appellate Report, *supra* note 78, at para. 163.
146. *Id.* (citing 1 THE NEW SHORTER OXFORD ENGLISH DICTIONARY ON HISTORICAL PRINCIPLES 187, 477 (L. Brown ed.)).
147. *See id.*

The Appellate Body used the stated "object and purpose of Article 3" to justify its decision.[148] In particular, the Appellate Body made reference to Article 3.1 which seeks to "harmonize [SPS] measures on *as wide a basis as possible . . .*," and to the preamble of the Agreement which seeks to "*further the use of harmonized [SPS] measures between Members on the basis of international standards . . . .*"[149] The Appellate Body read this language as indicating a clear acknowledgment that complete harmonization is a "goal," not a mandate.[150] In other words, the Agreement is merely encouraging harmonization rather than requiring conformity. The Appellate Body did not want to transform the international standards into binding norms without more specific and clear textual indication than that currently found in the Agreement.[151] Such a transformation, they argued, would unfairly encroach upon the sovereignty of the Member States.[152] Thus, "based on" cannot mean "conform to" as the SPS Agreement is currently drafted and accepted.

However, the impact of this holding may be of little consequence when viewed in light of the Appellate Body's characterization of Article 3.3. Article 3.3 holds: "Members may introduce or maintain sanitary or phytosanitary 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."[153] Thus, a Member may adopt a level of sanitary protection not "based on" the international standards, and indeed, set for itself a higher level of protection. The Appellate Body confirmed that this is "an autonomous right and not an "exception" from a "general obligation" under Article 3.1."[154]

Accordingly, it is difficult to impart any true substance or "teeth" to the obligations under Article 3.1. The fact that a Member may justify a departure from the international standards

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148. *Id.* at para. 165.

149. *Id.* (quoting SPS Agreement, *supra* note 32, at art 3.1, pmbl.) (emphasis added).

150. *See id.*

151. *Id.*

152. *See id.* For an in-depth look at interpretive principles in international law specifically addressing the recognition of state sovereignty, see 1 OPPENHEIM'S INTERNATIONAL LAW 1278 (R. Jennings and A. Watts eds., 9th ed. 1992) (noting that the "principle of *in dubio mitius* applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties.")

153. SPS Agreement, *supra* note 32, at art. 3.3.

154. Appellate Report, *supra* note 78, at para. 172.

and norms under Article 3.3 renders impotent any substantive requirement under Article 3.1 that Members "base" their sanitary measures on international guidelines. Whereas Article 3.1 alone could potentially eliminate a wide range of discriminatory trade regulations by requiring at least some conformity with international norms, Article 3.3 allows a Member an autonomous right to opt out of its Article 3.1 obligations. Once again, a great deal of discretion is left with the Members in their risk management affairs.

Furthermore, it is unclear how this right to choose compliments the underlying goal of harmonizing Members' SPS measures with international standards—a goal Article 3 was designed to address in the first place. The Appellate Body argues that the requirement for "sufficient scientific evidence" for measures adopted under Article 2.2, and a resulting Article 5.1 "risk assessment" will prevent Members from abusing their discretion under Article 3.3.[155] However, as noted above, the "risk assessment" need not endorse or represent a "mainstream scientific opinion," the "scientific justification" need not be based in the ordinary "empirical" sciences, and the measures taken need only be "rationally related" to the findings in the risk assessment.[156] This loose and ambiguous framework, established by the Appellate Body, can hardly serve as an effective restraint on a Member's discretion. Instead, it may operate to empower a Member to circumvent the policy of the Agreement and put direct restraints on international trade which are neither "necessary to protect human, animal or plant life or health" or scientifically justifiable under prevailing international opinion.[157]

IV. THE EU'S BAN ON "SPECIFIED RISK MATERIALS"

The EU's ban on Specified Risk Materials (SRMs) is likely justifiable under the SPS Agreement as interpreted by the

155. *See id.* at para. 177.

156. *See* discussion *supra* Parts III.B-D.

