#### **American University International Law Review**

Volume 21

Issue 2 Symposium: The Geneva Conventions and the Rules of War in the Post-9/11 and Iraq World

Article 4

2005

# Battle of the Beef, the Rematch: An Evaluation of the Latest E.C. Directive Banning Beef Produced with Growth Hormones and the U.S. Refusal to Accept the Directive as WTO Compliant

Darrel Chichester

Follow this and additional works at: http://digitalcommons.wcl.american.edu/auilr

Part of the Food and Drug Law Commons, Health Law Commons, International Law Commons, and the International Trade Commons

#### Recommended Citation

Chichester, Darrell. "Battle of the Beef, the Rematch: An Evaluation of the Latest E.C. Directive Banning Beef Produced with Growth Hormones and the U.S. Refusal to Accept the Directive as WTO Compliant." American University International Law Review 21, no.2 (2005): 221-276.

This Comment or Note is brought to you for free and open access by the Washington College of Law Journals & Law Reviews at Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in American University International Law Review by an authorized administrator of Digital Commons @ American University Washington College of Law. For more information, please contact fbrown@wcl.american.edu.

#### COMMENT

# BATTLE OF THE BEEF, THE REMATCH: AN EVALUATION OF THE LATEST E.C. DIRECTIVE BANNING BEEF PRODUCED WITH GROWTH HORMONES AND THE U.S. REFUSAL TO ACCEPT THE DIRECTIVE AS WTO COMPLIANT

#### **DARRELL CHICHESTER\***

INTRODUCTION	223
I. BACKGROUND	226
A. RESOLUTION OF THE INITIAL HORMONE DISPUTE	226
B. REQUIREMENTS OF A VALID RISK ASSESSMENT	229
C. MEMBERS MUST DEMONSTRATE A RATIONAL AND	
OBJECTIVE RELATIONSHIP BETWEEN RISK ASSESSMENT	
AND SPS MEASURES	231
D. THE SPS AGREEMENT PROVIDES AN EXCEPTION TO THE	
GENERAL REQUIREMENT THAT MEMBERS BASE THEIR	
SPS MEASURES ON A VALID RISK ASSESSMENT	233
E. THE E.C. SEEKS TO COMPLY WITH THE WTO WHILE	
MAINTAINING ITS PROHIBITION OF GROWTH-PROMOTING	
HORMONES	235

<sup>\*</sup> J.D. Candidate, 2006, American University Washington College of Law; B.A. Political Science and International Affairs, 1999, University of New Hampshire. I would like to thank the ILR staff and editors for their hard work in preparing this article for publication. Sheila Upadhyay served as my comment editor and deserves special acknowledgment for her patience and guidance. I want to thank Professor Penelope Pether who challenged me throughout the first year of law school and is responsible for the progress of my writing over the past few years. Most importantly, the love and support of my wife and daughter have kept me going through the toughest times, even though at times they must wonder if I'll ever come home. I love you both.

F. THE UNITED STATES REFUSES TO WITHDRAW ITS	
SUSPENSION OF CONCESSIONS, ASSERTING THAT THE	
NEW COUNCIL DIRECTIVE FAILS TO BRING THE E.C. INTO	
COMPLIANCE WITH THE DSB RULINGS AND	
RECOMMENDATIONS24	0
1. The United States Has Granted Most Favored Nation	
Status to the E.C. and Must Not Deviate from the	
Schedule of Concessions Unless Authorized to Do So 24	1
2. The DSB Grants Authorization to Suspend	
Concessions for Temporary Purposes Only24	5
II. ANALYSIS24'	
A. DIRECTIVE 2003/74/EC BRINGS THE E.C. HORMONE	
MEASURES INTO COMPLIANCE WITH ITS WTO	
OBLIGATIONS24	7
1. The E.C. Supports the Implementation of Its SPS	
Measures Under Council Directive 2003/74/EC with	
a Valid Risk Assessment24	9
a. The Risk Assessment Specifically Identifies the	
Risk that the Directive Is Employed to Combat24	9
b. The Risk Assessment Identifies Adverse Effects	
from the Increased Exposure to Hormone	
Residues in Meats Treated with Growth-	
Promoting Hormones25	1
c. The Risk Assessment Evaluates the Potential for	
Adverse Effects on Human Health to Occur25	5
d. The Risk Assessment Is Specific to the Effects	
Caused by Increased Exposure to Growth	
Hormone Residues Through the Consumption of	_
Treated Meats25	6
2. Council Directive 2003/74/EC is Rationally Related to	_
Its Supporting Risk Assessment25	8
3. The E.C. SPS Measures Are Valid Even Without a	_
Demonstration of Sufficient Scientific Evidence26	0
B. THE ACTION OF THE UNITED STATES CONSTITUTES	
Unilateral Action Inconsistent with Its	
OBLIGATIONS UNDER THE DISPUTE SETTLEMENT	_
Understanding	3
1. Council Directive 2003/74/EC is a "Measure Taken to	_
Comply" with the DSB Rulings26	2

2. The Continued Suspension of Concessions Constitutes	
Unilateral Action Taken to Redress a Violation or	
Existence of the E.C. SPS Measures	.266
3. The Continued Suspension of Concessions Is	
Unilateral Action in Violation of WTO Obligations	
Regardless of When the United States First Initiated	
the Suspension	.268
III. RECOMMENDATIONS	.270
A. THE DSB SHOULD USE THE U.S.—CONTINUED SUSPENSION	
OF OBLIGATIONS CASE TO DECLARE THE IMPORTANCE OF	
THE "PRECAUTIONARY PRINCIPLE"	.270
B. THE DSB SHOULD USE THE U.S.—CONTINUED SUSPENSION	
OF OBLIGATIONS CASE TO ESTABLISH THAT MEMBERS	
WHO REFUTE ANOTHER MEMBER'S COMPLIANCE WITH	
THE DSB MUST RESORT TO ARTICLE 21.5 PROCEEDINGS	.273
CONCLUSION	.275

#### INTRODUCTION

The U.S. beef industry has used growth hormones in meat production since the 1970s, and the European Communities ("E.C.") have resisted the introduction of such hormones into their meat supply for almost as long. Both sides have since been engaged in a battle influenced by powerful economic forces that refuse to let either side back down.<sup>2</sup>

The powerful U.S. beef industry and its interest in realizing profits from exporting a greater supply of beef at a lower cost motivates the United States to maintain pressure on the E.C.<sup>3</sup> Though the exact

<sup>1.</sup> See Friends of the Earth International, The Citizens' Guide to Trade, Environment and Sustainability: Trade Case-Study: Beef Hormone Dispute, http://www.foei.org/trade/activistguide/hormone.htm (last visited Nov. 7, 2005) (noting that part of the reason for the ban is that Europeans have expressed the desire to keep their meats free of growth hormones regardless of the potential risks).

<sup>2.</sup> See George H. Rountree, Note, Raging Hormones: A Discussion of the World Trade Organization's Decision in the European Union – United States Beef Dispute, 27 GA. J. INT'L & COMP. L. 607, 607-10 (1999).

<sup>3.</sup> See Chuck Lambert, Jan. - November 2001 Beef Exports Decrease .8% in Volume and 6% in Value, Jan./Feb. 2002, http://www.beef.org/newsjanuary

amount of lost profits varies depending on the source of the statistics, it is clear that the U.S. beef industry has suffered as a result of the ban.<sup>4</sup> At the same time, E.C. leaders are mindful of its health and safety conscious population that demands a voice when it comes to measures affecting their food.<sup>5</sup> E.C. leaders are in fact supported by examples of specific food trends resulting from European awareness and concern over food production.<sup>6</sup>

With neither side willing to back down, the dispute continues to rage on, once again making its way through the World Trade Organization's ("WTO") Dispute Settlement Body ("DSB").<sup>7</sup> However, this time the E.C. could finally be successful in its bid to

february20022764.aspx (stating that U.S. exports of beef between January 1 and November 30, 2001 totaled 1,171 metric tons of beef, with an estimated value of \$3.144 billion); see also Letter from Senator Chuck Grassley, Chairman, Senate Comm. on Finance, to Pascal Lamy, Trade Comm'r, European Comm'n (Nov. 18, 2004), available at http://www.useu.be/Article.asp?ID=1DF3BEE3-5EF5-4E1A-AEBF-6A276 59FCD2C (expressing severe criticism over the E.C.'s action, calling it a game of "smoke and mirrors" and proclaiming that the beef producers in the United States are the ones that are truly suffering).

- 4. See Kristin Mueller, Note, Hormonal Imbalance: An Analysis of the Hormone Treated Beef Trade Dispute Between the United States and the European Union, 1 DRAKE J. AGRIC. L. 97, 101 (1996) (suggesting that because the amount of potential profit is far greater than the actual dollar value of beef exported, there is a significant segment of the U.S. beef industry that is unable to maintain a productive level of non-hormone treated beef exports to Europe).
- 5. See Hormones: Conference Planned to Discuss Safety and Import Ban, AGRI SERV. INT'L NEWSLETTER, June 9, 1995 (conveying the sentiments of E.U. Agriculture Commissioner Franz Fischler that while the ban on hormones may undergo a review, the E.C. will not do so without taking into consideration consumer views).
- 6. See Mueller, supra note 4, at 102, n.50 (observing that beef consumption dropped in E.C. countries where illegal use of hormones developed, but consumption increased in those countries with a reputation for having hormone-free meat).
- 7. See Press Release, European Comm'n, E.U.—U.S.: E.U. Requests WTO to Confirm that There is No Justification for US/Canada to Continue to Apply Sanctions (Nov. 8, 2004), http://europa.eu.int/rapid/pressReleasesAction.do? reference=IP/04/1345&format=HTML&aged=0&language=EN&guiLanguage=en [hereinafter Press Release, E.U. Requests WTO to Confirm No Justification] (discussing the E.C.'s initiation of a new WTO action to compel the United States to withdraw its sanctions against E.U. exports, imposed in retaliation to the E.U. ban on hormone-treated beef).

have the WTO validate its hormone policy.<sup>8</sup> Additionally, the United States might find itself with a slap on the wrist from the WTO for failing to abide by the rules of the game.<sup>9</sup>

Part I of this Comment will review the initial *E.C.—Hormones* Panel and Appellate Reports and the standards established therein, <sup>10</sup> as well as the U.S. refusal to accept the new Directive as bringing the E.C. into compliance with the DSB rulings. <sup>11</sup> Part II analyzes the new Directive and demonstrates how it meets the requirements of the DSB's rulings and recommendations. <sup>12</sup> Part II also analyzes the validity of the U.S. action in making the determination that the E.C. measures remain inconsistent with the Agreement on Sanitary and Phytosanitary Measures ("SPS Agreement") and argues that the DSB should find the United States in violation of the WTO dispute settlement process. <sup>13</sup> Finally, Part III will recommend that the DSB begin evaluating sanitary and phytosanitary measures ("SPS measures") with a greater emphasis on the "precautionary principle." <sup>14</sup> Part III also argues that the DSB should require original

<sup>8.</sup> See infra Part II.A (arguing that the E.C. has met the requirements for maintaining its hormone policy despite not conforming to international standards).