157. SPS Agreement, *supra* note 32, pmbl. In other words, it would not be a difficult task, within this framework, for a Member to come up with a "pretextual" justification for what may actually be a "disguised restriction on international trade" – thus, undermining a primary goal of the Agreement. *See id.* Though this would unlikely be for selfish economic gains, it would nonetheless needlessly restrict international trade. This has already been noted by the EU farm ministers when they once again extended the implementation date of the ban another year (until January 1, 2000). *See EU Delays Animal Parts Ban*, *supra* note 2.

Appellate Body.[158] However, this result would be incongruous with the stated policy of the Agreement because the ban is likely motivated by political pressures, is not based on mainstream scientific views, and issued largely in response to "consumer anxiety" rather than scientific certainty.

As discussed in Part III.A above, the role of the Precautionary Principle in the context of the Agreement is still ambiguous.[159] Nonetheless, the dicta of the Appellate Body's opinion suggested an implicit approval of the Precautionary Principle in Article 5.7[160]—though the specific role of the Principle or weight given to such an approach was left for determination on another occasion. Furthermore, and perhaps suggestive of endorsement of a precautionary "approach" at the least, the Appellate Body noted that a panel presiding over an SPS dispute should consider that governments are frequently overcautious where potentially irreversible risks to human health or life are concerned.[161] Thus, in the context of the Mad Cow scare and the proposed ban on SRMs,[162] the EU may arguably look to the Precautionary Principle to justify its SPS measure. This conclusion is more likely in this instance than in the context of the Hormones Dispute, where the potentially irreversible risks to human health and life are more conclusively documented.[163] At the very least, apart from any ruling on Article 5.7, a presiding panel[164] may well consider such risks to life or health when addressing the means of risk management inherent in the SPS measure, or the proposed ban on SRMs in this instance.[165] In other words, a panel may have the authority to be more permissive as to restrictive trade measures where identifiable and harmful contaminants are at issue.

This case is also distinguishable from the Hormones Dispute in other aspects. Here, the EU has carried out risk assessments

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158. For a recap of the proposed SRM ban and its implications for the U.S. pharmaceuticals industry, see discussion *supra* Part I. *See also, e.g.*, Buckley, *Talks on BSE*, *supra* note 4, at 8.

159. *See* discussion *supra* Part III.A.

160. *See* Appellate Report, *supra* note 78, at para. 124 (noting that Article 5.7 embodies the Precautionary Principle).

161. *See id.*

162. *See* discussion *supra* Part I.

163. In the Hormones Dispute, the very safety of the banned materials was at issue, whereas here it is generally conceded that BSE does pose a serious threat to human health or life. Indeed, scientists have found a link between BSE and the human version of mad cow's disease (Creutzfield-Jakob disease) which is an incurable degenerative brain disease in humans. *See* Parker-Pope & Wolf, *supra* note 26, at A14.

164. The panel would be convened if the United States brought a formal complaint to the WTO.

165. *See* Appellate Report, *supra* note 78, at para. 124.

finding a specific link between eating contaminated beef products and contracting the life threatening Cruetzfield-Jakob disease.[166] Thus, while the Appellate Body found that the EU did not perform a risk assessment in the Hormones Dispute, it would likely find the opposite in the SRM dispute. Because this primary obligation under the SPS Agreement has been met, the panel would then be free[167] to determine whether the proposed ban is "based on" the risk assessment[s].[168]

However, as noted above, this is not an arduous task. Indeed the standard set by the Appellate Body only requires a "rational relationship" between the proposed SPS measure and the risk assessment.[169] Furthermore, the views expressed in the EU's risk assessment need not even convey mainstream scientific opinion.[170] Thus, even if the United States—or any other interested party—had a different "scientific" opinion, the Appellate Body nonetheless indicated tacit approval of such an assessment as justification for the proposed ban. While it is unclear exactly how a future panel will interpret the "rational relationship," the Appellate opinion certainly suggests a high degree of deference to a Member's discretion and a low level of scrutiny to be applied by the panel in its resolutions. Here, a blanket ban on potential sources of BSE or SRMs would clearly have a rational relation to the goal of protecting consumers from the potential health risks of the SRMs.

The proposed ban is also supported by the Appellate Body's broad notions of science. Specifically pertinent are those scientifically unquantifiable risks and the real world effects of the risk—contrasted with the risks in a vacuum. The breadth of these unquantifiable real world risks was left undetermined, but given the Appellate Body's acknowledgment (and endorsement) of political autonomy, and the pervasive influence of social policies in risk management decisions, it is likely that consumer anxiety or political influence could be a legitimate, or even primary, justification for the ban—a ban which is only tangentially, or rationally, related to the underlying science and actual risk the SRMs pose. The problem this presents is that the ban is so excessive in its scope[171] when considering the actual risk posed,

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166. *See* Parker-Pope & Wolf, *supra* note 26, at A14.

167. This was not the case in the once Hormones Dispute, where the Panel abstained from looking further once the EU failed in its primary obligation. *See supra* notes 90-91 and accompanying text.

168. *See* discussion *supra* Part III.B.

169. *See* Appellate Report, *supra* note 78, at para. 193.

170. *See id.* at para. 194.

171. The justification for such a broad scope is to eliminate fears of a non-uniform or discriminate ban.

and that the ban itself has only a tenuous, albeit rational, relationship to the risk assessment—a risk assessment which may permissibly be biased towards a non-conventional scientific view.

Though the SPS Agreement purports to prevent Members from enacting measures "more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection,"[172] the leniency afforded Members in choosing their level of sanitary protection coupled with the rational relationship test explained above have the paradoxical effect of letting a Member dictate to the world what is justifiable under the Agreement rather than having the Agreement dictate what is permissible to the Member. This result is contrary to the purpose of the Agreement—establishing more adherence to international norms and eliminating trade restrictions which are unjustifiable and unnecessary.

Further, while the SPS Agreement speaks broadly of eliminating "disguised restriction[s] on international trade,"[173] it is unclear what these restrictions constitute. Is there an "improper motive" requirement? Presumably, the Agreement speaks largely to Members" concerns about protectionist or arbitrary measures which adversely effect international trade, but whether it speaks to more benign restrictions which arise to ease consumer anxiety or to preserve political power or confidence is uncertain. Indeed, the proposed SRM ban is likely a direct result of the latter. While there may be no ill motive in this situation, restrictions which arise from political and social pressures nonetheless can have an adverse impact on international trade and should be expressly condemned under the Agreement. Indeed, this leads back to the original thesis of this Note: Placing restrictions on the global market is not the proper means for regaining "consumer confidence" in what is largely an intrastate issue.[174]

The proposed ban seems to be the result of political pressures and attempts to address consumer anxieties in the wake of the Mad Cow scare rather than actual scientific risks.[175]

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172. SPS Agreement, *supra* note 32, at art. 5.6.

173. *Id.* at pmbl.

174. *See* discussion *supra* Part I.

175. There is well-documented evidence that the ban will severely hurt the British economy as well, thus eliminating any concerns of protectionism or ill-motive. In fact, opposition to the ban has come from tallow producers within the EU as well. *See, e.g., Industry Sees Minimal BSE Risk*, Dow Jones Int"l. News, Sept. 8, 1997, *available in* WESTLAW, DJINPLUS Database. Indeed, it was likely that the effect on the United States pharmaceuticals industry was not contemplated at the time of the ban. *See Mad Cow Disease: Massive Beef Export Fraud Uncovered*, EUR. REP., Sept. 3, 1997, *available in* 1997 WL 13046321.