<sup>9.</sup> See infra Part II.B (suggesting that the United States acted unilaterally, in contravention of the WTO's Understanding Governing the Settlement of Disputes, when it failed to bring an Article 21.5 proceeding against the new E.C. Directive).

<sup>10.</sup> See infra Part I.A (outlining the E.C. hormone ban and the legal grounds for the DSB's invalidation of Council Directive 96/22/EC).

<sup>11.</sup> See infra Part I.B-F (discussing the rules and procedures of dispute resolution and the United States' continued suspension of concessions).

<sup>12.</sup> See infra Part II.A.

<sup>13.</sup> See infra Part II.B (arguing that the United States acted unilaterally in breach of its WTO obligations); see also Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments — Results of the Uruguay Round, 1867 U.N.T.S. 493, 496-97 (1994) [hereinafter SPS Agreement] (establishing the procedures to which Members must adhere when developing measures to protect human and sanitary health); World Trade Org., A Summary of the Final Act of the Uruguay Round: Agreement on Sanitary and Phytosanitary Measures, http://www.wto.org/english/docs\_e/legal\_e/ursum\_e.htm #bAgreement (last visited Nov. 7, 2005) (noting that the purpose of the agreement is "to harmonize sanitary and phytosanitary measures on as wide a basis as possible," while still recognizing that nations must retain a degree of sovereignty in their choices of health and safety measures).

<sup>14.</sup> See infra Part III.A (urging the WTO to acknowledge the importance of the "precautionary principle" embodied within Article 5.7 of the SPS Agreement by

complainants to follow the mandate of Article 21.5 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU") when another Member enacts a new SPS measure designed to comply with a prior DSB ruling, regardless of whether the DSB previously authorized an initial suspension of concessions.<sup>15</sup>

#### I. BACKGROUND

#### A. RESOLUTION OF THE INITIAL HORMONE DISPUTE

The E.C. first banned the importation of consumable meats produced with the aid of growth-promoting hormones in 1989.<sup>16</sup> The United States immediately sought action under international trade law to remove this hormone ban, which it considered an illegal trade barrier.<sup>17</sup> However, it was not until the Members of the General Agreement on Tariffs and Trade (GATT 1994) established the WTO and the SPS Agreement that the United States had an appropriate vehicle through which to raise its concerns over the E.C. prohibition.<sup>18</sup>

looking more closely at whether SPS measures are arbitrary or unjustifiably discriminatory).

- 15. See infra Part III.B (arguing that the language of Article 21.5 is neutral and thus must apply equally to all Members regardless of whether the DSB previously awarded a Member the right to suspend concessions in the same matter).
- 16. See EUROPEAN COMM'N, SCIENTIFIC COMMITTEE ON VETERINARY MEASURES RELATING TO PUBLIC HEALTH, ASSESSMENT OF POTENTIAL RISKS TO HUMAN HEALTH FROM HORMONE RESIDUES IN BOVINE MEAT AND MEAT PRODUCTS 1 (1999), http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/sci\_opinion\_en.htm [hereinafter 1999 SCVPH REPORT] (explaining that the ban on such meat products extends to animals treated by any method of hormones that are administered with the intent of facilitating growth in the animal).
- 17. See Mueller, supra note 4, at 99-100 (stating that the United States and the E.C. worked under the GATT provisions to find a compromise). The United States demanded that parties employ the scientific method of the GATT "Standard Code" to evaluate the issues. Id. at 100. However, the Europeans sought resolution under the GATT "national treatment" basis, whereby foreign and domestic products are treated equally. Id.
- 18. See SPS Agreement, supra note 13; see also David A. Wirth, The Role of Science in the Uruguay Round and NAFTA Trade Disciplines, 27 CORNELL INT'L L.J. 817, 823-24 (1994) (concluding that the dispute between the United States and the E.U. over the E.U.'s prohibition of hormone-treated beef provided the impetus

In 1996, the E.C. reformulated its policy, providing for a complete ban on some of the most commonly used growth-promoting hormones for beef production.<sup>19</sup> The United States subsequently brought the dispute before the DSB on January 31, 1996, asserting that Council Directive 96/22/EC constituted food safety measures that did not comport with the SPS Agreement.<sup>20</sup> The DSB Panel Report agreed that the measures were inconsistent,<sup>21</sup> and the Appellate Body affirmed this conclusion after amending the report.<sup>22</sup>

for many of the provisions in the SPS Agreement). The SPS Agreement "was designed to prevent the abuse of . . . phytosanitary measures," which can include measures that may otherwise be identified as "non-tariff barriers to trade." *Id.* 

- 19. See Council Directive 96/22, pmbl. ¶ 4, arts. 4-5, 1996 O.J. (L 125) 3, 5-6 (EC) (setting forth a total ban on the use of hormones where they are used for the specific purpose of growth promotion). The Directive sets out certain exceptions for which the Member States and importers may use the various hormones. Id. The permissible uses include therapeutic purposes, zootechnical treatment, estrus synchronization, and treatment of foetus maceration, mummification and pyometra in cattle. Id. Even when administering the hormones for approved usages, Member States must follow the strict guidelines laid out by the Directive. Id.; see also Ellin Doyle, Food Research Institute, Human Safety of Hormone Implants Used to Promote Growth in Cattle: A Review of the Scientific Literature 2 (2000) (observing that these growth promoting hormones are widely used not only in the United States, but also in Canada and Australia). Doyle indicates that, as of July 2000, thirty countries had approved the use of at least one of these hormones for the purpose of growth promotion in meat production. Id.
- 20. See Request for Consultations by the United States, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/1 (Jan. 31, 1996) [hereinafter U.S. Request for Consultations] (explaining that the United States viewed the E.C.'s measures as inconsistent with the GATT 1994, Article III or Article XI; the Agreement on Technical Barriers to Trade, Article 2; and the Agreement on Agriculture, Article 4). Specifically, the United States believed that the E.C.'s Directive violated Articles 5.1, 5.5, 3.3, and 3.1 of the SPS Agreement. Id. ¶ 9.1.
- 21. See Panel Report, E.C. Measures Concerning Meat and Meat Products (Hormones), ¶¶ 8.28, 8.30, WT/DS26/R/USA (Aug. 18, 1997) [hereinafter Panel Report, E.C. Measures] (concluding that of the original agreements to which the United States cited, the SPS Agreement and GATT were applicable to the dispute). The Panel found that an analysis of the E.C.'s measures based on GATT 1994 was unnecessary because, as a threshold matter, the measures were inconsistent with the SPS Agreement. Id. ¶ 8.272. The Panel ultimately held that the E.C. Directive was inconsistent with Articles 5.1, 5.5, 3.3, and 3.1 of the SPS Agreement. Id. ¶ 9.1.
- 22. See Appellate Body Report, E.C. Measures Concerning Meat and Meat Products (Hormones), ¶ 253, WT/DS26/AB/R (Jan. 16, 1998) [hereinafter Appellate Report, E.C. Measures] (upholding the Panel's finding that the E.C.

The final report concluded that the E.C. measures were inconsistent only with Articles 3.3 and 5.1 of the SPS Agreement.<sup>23</sup> Article 3.3 permits Members to adopt SPS measures that provide a higher level of protection than those following international standards.<sup>24</sup> However, SPS measures that do not comply with the requirements of Article 5 of the SPS Agreement are also inconsistent with Article 3.3 of the SPS Agreement.<sup>25</sup> Most importantly, Members must base all of their SPS measures on an assessment of the risks to human health ("risk assessment") that is specific to the harms the SPS measures are designed to confront.<sup>26</sup>

measures were inconsistent with Articles 3.3 and 5.1 of the SPS Agreement, despite noting several points of error committed by the panel); see also Dispute Settlement Body, Minutes of Meeting Held on Feb. 13, 1998, 8, WT/DSB/M/42 (Mar. 16, 1998) (providing an in-depth description of the comments made in the meeting in which the Appellate Body decided to uphold the Panel Report). See generally Notification of an Appeal by the European Communities, EC Measures Concerning Meat and Meat Products (Hormones), WT/DS26/9 (Sept. 25, 1997) (citing the specific areas of law under the SPS Agreement in which the E.C. believed that the Panel was incorrect in its initial determination); Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2 art. 16.4, Legal Instruments — Results of the Uruguay Round, 1869 U.N.T.S. 401, 411, 33 I.L.M. 1125 (1994) [hereinafter DSU] (establishing that unless a party to a dispute gives notice of its intention to appeal or the Members of the DSB decide otherwise by consensus, the DSB adopts all panel reports within sixty days of the report being circulated); Appellate Body Report, Working Procedures for Appellate Review, WT/AB/WP/5, R. 20(1) (Jan. 4, 2005) (providing the requirements for a notice of appeal, which include notification in writing to the DSB that follows the requirements of paragraph 4 of Article 16 of the DSU, with concurrent notification to the WTO Secretariat).

- 23. See Appellate Report, E.C. Measures, supra note 22,  $\P$  253 (reversing the Panel's conclusions that Directive 96/22/EC was inconsistent with Articles 3.1 and 5.5 of the SPS Agreement). The Appellate Body also reversed several of the panel's general interpretations of the SPS Agreement. *Id.*
- 24. See SPS Agreement, supra note 13, art. 3.3 (stating that the adoption of SPS measures that are more protective than international standards must be based on scientific justification).
- 25. See Appellate Report, E.C. Measures, supra note 22,  $\P$  177 (concluding that in "consideration of the object and purpose of Article 3... compliance with Article 5.1 was intended as a countervailing factor" to the well recognized right of Members to determine their own appropriate level of SPS protection).
- 26. See SPS Agreement, supra note 13, art. 5.1 (providing that this "risk assessment" can be conducted "as appropriate to the circumstances" that surround the implementation of the specific SPS measures); see also Appellate Report, E.C.

The DSB determined that the E.C. failed to meet the requirement of basing its measures on a valid risk assessment because none of the reports the E.C. relied upon to support its measures concluded that there was a risk to human health.<sup>27</sup> In fact, the Panel noted that all of the E.C.'s studies concluded the use of growth hormones was safe, assuming good veterinary practice.<sup>28</sup> Therefore, the DSB declared the Directive to be inconsistent with the E.C.'s obligations under the SPS Agreement.<sup>29</sup>

#### B. REQUIREMENTS OF A VALID RISK ASSESSMENT

The initial E.C.—Hormones Panel Report held that a valid risk assessment, relevant to the use of growth hormones, must identify the potential adverse risks associated with the presence of contaminants in products intended for human consumption.<sup>30</sup> This

- 27. See Appellate Report, E.C. Measures, supra note 22, ¶¶ 196-98 (recognizing that while the E.C. did produce one expert opinion, which found a risk to human health, the study did not focus specifically on the risk posed by the consumption residues found in meats treated with the growth hormones in dispute).
- 28. See id. ¶¶ 196-97 (agreeing with the Panel's conclusion that the SPS measures were not rationally supported by the studies to which the E.C. cited).
- 29. See id. ¶¶ 207-08 (affirming the panel's ultimate conclusion that the E.C. prohibition on the use of growth hormones in meat production and the related prohibition on the importation of such meats was not based on a risk assessment). The Appellate Report also reversed the Panel's conclusion that the scientific information that the E.C. submitted constituted a valid risk assessment under the SPS agreement. Id.
- 30. See SPS Agreement, supra note 13, Annex A ¶ 4 (defining two types of risk assessments). The first type of risk assessment covers the possibility of entry or spread of disease and the possible resulting harms. Id. The second type of risk assessment covers adverse health effects from "additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs." Id.; see also Panel Report, E.C. Measures, supra note 21, ¶ 8.98 (affirming that the residues found in meats treated with the six hormones in dispute are included within the definition of contaminants).

Measures, supra note 22, ¶ 180 (agreeing with the Panel that Articles 2.2 and 5.1 of the SPS Agreement should be read together, as "the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1"); SPS Agreement, supra note 13, Annex A art. 2.2 (stating that "Members shall ensure that any sanitary or phytosanitary measure" applies only to situations in which the measure is necessary to protect human, animal or plant health and that Members must base these measures on scientific principles and sufficient scientific evidence).

evaluation must include (1) an identification of the particular risk to human health, and (2) an evaluation of the potential for those adverse effects to occur.<sup>31</sup> The Appellate Body agreed with the Panel that the E.C. failed to meet these requirements, but also determined that the DSB must equate the term "potential" with the notion of possibility rather than probability.<sup>32</sup> In reaching this conclusion, the Appellate Body rejected the Panel's implication that a risk assessment must establish a minimum quantifiable level of risk.<sup>33</sup>

The DSB has also established that each of the elements identified by the *E.C.—Hormones* Panel must also meet a specificity requirement.<sup>34</sup> The *Japan—Measures Affecting Importation of Apples* Appellate Body concluded that Japan's risk assessment, which evaluated all possible modes of importation of Fire Blight,<sup>35</sup> was not

<sup>31.</sup> See Panel Report, E.C. Measures, supra note 21, ¶ 8.98 (citing the language of Article 5.1 of the SPS Agreement as being determinative of the requirements for a valid risk assessment).

<sup>32.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 184 (concluding that the term probability would indicate a "higher threshold of potentiality" than implied by the use of "possibility" in the SPS Agreement, as it adds a "quantitative dimension to the notion of risk"). But see Appellate Body Report, Australia—Measures Affecting Importation of Salmon, ¶ 123, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter Appellate Report, Australia—Salmon] (revisiting the Appellate Body's conclusion from E.C.—Hormones that the term probability should be understood as degrees of likelihood, and concluding that the term "likelihood" connotes probability).

<sup>33.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  186 (concluding that a panel is authorized to determine merely whether a disputed SPS measure is based on a valid risk assessment, which means the panel's authority extends only to determining "whether [the] measure is sufficiently supported . . . by the risk assessment"). A panel does not have the authority to require that a risk assessment contain indications of the "magnitude of risk" involved. Id.

<sup>34.</sup> See Appellate Body Report, Japan—Measures Affecting Importation of Apples, ¶¶ 202-03, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter Appellate Report, Japan—Apples] (reviewing the section of the analysis in E.C.—Hormones in which the Appellate Body concluded that it is insufficient for a Member to evaluate the potential adverse health effects of a contaminant in general, but rather must evaluate the potential for adverse affects specific to the manner of the contaminant and the precise method of exposure).

<sup>35.</sup> See Panel Report, Japan—Measures Affecting the Importation of Apples, ¶¶ 2.1-6, WT/DS245/R (July 15, 2003) [hereinafter Panel Report, Japan—Apples] (stating that Fire Blight is a plant disease that affects immature apples, explaining the history of its spread from the United States to other countries, and noting how the disease affects apples).

specific enough to support sanitary measures against apples, since apples were merely one mode of importation.<sup>36</sup> The *E.C.—Hormones* Appellate Report similarly concluded that the E.C.'s risk assessment was not specific because its studies did not evaluate the potential risk based on the specific use of hormones as growth promoters.<sup>37</sup>

#### C. MEMBERS MUST DEMONSTRATE A RATIONAL AND OBJECTIVE RELATIONSHIP BETWEEN RISK ASSESSMENT AND SPS MEASURES

Once a Member establishes that a valid risk assessment exists, the Member must demonstrate that its measure is *based on* that risk assessment.<sup>38</sup> The key to whether an SPS measure is "based on" a risk assessment is that the measure is "sufficiently supported or reasonably warranted by the risk assessment."<sup>39</sup> Specifically, a reasonable relationship requires a finding that "sufficient" scientific evidence supports the SPS measure.<sup>40</sup> The *Japan—Measures* 

<sup>36.</sup> See Appellate Report, Japan—Apples, supra note 34,  $\P$  203 (suggesting that Japan could not have asserted that a more specific risk assessment would find the same results because the risk of entry of Fire Blight varies according to the different modes of contamination).

<sup>37.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶¶ 199-200 (concluding that the studies the E.C. cited were not specific enough because they failed to consider the specific risk that might arise from human consumption of meat and meat products containing residues of the prohibited hormones). Those studies merely evaluated the general "carcinogenic potential of entire categories of hormones." Id.

<sup>38.</sup> See id. ¶¶ 192-94 (rejecting the Panel's conclusion that the term "based on" requires that SPS measures strictly conform to their supporting risk assessments).

<sup>39.</sup> See id. ¶ 186 (affirming the panel's conclusion that a degree of uncertainty will always exist because science can never prove to an "absolute certainty that a given substance will not ever have adverse health effects" (emphasis in original)). The Appellate Body stated unequivocally that "this theoretical uncertainty" is not the type of risk that Members should evaluate in a valid risk assessment. Id. However, the Appellate Report rejected the Panel's assertion that a valid assessment of risk is limited to only what is scientifically measurable in a laboratory. Id. ¶ 187. The Appellate Report concluded that "risk in human societies as they actually exist" is an essential element that may be included in a valid risk assessment. Id.

<sup>40.</sup> See Appellate Body Report, Japan—Measures Affecting Agricultural Products II, ¶ 73, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter Appellate Report, Japan—Agricultural Products] (concluding that the term 'sufficient' requires an "adequate relationship between two elements").

Affecting Agricultural Products II Appellate Body affirmed the Panel's conclusion that Japan failed to provide sufficient evidence to conclude that different varieties of the same product required individualized testing where one test was sufficient for all varieties of the same product.<sup>41</sup> Members must demonstrate sufficient scientific evidence by showing a rational or objective relationship between the SPS measures and the risk assessment conclusions.<sup>42</sup>

The DSB determines the existence of such a rational or objective relationship on a "case-by-case basis." In its evaluation, the DSB focuses on whether a Member's risk assessment "takes into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods," as well as "risks arising from failure to comply with the requirements of good veterinary practice . . ., [and] risks arising from difficulties of control, inspection and enforcement of . . . good veterinary practice." This does not mean that a Member must undertake the study on its own, or that the Member must obtain an assessment from

<sup>41.</sup> See id. ¶ 84 (noting that Article 2.2 requires "a rational and objective relationship between the SPS measure and the scientific evidence"). Varietal testing is a procedure by which exporters of certain agricultural products to Japan may demonstrate effective quarantine providing the same level of protection against the presence of the codling moth, something of quarantine significance to Japan, which would be achieved by a prohibition on imports of the products at issue. Id. ¶ 2; see also Panel Report, Japan—Measures Affecting Agricultural Products II, ¶ 8.42 WT/DS76/R (Oct. 27, 1998) [hereinafter Panel Report, Japan—Agricultural Products] (acknowledging that varietal differences do not impact the effective quarantine methods).

<sup>42.</sup> See Appellate Report, Japan—Agricultural Products, supra note 40, ¶¶ 72-85 (concluding that Japan's varietal testing requirement for imported apples, cherries, nectarines and walnuts is not rationally supported by sufficient scientific evidence).

<sup>43.</sup> See id. ¶ 84 (affirming that the quality and quantity of the scientific evidence are key elements in the evaluations, which must be made with a view towards the "particular circumstances of the case").

<sup>44.</sup> Appellate Report, *E.C. Measures*, *supra* note 22, ¶ 205 (concluding that the Panel erred in rejecting the use of non-scientific variables in a valid risk assessment, including the non-compliance with good veterinary practice when administering hormones during the meat production process); *see also* SPS Agreement, *supra* note 13, arts. 5.2-5.3 (stating that Members may also take into account certain ecological, environmental, and "relevant economic" factors).

an independent body.<sup>45</sup> Nor does this mean that a risk assessment arriving at an alternative conclusion than other similar studies is per se invalid.<sup>46</sup> In fact, under Article 5.7 of the SPS Agreement, Members may base their measures on "available pertinent information" when there is a lack of scientific evidence.<sup>47</sup> The determinative factor is simply whether a rational and objective relationship exists between the risk assessment and the SPS measure that it supports.<sup>48</sup>

#### D. THE SPS AGREEMENT PROVIDES AN EXCEPTION TO THE GENERAL REQUIREMENT THAT MEMBERS BASE THEIR SPS MEASURES ON A VALID RISK ASSESSMENT

According to the Panel Report in Australia—Measures Affecting Importation of Salmon, Article 5.7 is the sole exception to the general rule that Members must base their SPS measures on a valid risk assessment.<sup>49</sup> Additionally, the exception permits only a provisional deviation from the general rule.<sup>50</sup> The Australia—Salmon

<sup>45.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 190 (noting that a Member may rely on a risk assessment produced by another Member when evaluating whether to adopt a particular SPS measure). The Appellate Body also dismissed, as an error of law, the Panel's indication that Article 5.1 contains a procedural requirement that mandates that Members take risk assessments into account when enacting the SPS measures. Id. ¶¶ 188-89.

<sup>46.</sup> See id. ¶ 194 (stating that existing differences in opinion on the level of risk is merely an indication of a valid scientific uncertainty).

<sup>47.</sup> See SPS Agreement, supra note 13, art. 5.7 (indicating that the SPS Agreement permits provisional adoption of such measures in an effort to reach a more objective risk assessment).

<sup>48.</sup> See discussion infra Part II.A.2 (arguing that there is a rational and objective relationship between the E.C. risk assessment and Council Directive 2003/74).

<sup>49.</sup> See Panel Report, Australia—Measures Affecting Importation of Salmon, ¶ 8.57, WT/DS18/R (June 12, 1998) [hereinafter Panel Report, Australia—Salmon] (holding that the phrase "as appropriate to circumstances" within Article 5.1 of the SPS Agreement does not provide an exception to the general rule of basing SPS measures on a risk assessment, but merely refers to the methods by a which a risk assessment is conducted).

<sup>50.</sup> See id. (concluding that because Australia enacted the measure at issue more than twenty years prior to the hearing of this case, Australia could not rely on Article 5.7, and the SPS measure could not be considered to be a provisional measure).