It is well-documented that the purpose of the blanket ban on British Beef exports was to address consumer confidence in British Beef and the Beef market in general.[176] Indeed, the Labour Party disparaged Tory ministers for having a "reckless disregard for public health" by not initially including beef derivatives (tallow and gelatin) in the ban, and also encouraged the government to "reassure the public by going further than the scientific advice."[177]

Evidence indicates that hesitancy by the European Commission and political indecisiveness during the initial phases of the Mad Cow Scare led to the more decisive and overreaching action in the current proposal. The plans for the proposed ban were initially rejected by the European Commission,[178] but were revived when threats of censure arose amid accusations of "mishandling" the Mad Cow crisis and when the Commission narrowly escaped removal and a vote of no confidence in February of 1997 by the Parliament.[179] Arguably, the proposed ban arose more from concerns of political censure and reassuring consumer confidence than from legitimate concerns for public health or actual scientific risks posed from the banned imports—especially those from countries where there has been no documented outbreak of Mad Cow disease. Because Mad Cow disease is largely an intrastate issue, at least within the EU, the import ban is not justifiable on grounds of regaining consumer confidence. Nonetheless, the ban is likely permissible as the Appellate Body interpreted the SPS Agreement.

V. CONCLUSION AND RECOMMENDATIONS

Article 3.1 of the SPS Agreement reads: "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations . . . ."[180] However, the Appellate Body read this provision too narrowly, ultimately undermining the very goal of

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176. *See* Parker-Pope & Wolf, *supra* note 26, at A14.

177. Patrick Wintour, *Ministers Defy Beef Outcry Children Under "No Greater Threat"*, GUARDIAN (London), Mar. 26, 1996, at 1, *available in* 1996 WL 4016818.

178. *See* Mike Smith, *Offal at the Heart of the Dispute*, FIN. TIMES (London), Oct. 16, 1997, at 4, *available in* 1997 WL 14786576.

179. *See Mad Cow Disease: EP Committee Dissatisfied Over Disciplinary Issues*, EUR. REP., Oct. 15, 1997, *available in* 1997 WL 13047256. Several officials in the Commission's Directorate-General VI (Agriculture and Rural Development) were singled out for mishandling the crisis and disciplinary action was called for from several sources within the Commission. *See id.*

180. SPS Agreement, *supra* note 32, at art 3.1.

harmonization that Article 3 was designed to address. Harmonization on as wide a basis as possible should mean that conformity should be the rule, not the exception as the Appellate Body seemed to reason. In other words, a Member should have to more than merely consider the international recommendations, a Member should be required to adhere to the norm unless extenuating circumstances demand an exception.[181] The Appellate Body got tangled in strict textualism and refused to read "conformity" into a statute which only stated "based on," but such an interpretation ignores a basic tenet of purposivism—every statute is enacted for a purpose.[182] Here, the stated purpose of Article 3 was harmonization with international standards. If a Member need only refer to international norms as guidelines, the Member will have little incentive to harmonize its SPS measure to the international recommendations where doing so does not serve its particular agenda. The Appellate Body noted that harmonization is a goal, not a mandate, but the goal will likely never be achieved unless conformity is the rule, not the exception.[183]

Furthermore, a Member's Article 3.3 right to set its own level of SPS protection—specifically higher than that suggested by the international norms—should not be an "autonomous" right as suggested by the Appellate Body.[184] Rather, this right to set a higher level of SPS protection should be an exception from a general obligation of conformity under Article 3.1. The exception would apply in those circumstances where: (1) the science is unclear and, (2) the magnitude of the risk is great—both economically and in terms of human health or life. This would ensure that the costs of the SPS measure, which departs from the international norms, never exceed its benefits, while simultaneously balancing the need to defer to caution where the science is unclear. However, where there is a general consensus regarding the underlying science, Article 3.1 should be the rule. This reading not only better serves the need for harmonization of standards for international trade, but also does not render Article 3.1 an apparent nullity with no real "teeth" as is the case with the Appellate Body interpretation. If a Member can justify a departure from international norms, and this would serve the Member's

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181. An example of an extenuating circumstance is the absence of an international norm or recommendation at the time the measure is being proposed.

182. Indeed, the title itself, "Harmonization," offers textualist support for a theory that harmonization should be the rule, not the exception.