Panel concluded that Australia could not validate its prohibition on the importation of fresh chilled or frozen salmon under Article 5.7's exemption.<sup>51</sup> Australia had its SPS measures in place for more than twenty years and had clearly not maintained them as provisional.<sup>52</sup>

The Japan—Agricultural Products II Appellate Body acknowledged Article 5.7 as a "qualified exemption" and provided that Members must first meet four requirements: (1) the relevant scientific evidence must be insufficient; (2) the SPS measures must be based on the available scientific information; (3) Members must continue to gather information to conduct "a more objective risk assessment"; and (4) Members must review the measure in light of new information "within a reasonable period of time." The DSB concluded that Japan was not seeking to obtain more information to produce a more objective risk assessment within a reasonable period of time, as the SPS Agreement requires when invoking Article 5.7.55

The E.C.—Hormones Appellate Body concluded that the E.C. did not base its SPS measures on a valid risk assessment, within the meaning of Article 5.1, because the E.C. failed to produce reports finding a risk to human health.<sup>56</sup> Because they were not based on a

<sup>51.</sup> See id. (rejecting Australia's contention that Article 5.1 provided an exception to the general rule that SPS measures must be based upon a valid risk assessment demonstrating sufficient scientific evidence).

<sup>52.</sup> Id. ¶ 8.57.

<sup>53.</sup> See Appellate Report, Japan—Agricultural Products, supra note 40, ¶ 80 (explaining that Article 5.7 operates as an exception to Article 2.2's requirement that countries cannot adopt SPS measures without "sufficient scientific evidence").

<sup>54.</sup> Id. ¶ 89 (stating that if a Member fails to meet one of the requirements the DSB will find the SPS measure inconsistent with the SPS Agreement). These requirements are "cumulative in nature" and must be considered as having equal importance. Id.

<sup>55.</sup> See Panel Report, Japan—Agricultural Products, supra note 41, ¶¶ 8.59-8.60 (acknowledging that Japan had collected data from importing countries, and that such information is applied validly in this respect, but relying on this information alone did constitute total compliance with Article 5.7); see also Appellate Report, Japan—Agricultural Products, supra note 40, ¶ 92 (maintaining that "the information collected by Japan did not 'examine the appropriateness'" of the varietal testing and assess whether varietal testing produces a more effective method by which to prevent the importation of the codling moth).

<sup>56.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 208. Furthermore, the E.C. in fact provided evidence only as to the administration of the disputed hormones that is conducted while observing good veterinary practice and did not

valid risk assessment, the E.C. SPS measures were inconsistent with the requirements of Article 5.1 of the SPS agreement.<sup>57</sup> Consequently, because the SPS measures were not consistent with Article 5.1, they were also inconsistent with Article 3.3.<sup>58</sup> The DSB did not undertake an assessment of the SPS measures under Article 5.7 because the E.C. specifically stated that Council Directive 96/22/EC was not a provisional measure.<sup>59</sup>

# E. THE E.C. SEEKS TO COMPLY WITH THE WTO WHILE MAINTAINING ITS PROHIBITION OF GROWTH-PROMOTING HORMONES

The E.C. adopted Council Directive 2003/74/EC on October 14, 2003 in an effort to comply with the DSB.<sup>60</sup> The preamble of the Directive carefully puts forth the E.C.'s rationale for maintaining the prohibition on certain growth-promoting hormones.<sup>61</sup>

- 59. See Panel Report, E.C. Measures, supra note 21, ¶ 8.249.
- 60. See Council Directive 2003/74, pmbl. ¶ 3, 2003 O.J. (L 262) 17 (EC) [hereinafter Directive 2003/74] (indicating that Directive 2003/74 is the result of a concerted effort by the E.C. to produce a "complementary risk assessment," the impetus for which was the outcome of the initial E.C.—Hormones case); see also Press Release, European Comm'n, EU Complies with WTO Ruling on Hormone Beef and Calls on USA and Canada to Lift Trade Sanctions (Oct. 15, 2003), http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/1393&format=HTML&aged=1&language=EN&guiLanguage=en [hereinafter Press Release, EU Complies with WTO Ruling on Hormone Beef] (quoting the E.U. Trade Commissioner as stating, "[t]oday's move shows that we are fully committed to abiding by our WTO obligations. . . . I now call on the United States and Canada to lift their trade sanctions against the E.U.").
- 61. See Directive 2003/74, supra note 60, pmbl. ¶ 13 (declaring that the measures "are necessary to achieve the chosen level of health protection"); see also

<sup>&</sup>quot;provid[e] an assessment of the potential adverse effects related to non compliance" with good veterinary practices. *Id.*  $\P$  207.

<sup>57.</sup> See id.  $\P$  208 (noting that the only evidence the E.C. provided was actually contrary to the SPS measures).

<sup>58.</sup> See id. ¶ 177 (affirming that the purpose of Article 3 is to dovetail the SPS measures of the Members of the agreement while allowing the Members to retain their rights and duties to "protect the life and health of their people"); see also id. ¶ 209 ("[A]n SPS measure to be consistent with Article 3.3, has to comply with, inter alia, the requirements contained in 5.1."). The requirements of a risk assessment supported by "sufficient scientific evidence" under Articles 5.1 and 2.2 are necessary to maintain this balance between the individual rights of the Members and shared interests created by the SPS Agreement. Id. ¶ 177.

The fundamental problem with the E.C.'s implementation of its measures prior to Council Directive 2003/74/EC was not that the E.C. failed to cite scientific evidence.<sup>62</sup> Rather, the evidence the E.C. cited demonstrated little, if any, support for the conclusion that its measures were justified.<sup>63</sup> The E.C. now claims that scientific evidence supports the implementation of Directive 2003/74/EC.<sup>64</sup>

The crux of the E.C. claim is that current scientific evidence demonstrates an identifiable risk to humans from the consumption of hormone residues from treated meats, particularly those treated with Oestradiol  $17\beta$ . The E.C. also asserts that adverse health effects can

Press Release, EU Complies with WTO Ruling on Hormone Beef, *supra* note 60 (emphasizing that public health and consumer protection are the E.C.'s top priorities when considering food safety and that its approach is "guided by independent scientific advice").

- 62. See Panel Report, E.C. Measures, supra note 21, ¶¶ 8.108-09 (listing the variety of reports upon which the E.C. relied in its arguments, including reports from scientific bodies that are both a part of and independent from the European Union). The Panel also noted that the E.C. referenced several articles and opinions from individual scientists that were relevant to the issue of using hormones as growth promoters in meat intended for consumption. Id. The Panel accepted the scientific nature of these reports and, in fact, made the assumption that they collectively met the requirements for demonstrating the existence of a risk assessment. Id. ¶ 8.111.
- 63. See id. ¶ 8.124 (concluding that none of the reports, articles and opinions referenced by the E.C. to support its conclusion that the prohibition of meat and meat products produced with growth hormones is justified demonstrates an "identifiable risk" to human health from the consumption of such meats and meat products); see also id. ¶ 8.139 (noting the E.C. argument that risks do arise from the disputed hormones in the context of the "nature and mode of action of the hormones; . . . the action of metabolites; . . . the action of combinations (or cocktails) of hormones and from multiple exposure of humans; . . . problems related to detection and control of hormones; . . . [and] the administration and use of hormones"). The Panel concluded, however, that the E.C. failed to provide any evidence to contradict the finding that all of these risks are alleviated through the use of good veterinary practices. Id. ¶ 8.142.
- 64. See Press Release, E.U. Complies with Hormone Beef Ruling, supra note 60 (observing that the E.U. initiated the process to enact the new Directive only after the Scientific Committee on Veterinary Measures Relating to Public Health concluded there were in fact certain health risks to humans from the consumption of meat produced with growth promoting hormones).
- 65. See Directive 2003/74, supra note 60, pmbl. ¶¶ 8, 10 (suggesting that the determination to maintain the prohibition as to all six hormones and expand the prohibition against Oestradiol 17 $\beta$  is supported by a full scientific evaluation of the hormones within the 1999 SCVPH report). The Directive also notes that the

be envisaged for the other five hormones,<sup>66</sup> even though there is insufficient evidence to quantify the possibility of risk to human health.<sup>67</sup>

In addition to maintaining the restrictions on all of the hormones in dispute, the new Directive actually increases the restriction on the use of Oestradiol  $17\beta$ . Accordingly, the Directive continues to establish a level SPS protection higher than that of relevant international standards, which currently do not restrict the use of most of the hormones in dispute. Article 3.3 of the SPS Agreement does in fact allow Members to enact SPS measures that establish a higher level of SPS protection than would be achieved by measures

conclusions of the 1999 SCVPH report were reviewed twice, once in 2000 and once in 2002, after the Committee became aware of new scientific information. Id.  $\P$  8. In both reviews the committee affirmed the findings of the 1999 SCVPH report. Id.

- 66. See id. ¶ 7 (indicating that it is impossible to assess the risk to public health arising from these hormones based upon the consideration of epidemiological findings and the current scientific understanding of the intrinsic properties of the hormones).
- 67. See 1999 SCVPH REPORT, supra note 16, at 72-73 (suggesting that the insufficiency of available data stems from a general "lack of understanding of critical development periods" in humans, as well as the "uncertainties in the estimates of endogenous hormone production rates and metabolic clearance capacity").
- 68. See Directive 2003/74, supra note 60, pmbl. ¶ 6 (stating that the scientific evidence demonstrates that the scientific community should recognize Oestradiol  $17\beta$  as a cancer-causing agent, "as it exerts both tumor-initiating and tumor-promoting effects . . ."). For other hormones, Members must apply the prohibitions on a provisional basis. *Id.* art. 3. The Directive sets a deadline of October 14, 2004 for the termination of all usages of Oestradiol  $17\beta$ . *Id.* art. 2(1).
- 69. See Panel Report, E.C. Measures, supra note 21, ¶ II.11 (explaining that the SPS Agreement recognizes the standards set by the CODEX Alimentarius Commission as the relevant international standards by which Members should evaluate their food safety measures). The CODEX Alimentarius Commission is a joint Food and Agriculture Organization/World Health Organization ("FAO/WHO") commission charged with developing food safety standards in order to protect consumer health and promote fair trade practices. Id. ¶ II.12; see also Food and Agriculture Organization of the United Nations, CODEX Veterinary Drug Residues in Food(Sept. http://faostat.fao.org/faostat/collections?subset=FoodQuality [hereinafter CODEX Alimentarius] (listing five of the six hormones at dispute in the E.C.—Hormones case and indicating that adverse health effects from consumption of residues from these hormones is *unlikely*, assuming that good veterinary practices are in place).

based on the relevant international standards, guidelines or recommendations."<sup>70</sup> However, the SPS Agreement permits such measures only where there is scientific justification,<sup>71</sup> a requirement that the Appellate Report further determined requires a valid risk assessment under Article 5.1.<sup>72</sup> The E.C. maintains that sufficient scientific evidence supports the new Directive, as reported in a 1999 study by the Scientific Committee on Veterinary Measures Relating to Public Health ("SCVPH"),<sup>73</sup> and in two follow-up reports by the same committee confirming the continued validity of the results in the 1999 report.<sup>74</sup>

- 71. See Laurent A. Ruessmann, Putting the Precautionary Principle in Its Place: Parameters for the Proper Application of a Precautionary Approach and the Implications for Developing Countries in Light of the DOHA WTO Ministerial, 17 AM. U. INT'L L. REV. 905, 927 (2002) (remarking that the use of Article 3.3 is permitted only where a Member deems it necessary to achieve its determined level of appropriate SPS protection). Ruessmann concludes that Article 3.3 recognizes the prerogative of Members to adopt what they consider to be the appropriate levels of protection. Id.
- 72. See supra notes 25-26 and accompanying text (describing the conclusions of the Appellate Body, which held that to meet the requirements of Article 3.3, Members must adhere to the requirements of Article 5).
- 73. See 1999 SCVPH REPORT, supra note 16; European Comm'n, Scientific Committees: Food Safety, http://europa.eu.int/comm/food/committees/scientific/index\_en.htm (last visited Nov. 7, 2005) (explaining that the European Commission appoints the SCVPH in accordance with Commission Decision 97/579/EC); see also European Comm'n, Scientific Committee on Veterinary Measures Relating to Public Health: Mandate, http://europa.eu.int/comm/food/fs/sc/scv/index\_en.html (last visited Nov. 7, 2005) (indicating that the SCVPH's specific mandate is to answer "scientific and technical questions concerning consumer health and food safety, and relating to zoonotic, toxicological, veterinary and notably hygiene measures applicable to the production, processing, and supply of food of animal origin").
- 74. See Directive 2003/74, supra note 60, pmbl. ¶8 (presenting the process that the E.C. took in evaluating the scientific risks to humans from the consumption of the cited growth hormones, which included reviewing all revised reports provided by the various scientific bodies); see also supra note 64 and accompanying text

<sup>70.</sup> SPS Agreement, supra note 13, art. 3.3 (noting also that such measures must still maintain consistency with other relevant provisions of the Agreement); see also Kevin C. Kennedy, Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions, 55 FOOD & DRUG L.J. 81, 96, 98 (2000) (commenting on the Appellate Body's recognition in Japan—Agricultural Products II that "Article 3.3 . . . was not written into the SPS Agreement . . . [to allow] for otherwise inconsistent" measures, and therefore, measures must be consistent with the provisions of Article 5 when Members resort to Article 3.3 justification).

The E.C. requested the SCVPH's services subsequent to the DSB's 1998 ruling, when seeking further scientific evidence to establish justification for its measures. The E.C. invited the SCVPH to evaluate the potential risks to human health from the consumption of meat containing residues from the individual growth hormones its SPS measures prohibit. The report concluded that there is an identifiable risk of increased exposure to such residues, and consequently an increased potential for risks to human health.

(discussing the announcement of Directive 2003/74/EC and the Europeans' belief that the Directive brings the hormone measures into compliance with the DSB's rulings and recommendations).

- 75. See Press Release, European Comm'n, Commission Proposes Revised Legislation Banning Hormones as Growth Promoters (May 24, 2000), http://europa.eu.int/comm/dgs/health\_consumer/library/press/press55\_en.html [hereinafter Press Release, Legislation Banning Hormones] (conveying that in addition to the initial request for the SCVPH to conduct a study of the potential for adverse health affects from the consumption of hormone residues in meats, the E.C. also asked the committee to review its findings in light of new information that arose after the 1999 report).
- 76. See 1999 SCVPH REPORT, supra note 16, at 1 (implying that part of the SCPVH's mandate was to evaluate whether it was necessary for the E.C. to revise its previous risk assessments concerning the affects of growth hormone on human health in light of new scientific evidence). SCPVH's mandate went beyond evaluating basic scientific principles about the hormones themselves, extending to an evaluation of the interaction of residues from the hormones and providing a better "understanding of the critical role of imprinting in determining subsequent development outcomes, the role of hormones in perinatal development, . . . [and] the increase in a number of hormonally mediated, . . . autoimmune and allergic diseases." Id. at 2.
- 77. See id. at 36 (stating that consumption of Oestradiol 17β-treated beef results in an increased exposure to oestrogens of up to 84 ng per person per day). The normal rate of intake is 6.8 ng per person per day. Id. The excess exposure to testosterone from the consumption of treated beef can reach as high as 189 ng per person per day. Id. at 48. This represents thirty-three percent of the acceptable daily intake established by the FDA. Id. Consumption of beef treated with progesterone results in an increased exposure level of between 64 and 467 ng per person per day. Id. at 52. Any exposure to trenbolone acetate and melengestrol acetate would be in excess of normal exposure because these hormones do not occur naturally. Id. at 55, 67. Consumption of 500 g of beef per person per day can result in consumption of Zeranol as much as 128 ug per person per day, almost four times the acceptable daily intake. Id. at 64.
- 78. See id. at 73 (outlining the envisaged adverse health affects resulting from the increased exposure to the studied hormones, which include increased risk of cancer and developmental and neurobiological problems).

These findings prompted the E.C. to maintain its prohibition by enacting a new Directive.<sup>79</sup>

F. THE UNITED STATES REFUSES TO WITHDRAW ITS SUSPENSION OF CONCESSIONS, ASSERTING THAT THE NEW COUNCIL DIRECTIVE FAILS TO BRING THE E.C. INTO COMPLIANCE WITH THE DSB RULINGS AND RECOMMENDATIONS

The E.C. promptly notified the DSB and the United States in October, 2003 that Directive 2003/74/EC brought the E.C. measures into compliance with the DSB rulings and recommendations.<sup>80</sup> Consequently, the E.C. expected the United States to withdraw the suspension of concessions.<sup>81</sup> However, the United States steadfastly rejected the notion that the new E.C. Directive did anything to bring

<sup>79.</sup> See Press Release, Legislation Banning Hormones, supra note 75 (emphasizing the importance of the findings of the 1999 SCVPH report and the follow-up review in bolstering the E.C.'s commitment to maintaining the prohibition on the use of growth hormones in consumable meats and the importation of such meats).

<sup>80.</sup> See Communication from the European Communities, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/22 (Oct. 28, 2003) [hereinafter EC Communication 22] (informing the DSB that the E.C. had taken steps to produce a valid risk assessment in accordance with the DSB's recommendations and rulings in E.C.—Hormones, and that the E.C. considered its adoption of Directive 2003/74/EC as bringing the hormone measures into full compliance with those rulings and recommendations); Dispute Settlement Body, Minutes of Meeting Held in the Centre William Rappard on November 7, 2003, ¶ 28, WT/DSB/M/157 (Dec. 18, 2003) [hereinafter Nov. 7, 2003 DSB Meeting Minutes] (stating that the E.C. raised the issue of its compliance with the DSB's rulings at the DSB's meeting and sought a response from the U.S. and Canadian delegations); see also supra notes 60-64 and accompanying text (discussing the procedures that the E.C. took prior to enacting Directive 2003/74/EC and the E.C.'s belief that these measures provided the necessary support required in order for the United States and the DSB to conclude that the E.C. met its obligations under the SPS Agreement). See generally Directive 2003/74, supra note 60, art. 11(a) (suggesting that the E.C. did not secure passage of the Directive until 2003); Press Release, Legislation Banning Hormones, supra note 75 (noting that the initial proposal for the revised policy occurred in May of 2000).

<sup>81.</sup> See EC Communication 22, supra note 80 (indicating that with the publication and entry into force of Directive 2003/74/EC the suspension of concessions by the United States and Canada, "[was] no longer justified"); see also Nov. 7, 2003 DSB Meeting Minutes, supra note 80, ¶ 28 (stating that the E.C. argued at a DSB meeting that the United States and Canada should withdraw the suspension of concessions in accordance with Article 22.8 of the DSU).

the SPS measures into compliance.<sup>82</sup> In reaction to the immediate U.S. dismissal of the Directive, the E.C. brought the matter before the WTO in November 2004,<sup>83</sup> claiming the U.S. action was inconsistent with GATT 1994 Articles I and II and DSU Articles 23.1, 23.2(a), 22.8, and 21.5.<sup>84</sup>

# 1. The United States Has Granted Most Favored Nation Status to the E.C. and Must Not Deviate from the Schedule of Concessions Unless Authorized to Do So

Because the United States has granted most favored nation status to the E.C. under Article I of GATT 1994, the DSB will deem the continued suspension of concessions inconsistent with Articles I and II of GATT 1994, unless the WTO authorizes the suspension.<sup>85</sup> The

<sup>82.</sup> See Nov. 7, 2003 DSB Meeting Minutes, supra note 80,  $\P$  30 (observing that it had been almost six years since the DSB recommended that the E.C. bring its SPS measures into compliance with WTO obligations and the United States did not believe that the adoption of Directive 2003/74/EC could be considered to be in full compliance with the DSB's rulings and recommendations). The United States indicated that it viewed the new Directive as merely a re-labeling of the original Directive, which was found to be inconsistent with the SPS Agreement. *Id*.

<sup>83.</sup> See Request for Consultation by the European Communities, United States—Continued Suspension of Obligations in the E.C.-Hormones Dispute, WT/DS320/1 (Nov. 10, 2004) [hereinafter E.C. Request for Consultation] (outlining the history of the dispute, the action taken by the E.C. to bring its measures into compliance, and the E.C.'s subsequent unilateral action).

<sup>84.</sup> See Request for the Establishment of a Panel by the European Communities, United States—Continued Suspension of Obligations in E.C.-Hormone Dispute, WT/DS320/6 (Jan. 14, 2005) [hereinafter E.C. Panel Request] (asserting that the United States refused an agreement for resolving the current dispute and requesting that the DSB address the E.C.'s request for the formation of a panel at the DSB meeting on January 25, 2005).

<sup>85.</sup> See Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, WTO Agreement, Apr. 15, 1994, Annex 1A, art. 1(a), Legal Instruments — Results of the Uruguay Round, 33 I.L.M. 1125, 1154 (1994) [hereinafter GATT 1994] (annexing the provisions of the General Agreement on Tariffs and Trade 1947 into GATT 1994, with certain amendments and modifications). Members must not accord less favorable treatment to other Members of GATT 1994 than that provided for in the relevant parts of the Schedule of Concessions. Id. art. 2, ¶ 1(a); see also World Trade Org., Goods Schedules: Members' Commitments (Jan. 13, 2003), http://www.wto.org/english/tratop\_e/schedules\_e/goods\_schedules\_e.htm (explaining that each schedule of concessions is divided into four parts). The first two parts are most relevant to the beef hormone dispute. Id. The first part sets the applicable duty rates for trade

DSB authorized the United States to suspend concessions in 1999,<sup>86</sup> after the E.C. failed to bring its SPS measures into compliance by the fifteen month deadline the WTO Arbitration Body set in 1998.<sup>87</sup>

Despite the E.C.'s assertions to the contrary, 88 the United States maintains that no E.C. actions have changed this authorization. 89 The

generally among the Members to the agreement. *Id.* The second part of the schedule sets out the duty rates to be applied among those nations receiving most favored nation treatment. *Id.*; DSU, *supra* note 22, app. 1 (indicating that the Agreement Establishing the World Trade Organization is covered under the DSU).