183. This is likely so because the self-interest of the Member at some point will outweigh the needs of the greater community where discretion is given to the Member to conform or not conform.

184. *See* Appellate Report, *supra* note 78, at para. 172.

interest,[185] why would the Member choose to bind itself nonetheless to the international standard? Reading conformity as the rule in Article 3.1 would effectively provide this incentive.

Furthermore, Article 5.7 should be dropped completely. Article 5.7 implicitly embodies the Precautionary Principle and allows a Member to adopt a precautionary approach where scientific evidence is insufficient with regard to the actual risks the SPS measure seeks to eliminate. The incorporation of Article 5.7 only hopelessly and needlessly confuses a uniform interpretation of the SPS Agreement. If the Precautionary Principle ever becomes a universally accepted principle of international law then it will necessarily be incorporated into Articles 5.1 and 5.2, which direct Members to consider risk assessment techniques developed by the relevant international organizations and relevant scientific processes.[186] Otherwise, the Precautionary Principle is being "force" upon the Members not all who may on its relevance and its proper role in the context of the Agreement.[187] The inequitable result would be even more apparent where the scientific risks are truly uncertain, yet the probable magnitude of the risk is low. In such an instance, largely on the basis of "insufficient" science, a Member could adopt a precautionary approach and upset international trade even where the potential magnitude of the risk is low. Rather, a cost/benefit paradigm, as in the suggested application of Articles 3.1 and 3.3 above, would be a more efficient manner of risk management where the relevant science is uncertain.

Finally, the Article 5.1 requirement that the SPS measure must be "based on" a scientific risk assessment should require more than a rational relation.[188] Requiring a mere rational relation subverts the goal of making science a more prevalent factor in international trade regulation by giving Members too much discretion to base their risk management decisions primarily on non-scientific, political, or social factors. The rational relationship test requires only a tangential relationship between the SPS measure and the underlying science. At least an intermediate level of scrutiny should be applied, and the

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185. Self-interest could mean *political* as suggested by the instant case.

186. *See* SPS Agreement, *supra* note 32, at arts. 5.1-5.2.

187. For example, the United States argued in the Hormone's Dispute that the Precautionary Principle was not yet an international norm. *See generally* U.S. Panel Report, *supra* note 20, at para. 8.23. While each Member clearly ratified the Agreement, including Article 5.7, the wording of 5.7 was sufficiently ambiguous as to the extent it actually embodied the Precautionary Principle per se. However, The Appellate Body laid uncertainty to rest when it announced that Article 5.7 did reflect the Precautionary Principle. *See* Appellate Report, *supra* note 78, at para. 124.

188. *See* SPS Agreement, *supra* note 32, at art. 5.1.

relationship should be substantial rather than rational. This approach would appropriately balance the discretionary needs of public policy makers with the rights of the effected Members not to have their trade disrupted by primarily internal or intrastate political agendas of sister States. It is important to recognize that effective regulation of international trade requires consideration of non-scientific factors, such as politics and economics, but at the same time coordination of international trade among the many nations of the world requires some level of uniformity in application.[189] Though subject to slight variation, science is a norm which could set uniform standards for trade regulations for public health and welfare because science is precisely what identifies risks to human life or health at the outset. The SPS Agreement was intended to be a step in that direction. Therefore, the SPS Agreement should be interpreted by the WTO as encouraging the adoption of science as an international regulatory norm. Unfortunately, the rational relationship test falls short of that mark. In light of this shortcoming, Members likely have the discretion to enact SPS measures largely to ease consumer anxiety.[190] Such results are both contrary to the purpose of enacting the SPS Agreement and to the elimination of regulations which are neither necessary for the protection of human health nor justified by science.

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189. Uniformity is important to prevent arbitrary, retaliatory or capricious trade wars, sanctions, etc.

190. Members also like such discretion to save their political careers, as in the EU's proposed import ban. *See supra* note 178 and accompanying text.

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