- 86. See Decision by the Arbitrators, European Communities—Measures Concerning Meat and Meat Products (Hormones), Annex II, WT/DS26/ARB (July 12, 1999) [hereinafter Decision by the Arbitrators, Hormones] (listing precisely the proposed items on which the United States could impose retaliatory tariffs until the E.C. brought its measures into compliance with the DSB rulings and recommendations).
- 87. See Award of the Arbitrator, European Communities-Measures Concerning Meat and Meat Products (Hormones), ¶ 48, WT/DS26/15 (May 29, 1998) (concluding that fifteen months would be a reasonable amount of time for the E.C. to bring its measures into compliance with the DSB rulings and recommendations). The Arbitration panel ruled that the fifteen months would run from February 13, 1998, the date the DSB adopted the Panel and Appellate Body Reports. Id.; see also Communication from the European Communities, European Communities—Hormones, WT/DS26/18 (May 12, 1999) [hereinafter E.C. Communication 18, E.C.—Hormones] (confirming that the E.C. informed the DSB on May 12, 1999, the day before the deadline to comply with the rulings and recommendations of the DSB, that it was not in a position to lift the existing ban on growth promoting hormones); Recourse by the United States to Article 22.2 of the DSU, European Communities—Measures Concerning Meat and Meat Products (Hormones), at 1-2, WT/DS26/19 (May 18, 1999) [hereinafter U.S. Recourse to Article 22.2, E.C.—Hormones] (observing that the United States subsequently submitted a request for authorization to suspend concessions to the E.C. on May 17, 1999). The United States claimed that the total impairment or nullification suffered as a result of the E.C. measures was \$202 million, and, therefore, it sought to suspend concessions in the same amount per year until the E.C. measures were brought into compliance with its WTO obligations. Id.
- 88. See Press Release, E.U. Requests WTO to Confirm No Justification, supra note 7, (stating that the E.C. eliminated the "deficiencies" in its previous hormone policy by basing the new Directive on a complete scientific risk assessment conducted between 1999 and 2002).
- 89. See generally GLOBAL AGRICULTURE INFORMATION NETWORK, USDA FOREIGN AGRICULTURAL SERVICE, GAIN REPORT NO. E23193, EUROPEAN UNION TRADE POLICY MONITORING: EUROPEAN UNION BANS ESTRADIOL, FOREIGN AGRICULTURAL SERVICE (2003), http://www.fas.usda.gov/gainfiles/200311/145986807.pdf. [hereinafter GAIN REPORT I] (discussing Directive 2003/74/EC and the possibility that the Directive meets the DSB's recommendations and rulings to bring the E.C. in compliance with WTO

U.S. action clearly illustrates its contention that the E.C. Directive does not bring the E.C. measures into full compliance with the DSB. 90 However, the E.C. insists the United States cannot make this determination unilaterally. 91 Rather, the E.C. claims that the United States must resort to the DSB for such a determination. 92

The DSB will resolve this particular element of the dispute according to the rules and procedures that govern the suspension of concessions as provided in the DSU.<sup>93</sup> DSU Article 23.1 grants Members the right to seek redress for violations of WTO obligations.<sup>94</sup> However, Article 23.1 also requires that Members who seek to redress violations abide by these rules and procedures.<sup>95</sup>

obligations). The report states that the Directive still fails to meet the standards for a valid risk assessment as outlined by the DSB in *E.C.—Hormones*. *Id.* at 2. The report also claims that the SCVPH reports relied on by the E.C. do little more than "discuss potential problems with earlier risk assessments" and provide a collection of comments on seventeen "narrowly selected studies." *Id.* The report determines that there are no conclusions "based on modern risk assessment principles." *Id.* 

- 90. See Nov. 7, 2003 DSB Meeting Minutes, supra note 80, ¶ 29 (relaying the U.S. allegation that the E.C. measures are still not "based on science," and that "no increased health risk had ever been associated with the consumption of meat from animals treated with growth-promoting hormones"). The United States specifically cited the joint FAO/WHO Expert Committee on Food Studies which found that the range of consumption of the questioned meat products presented no danger to human health, as there was a large margin of safety for the consumption of such products. Id.
- 91. See E.C. Request for Consultation, supra note 83, at 2-3 (alleging that the United States acted unilaterally by failing to initiate dispute settlement proceedings in accordance with Article 21.5 of the DSU to determine whether the new E.C. Directive was inconsistent with the E.C.'s WTO obligations).
- 92. See id. at 2 (stating that the U.S. action did not comply with GATT 1994 Articles I and II, and Articles 23.1, 23.2(a), 23.2(c), 22.8, and 21.5 of the DSU); see also Press Release, E.U. Requests WTO to Confirm No Justification, supra note 7 (quoting E.U. Trade Commissioner Pascal Lamy as stating that the E.U. had "put in place revised legislation based on a thorough and independent scientific risk assessment" and if the United States believed that the new legislation failed to comply with the DSB's rulings and recommendations, then the proper course of action was to suspend its sanctions and bring the matter before the DSB, according to the relevant rules of procedure).
- 93. See generally DSU, supra note 22, Annex 2, art. 3(7) (placing great emphasis on the ability of Members to resolve disputes amongst themselves, but establishing clear procedures for situations in which Members are not able to arrive at a mutually agreeable understanding).
- 94. See Susana H. Puente, Section 301 and the New WTO Dispute Settlement Understanding, 2 ILSA J. INT'L & COMP. L. 213, 221-22 (1995) (suggesting that

Similar to the *E.C.—Hormones* dispute, in *U.S.—Certain E.C. Products*, the E.C. brought a claim against the United States for its continued suspension of concessions against various European imports. The DSB authorized the United States to suspend concessions after the DSB concluded that certain E.C. measures were inconsistent with its WTO obligations. Importantly, the *U.S.—Certain E.C. Products* Panel determined that the term 'redress' suggests Member action taken in response to either a *perceived* violation or an actual DSB-*determined* violation. The Panel ultimately concluded that the United States acted inconsistently with its WTO obligations when it failed to abide by the DSU and acted unilaterally to redress a mere perceived violation.

The U.S.—Section 301 Trade Act Panel further emphasized that DSU Article 23.2(c) specifically includes a prohibition on Members making unilateral determinations of inconsistency prior to exhausting

- 95. See Panel Report, United States—Section 301-310 of the Trade Act of 1974, ¶ 7.43, WT/DS152/R (Dec. 22, 1999) [hereinafter Panel Report, U.S.—Section 301 Trade Act] (stating how Article 23.1 provides a "general duty of a dual nature," which grants Members recourse within the DSU's multilateral process when seeking the "redress of a WTO inconsistency"). This general duty requires that the Members make use of the DSU settlement system to the exclusion of all other systems. Id.
- 96. See Panel Report, United States—Import Measures on Certain European Community Products from the European Communities, ¶ 1.4, WT/DS165/R (July 17, 2000) [hereinafter Panel Report, U.S.—Certain E.C. Products] (indicating that the E.C. brought the matter before the DSB because it alleged that the United States unilaterally imposed greater sanctions against the E.C. than the arbitrators had authorized).
- 97. See id.  $\P$  2.16 (stating that the arbitrators gave the United States authorization to suspend concessions on certain E.C. products in the amount of \$191.4 million per year).
- 98. See id. ¶¶ 6.22, 6.26 (concluding that the imposition of contingent liabilities on certain imports constituted the imposition of debts on those imports, also placing upon them obligations because the additional liabilities indicated that the United States was "seeking to redress,' what it *perceived* to be a WTO violation" (emphasis added)).
- 99. See id. ¶¶ 7.1(a), 7.1(b), 7.1(d) (holding that when the United States initiated retaliatory measures it was seeking to "redress a WTO violation," which therefore brought the measure within the scope of Article 23.1, which prohibits unilateral action).

the requirements of Article 23.1 impose a "positive obligation" upon WTO Members to utilize the DSU process to resolve disputes).

DSU procedures.<sup>100</sup> There the E.C. brought a dispute before the DSB, claiming that provisions in the United States Trade Act of 1974, which provide for the possibility of U.S. unilateral action, were inconsistent with the DSU.<sup>101</sup> Though the Panel concluded that the language of Section 304 in particular was facially inconsistent with the DSU,<sup>102</sup> the section did not constitute unilateral action because it provided an exception for matters covered by the WTO.<sup>103</sup>

# 2. The DSB Grants Authorization to Suspend Concessions for Temporary Purposes Only

Whether the DSB will consider a Member's actions to be unilateral depends in part upon whether the DSB authorized the action taken.<sup>104</sup> After the E.C. failed to comply with the DSB within

<sup>100.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96,  $\P$  6.37-6.38 (concluding that "suspension of concessions . . . should be used as a last resort" and may only be undertaken with authorization from the DSB).

<sup>101.</sup> See Panel Report, U.S.—Section 301 Trade Act, supra note 95, ¶¶ 2.1-2.10 (discussing the provisions of Sections 301(a) of the Trade Act, which include language allowing the United States Trade Representative to take certain actions, "subject to the specific directions . . . of the President [of the United States]" in situations where "the rights of the United States under any trade agreement are being denied" or violated). The Panel observed, however, that the Act also provides that such action is unnecessary in the event of WTO involvement. Id. ¶ 2.4.

<sup>102.</sup> See id. ¶ 7.96 (remarking that the statutory language of the Trade Act created a "real risk" for the trading community that the U.S. Trade Representative would find inconsistencies with international trading agreements, which effectively "removes the guarantee which Article 23 is intended to give"). Such action is prohibited under Article 23.2(a) of the DSU and thus inconsistent with the DSU itself. *Id.* 

<sup>103.</sup> See id. ¶ 7.108 (stating that the Trade Act provides a measure of administrative discretion in that the U.S. Trade Representative is limited in the case of situations covered by the WTO to acting only after the completion of DSU proceedings).

<sup>104.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96,  $\P$  6.86 (concluding that the United States acted unilaterally when it imposed an increased bonding requirement on certain E.C. imports because the United States did not receive authorization through the DSU process to suspend concessions for any alleged WTO violation on the part of the E.C.).

a reasonable period of time,<sup>105</sup> the DSB granted the United States authorization to suspend concessions on the importation of certain E.C. goods and apply tariffs at 100 percent *ad valorem*, up to \$116.8 million per year.<sup>106</sup> Under DSU Article 22.8, the suspension of concessions is a temporary measure, and lasts only as long as the offending Member fails to comply with the DSB rulings.<sup>107</sup> The E.C. asserts that once the offending Member brings its measure into compliance, DSU Article 21.5 requires the non-offending Member to submit questions as to the measure's compliance to the WTO dispute settlement process.<sup>108</sup>

The United States maintains there is no distinction between the two E.C. measures and therefore it is not bound by Article 21.5 to resort to the DSB.<sup>109</sup> The E.C. claims that Directives 96/22/EC and

<sup>105.</sup> See supra note 87 (discussing the determination of the arbitrators to set the reasonable period of time at fifteen months for the E.C.'s compliance with the rulings and recommendations of the DSB).

<sup>106.</sup> See Decision by the Arbitrators, Hormones, supra note 86, ¶¶ 45-78, 84 (estimating the nullification and impairment caused by the ban on importation of U.S. high quality beef to be \$32,664,776 and nullification from the ban on the importation of edible beef offal to be \$84,095,731 and concluding that an award of \$116.8 million is consistent with Article 22.4 of the DSU); see also DSU, supra note 22, art. 22.4 ("The level of the suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment.").

<sup>107.</sup> See Decision by the Arbitrators, European Communities—Regime for the Importation, Sale and Distribution of Bananas, ¶ 6.3, WT/DS27/ARB (Apr. 9, 1999) (reiterating the purpose of allowing the suspension of concessions is to motivate the offending Member to comply with the DSB and emphasizing that the authority to take unilateral action is removed once the Member achieves compliance).

<sup>108.</sup> See Appellate Body Report, Canada—Measures Affecting the Importation of Civil Aircraft, ¶ 36, WT/DS70/AB/RW (Aug. 2, 1999) [hereinafter Appellate Report, Canada—Civil Aircraft] (concluding that Article 21.5 does not apply to all measures, but is specific to "measures taken to comply" with the DSB's recommendations). Article 21.5 assumes that there is a distinction between the original measure found inconsistent, and the "measure taken to comply." Id.

<sup>109.</sup> See Nov. 7, 2003 DSB Meeting Minutes, supra note 80, ¶¶ 29-30 (reiterating that several studies produced by the E.C. over the years showed no risk of adverse health effects from the consumption of residues from growth hormones and that despite this evidence, the E.C. still maintains its unjustified ban, albeit under a new label).

2003/74/EC are separate and distinct, and thus any dispute must be brought before the DSB.<sup>110</sup>

#### II. ANALYSIS

The E.C. can comply with the DSB's rulings and recommendations by demonstrating that a valid risk assessment supports the new Directive. He Because the E.C. is able to do so, the DSB will likely conclude that the Directive is consistent with the SPS Agreement. However, regardless of the DSB's determination, the United States acted unilaterally by maintaining the suspension of concessions after the E.C. notified the United States of the new Directive. Thus, the DSB will likely find that this action is inconsistent with U.S. obligations under the DSU.

### A. DIRECTIVE 2003/74/EC BRINGS THE E.C. HORMONE MEASURES INTO COMPLIANCE WITH ITS WTO OBLIGATIONS

The Appellate Body did not mandate that the E.C. adopt a substantive change in policy.<sup>115</sup> In fact, Directive 2003/74/EC does little to substantively reformulate the prior E.C. hormone

<sup>110.</sup> See id.  $\P$  28 (noting that the DSB invalidated Directive 96/22/EC on the basis that it lacked a proper assessment of the risks and stating that the new Directive is fully supported by "a risk assessment performed by an independent scientific committee").

<sup>111.</sup> See discussion supra Part I.B (describing the requirements for a valid risk assessment).

<sup>112.</sup> See discussion infra Part II.A.

<sup>113.</sup> See discussion infra Part II.B (explaining that the determination of whether a Member acted unilaterally does not depend upon whether the Member's conclusions are ultimately correct).

<sup>114.</sup> See discussion infra Part II.B (arguing that the United States should have immediately brought the matter before the WTO upon notification from the E.C. that the new Directive brought the E.C. into compliance with the rulings and recommendations of the DSB).

<sup>115.</sup> See Appellate Report, E.C.—Hormones, supra note 22, ¶¶ 177, 208 (concluding that the E.C. measures in dispute were only invalid because the procedures used to support them were inconsistent with the requirements of Articles 3.3 and 5.1 of the SPS Agreement).

measures.<sup>116</sup> The United States argues the mere fact that the E.C. policy remains unchanged is sufficient to conclude that the E.C. remains in violation of its obligations under the SPS Agreement and, therefore, has not brought its measures into compliance with the DSB.<sup>117</sup> However, the United States misinterprets the actual DSB rulings and recommendations in making this assertion.<sup>118</sup>

Nowhere within the Panel, Appellate, or even Arbitration Body rulings and recommendations did the DSB conclude that the E.C. must withdraw its SPS measures to comply with the DSB.<sup>119</sup> Rather, each body stated that the "[DSB] requests the European Communities to bring its measures in dispute into conformity with its obligations [under the SPS Agreement]."<sup>120</sup> Therefore, compliance

<sup>116.</sup> See International Centre for Trade and Sustainable Development, EC Beef Hormone Dispute Drags On, BRIDGES WEEKLY TRADE NEWS DIGEST, Nov. 13, 2003, available at http://www.ictsd.org/weekly/03-11-13/story3.htm (observing that the new E.C. directive actually maintains the prohibition against five of the cited hormones). The E.C. asserts that it was maintaining the prohibition on the five hormones on a provisional basis because there was a potential threat to human health and the available scientific evidence was not sufficient to discount that potential. Id.; see also E.C. Communication 22, supra note 80, at 1-2 (informing the WTO and the United States that in adopting Directive 2003/74/EC, the E.C. considered itself in compliance with the DSB ruling, and accordingly sought the end of the U.S. suspension of concessions).

<sup>117.</sup> See Nov. 7, 2003 DSB Meeting Minutes, supra note 80, ¶¶ 29-30.

<sup>118.</sup> See Erin N. Palmer, Comment, The World Trade Organization Slips Up: A Critique of the World Trade Organization's Dispute Settlement Understanding Through the European Union Banana Dispute, 69 TENN. L. REV. 443, 470 (2002) (proposing that if the Appellate Body has specific suggestions on how a Member may bring its measures into compliance, the Body must make those recommendations known to the Member, otherwise the Body may only request that the Member bring its measures into compliance with the agreement at issue).

<sup>119.</sup> See Award of the Arbitrator, supra note 87, ¶ 32 (indicating the E.C. and the United States feel differently as to what constitutes compliance with the DSB). The E.C. believes that conducting scientific risk assessments are a "necessary first step' to bringing the E.C. measures into conformity," while the United States stated that conducting these risk assessments were "the only means of bringing [the E.C.] into conformity." Id. (emphasis in original).

<sup>120.</sup> Id.  $\P$  38 (acknowledging that while withdrawing an inconsistent measure is often the preferred method of compliance, it is not the only method).

in this case requires a mere showing that a valid risk assessment supports the E.C. SPS measures.<sup>121</sup>

Because the E.C. supports its new Directive with a valid risk assessment, as demonstrated below, the E.C. has in fact brought its measures into compliance with the DSB rulings and recommendations. Therefore, the E.C. may maintain its policy of banning the use of growth hormones in the production of meat and continue prohibiting the importation of such products, even though the Directive continues to set a level of sanitary protection higher than international standards.<sup>122</sup>

## 1. The E.C. Supports the Implementation of Its SPS Measures Under Council Directive 2003/74/EC with a Valid Risk Assessment

## a. The Risk Assessment Specifically Identifies the Risk that the Directive Is Employed to Combat

As a threshold matter, the DSB unequivocally equates the presence of growth hormone residues in meat with the meaning of contaminants under the SPS Agreement's definition of a risk assessment. Admittedly, the 1999 SCVPH Report concluded that humans would be exposed to all of the naturally-occurring hormones prohibited by the E.C. measures even if they are only untreated meat. The United States seizes upon this information, as it did in

<sup>121.</sup> See discussion supra Part II.A.1-3 (demonstrating that the DSB requires only that Members base their SPS measures on a valid risk assessment and rejects the idea that such measures must follow the general scientific trend).

<sup>122.</sup> See SPS Agreement, supra note 13, art. 3.3 (providing that measures not based on international standards must be supported by sufficient scientific evidence). See generally Terence P. Stewart & David S. Johanson, The SPS Agreement of the World Trade Organization and International Organizations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epozootics, 26 SYRACUSE J. INT'L L. & COM. 27, 28-30 (1998) (reviewing the international organizations upon which the DSB relies when determining what international standards it will apply in evaluating Members' SPS measures).

<sup>123.</sup> See SPS Agreement, supra note 13, Annex A, ¶ 4 (defining one version of risk assessment as an evaluation of the "presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs").

<sup>124.</sup> See 1999 SCVPH REPORT, supra note 16, at 27 (emphasizing that while the natural hormones are found in cattle and thus humans would consume these

the initial hormones dispute, to argue that such evidence clearly demonstrates that hormone residues are not contaminants.<sup>125</sup> However, this argument fails to properly acknowledge the fact that the 1999 SCVPH Report also concluded that the use of growth-promoting hormones in meats does in fact result in *increased* exposure to residues from even naturally-occurring hormones.<sup>126</sup> Furthermore, the report indicates that the increased level of exposure to these hormone residues is greater among certain individual consumers and varies among the individual hormones.<sup>127</sup>

Finally, the U.S.' argument is unpersuasive because there is logically no opportunity for humans to be naturally exposed to the synthetic hormones prohibited by the E.C. measures.<sup>128</sup> The presence of residues from such hormones is a complete contaminant under any evaluation, and as such, presents an increased risk of exposure from the consumption of treated meat.<sup>129</sup>

Thus, the risk assessment meets the initial requirement of risk identification, including a risk from naturally-occurring hormones, by identifying the presence of contaminants in the form of growth

hormones through eating even untreated meat, humans are not normally exposed to synthetic hormones, which must be added to feed for humans to face such exposure).

<sup>125.</sup> See GAIN REPORT I, supra note 89, at 2 (asserting that a "true state of the art risk assessment" would show that the level of Oestradiol is greater in eggs and other dairy products than it is in beef, regardless of whether the beef has been treated or not).

<sup>126. 1999</sup> SCVPH REPORT, supra note 16, at 28.

<sup>127.</sup> See id. at 28-30 (noting that because some of the hormones in dispute occur naturally in males and females, and can vary according to age and stage of physical development, the increased exposure to residues will result in different physiological effects and resulting health implications).

<sup>128.</sup> See id. at 27 (concluding that an assessment of a risk of increased exposure to residues of the hormones in question must begin with the knowledge that residues from naturally-occurring hormones will be found naturally in humans at some level above zero and residues from synthetic hormones should be found in humans naturally at a level of zero).

<sup>129.</sup> See Dale E. McNiel, The First Case Under the WTO's Sanitary and Phytosanitary Agreement: The European Union's Hormone Ban, 39 VA. J. INT'L L. 89, 97 (1998) (stating that the synthetic hormones act in a manner that is "basically similar to 'natural' hormones . . . but possess slightly different molecular structures").

hormone residues.<sup>130</sup> Therefore, the DSB must reject the U.S. argument and conclude that the E.C. presents sufficient evidence indicating a risk of increased exposure to a contaminant within the meaning of a risk assessment under the SPS Agreement.<sup>131</sup>

#### b. The Risk Assessment Identifies Adverse Effects from the Increased Exposure to Hormone Residues in Meats Treated with Growth-Promoting Hormones

Contrary to U.S. assertions, the E.C.'s risk assessment complies with the first requirement of adverse effects identification by identifying the possibility of several adverse developmental, immunological, neurobiological, immunotoxic, genotoxic, and carcinogenic effects on human health resulting from the consumption of meat containing residues from growth-promoting hormones. Confronted with this evidence the United States blindly asserts that the risk assessment does not rectify the errors of the previous risk assessment. This is a baseless attack that ignores the data contained in the SCVPH reports that demonstrate a risk to humans from the increased exposure to hormone residues. For example, the SCVPH concluded that "the pubertal growth spurt [in children] of both sexes is driven by Oestradiol [17 $\beta$ ]." Consequently, there is

<sup>130.</sup> See supra note 16 and accompanying text (explaining the biological nature of the individual hormones and the purpose of their use).

<sup>131.</sup> See supra note 30 and accompanying text (observing the Panel Body's determination that residues from growth-promoting hormones constitute contaminants within the meaning of the SPS agreement).

<sup>132.</sup> See 1999 SCVPH REPORT, supra note 16, at 73 (finding a risk from the consumption of beef treated with growth-promoting hormones, identifying in particular Oestradiol  $17\beta$  as posing the greatest risk to human health).

<sup>133.</sup> See supra notes 99-100 and accompanying text (discussing the U.S. refusal to withdraw its DSB-authorized suspension of concessions despite the E.C.'s assertion that it is now in compliance with the DSB's rulings and recommendations).

<sup>134.</sup> But see Global Agriculture Information Network, USDA Foreign Agriculture Service, Gain Report No. E23217, European Union Trade Monitoring: E.U. Presentation on Hormone Ban Directive (2003/74/EC), 2 (2003), http://www.fas.usda.gov/gainfiles/200311/145986807.pdf [hereinafter Gain Report II] (emphasizing that a U.K. study refuted the findings and conclusions of the SCVPH Report).

<sup>135. 1999</sup> SCVPH REPORT, supra note 16, at 43.

strong evidence that increased exposure to this hormone, "even . . . at very low doses," can alter children's growth and lead to an early onset of puberty. Therefore, even if the United States is correct to assume that the level of increased exposure is not overwhelming, 137 the evidence shows that minimal increases can lead to serious adverse effects. Is In light of the SCVPH findings, the DSB can only come to the conclusion that the E.C. risk assessment identifies adverse health effects from the increased exposure to growth hormone residues.

Furthermore, by identifying particular risks to human health, the present risk assessment overcomes the deficiencies of the risk assessment that the Panel and Appellate Body in *E.C.—Hormones* declared invalid.<sup>140</sup> The previous risk assessment failed to properly identify particular adverse effects on human health from the consumption of hormone-treated meats.<sup>141</sup> Rather, the cited studies from the purported risk assessment in the initial dispute made general

<sup>136.</sup> See id.

<sup>137.</sup> See U.S. Interagency Task Force on Beef Hormones, A Primer on Beef Hormones (Feb. 22, 1999), http://www.useu.be/issues/BeefPrimer022699.html (asserting that a boy would have to eat sixteen pounds of beef daily to increase his exposure to Oestradiol  $17\beta$  by one percent).

<sup>138.</sup> See European Comm'n, Scientific Committee On Veterinary Measures Relating to Public Health, Review of Previous SCVPH Opinions of 30 April 1999 and 3 May 2000 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products 19-20 (Apr. 10, 2002) [hereinafter 2002 SCVPH Report] (concluding that the risks resulting from exposure to hormones is greater if the exposure is early in life). This is a special concern considering that the three synthetic hormones referenced in the study readily pass through the placental barrier and accumulate in fetal tissue. *Id.* 

<sup>139.</sup> See infra note 146 (describing the DSB's consideration of sufficient scientific evidence as the key element of a valid risk assessment, not whether the assessment comes to the same conclusion as the general scientific community).

<sup>140.</sup> See supra notes 23-29 and accompanying text (recounting the Panel and Appellate Bodies' determination that the E.C. failed to demonstrate a valid risk assessment that identified a risk to human health from the consumption of meat treated with growth-promoting hormones).

<sup>141.</sup> See supra note 37 and accompanying text (discussing the Appellate Body's determination that the E.C.'s cited studies evaluated merely the risk posed by the consumption of growth-promoting hormones and not the specific risk posed by the consumption residues of such hormones found in meat).

conclusions regarding the safety of growth hormones.<sup>142</sup> In contrast, the SCVPH reports identify several specific potential adverse effects on human health from such consumption.<sup>143</sup>

Although the United States frequently cites scientific studies that conclude there is no risk of adverse health effects, the existence of these reports does not control the validity of the present risk assessment. As an initial consideration, many of these reports predate the SCVPH reports, demonstrating that the E.C. risk assessment used the latest scientific information. Moreover, the E.C. is not bound by such reports, but is legally justified in accepting a divergent opinion so long as it is based on sufficient scientific evidence.

<sup>142.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶¶ 196-97 (concluding that the general studies that the E.C. cited did not meet the necessary requirements of a valid risk assessment).

<sup>143.</sup> See supra notes 135-36 and accompanying text (discussing the specific adverse health affects identified by the SCVPH report, including the impact of these hormones on height and puberty).

<sup>144.</sup> See David G. Victor, The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment After Five Years, 32 N.Y.U. J. INT'L L. & POL. 865, 879-80 (2000) (urging that the SPS Agreement does not seek Member's harmonization of their measures directly to the current common international standard, but rather imposes a duty that Member's not act arbitrarily when instituting such measures and base them on sufficient scientific evidence).

<sup>145.</sup> See USDA FOREIGN AGRICULTURE SERVICE, U.S. MISSION TO THE EUROPEAN Union, WTO HORMONE CASE (2004),http://www.useu.be/ agri/ban.html#Opinion [hereinafter WTO HORMONE CASE] (referring to reports by the FAO/WHO Joint Expert Committee on Food Additives and other international groups concluding that the use of growth hormones in meat production poses no risk of adverse health effects to humans). The committee produced the latest of these cited reports in March 1999, prior to the first published report of the SCVPH. Id. But see GAIN REPORT II, supra note 134, at 2 (citing one study from the U.K. Veterinary Products Committee, published in October 1999-after the 1999 SCVPH Report—which also concluded that the usage of growth-promoting hormones in the production of beef posed no threat of adverse health effects for humans).

<sup>146.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 194 (emphasizing that Article 5.1 does not require following the opinions of the prevailing scientific view). Rather, the Appellate Body concluded that Article 5.1 merely requires sufficient scientific evidence, and divergent views may simply be an indication of a lack of a complete body of knowledge in a particular area. Id.

Additionally, the DSB will not accept the U.S. argument that the SCVPH was unduly biased. 147 The DSB mandates only that the body conducting the risk assessment adhere to generally accepted scientific methods of evaluation and acknowledge all of the available scientific evidence. 148 The DSB does not require the risk assessment to blindly accept the conclusions of other studies, 149 nor does it mandate that the body conducting the study be independent from the Member seeking the study. 150

The SCVPH reports meet the DSB requirements by (1) evaluating both basic traditional scientific principles of the hormones and also emerging concerns over how those hormones interact with human biology, taking into consideration non-scientifically quantifiable measures;<sup>151</sup> and (2) reviewing findings and studies from other scientific bodies as they become available in an effort to continually evaluate the SCVPH's conclusions.<sup>152</sup> The E.C. risk assessment is valid even if the SCVPH's process diverged from a strictly traditional methodology because the SPS Agreement specifically

<sup>147.</sup> See GAIN REPORT II, supra note 134, at 2 (alluding to the idea that because the committee that reviewed the findings of the U.K. Veterinary Products Committee in relation to the previous findings of the SCPVH had been virtually the same composition as the committee that created the initial SCPVH report, it was somehow unduly biased in concluding that the previous findings of the SCVPH were still valid).

<sup>148.</sup> See supra note 44 (summarizing the Appellate Body's determination that a Member's consideration of the available scientific evidence may be balanced with a Member's consideration of other non-scientific elements).

<sup>149.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  194 (concluding that a valid risk assessment may consider the prevailing scientific view while at the same time arriving at a different conclusion).

<sup>150.</sup> See supra note 45 and accompanying text (discussing the Appellate Body's conclusions that a Member is not required to undertake its own risk assessment or be wholly independent from the body conducting the assessment, and that an assessment conducted under either scenario may hold equal weight).

<sup>151.</sup> See 2002 SCVPH REPORT, supra note 138, at 8 (acknowledging that while this approach is different from a traditional approach to risk assessment, the DSB endorsed the procedure by concluding that risk assessments may consider risks as they would occur in the real world and not just within the laboratory).

<sup>152.</sup> See id. at 6-7 (stating that the purpose of the 2002 report was to revisit the findings of the 1999 report in light of seventeen studies commissioned by the E.C. and other recent scientific data provided by various international scientific bodies and to determine the current state of understanding on the adverse effects of growth hormones on human health).

allows for this type of flexibility among its Members.<sup>153</sup> Because the SCVPH's process adheres to the DSB-articulated methodology principles, the DSB will likely conclude that the risk assessment, as conducted, is valid and the E.C. may base its SPS measures on the SCVPH reports alone.<sup>154</sup>

# c. The Risk Assessment Evaluates the Potential for Adverse Effects on Human Health to Occur

The risk assessment also meets the second element of the adverse effects identification requirement because it evaluates the potential for occurrence of the identified adverse effects from *increased* consumption of residues from the targeted growth hormones.<sup>155</sup> For example, among the adverse effects that the SCVPH reports envisage, *in utero* exposure to hormone residues is one of the greatest areas of concern, as the reports show a link between exposure and adverse pre-pubertal development, as well as future development of cancer in adulthood.<sup>156</sup> Therefore, the reports not only clearly establish that cancer is an identifiable adverse effect, they also establish an identifiable potential that increased exposure to hormone residues will produce this adverse effect.<sup>157</sup>

<sup>153.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  129 (noting that the SPS Agreement grants "a certain degree of flexibility" to Members in meeting their Article 5.1 obligations, by allowing risk assessments to be conducted "as appropriate to circumstances").

<sup>154.</sup> See id. ¶ 187 (emphasizing that an evaluation of the available scientific evidence is merely the beginning of the overall objective of a valid risk assessment); see also discussion infra Part II.A.2 (arguing that the E.C. SPS measures are rationally and objectively related to the conclusions of the SCPVH reports and thus based on the E.C. risk assessment).

<sup>155.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  198 (affirming the Panel's conclusion that the risk assessment that the E.C. offered to support Council Directive 96/22/EC failed to evaluate the potentiality of occurrence of the specified risk because the studies relied upon did not focus on the particular risk potential resulting from the consumption of residues of the hormones administered to animals intended for consumption).

<sup>156.</sup> See 2002 SCVPH REPORT, supra note 138, at 20 (summarizing three studies of female twins with male co-twins that found that increased exposure to estrogen in utero has a significant influence on the development of cancer in adulthood).

<sup>157.</sup> See supra note 37 and accompanying text (reviewing the DSB's determination that the E.C. failed to meet the specificity requirement in the initial

While the United States cites the fact that the reports themselves do not set forth a quantifiable level of risk for the hormones at issue, <sup>158</sup> the DSB does not require the risk assessment to delineate such a quantifiable risk. <sup>159</sup> Rather, a Member meets its burden by showing that adverse effects are possible. <sup>160</sup> The SCVPH reports definitively conclude a possibility of adverse effects on human health from growth hormone residues exists, <sup>161</sup> despite the inability to provide quantitative measures of those risks. <sup>162</sup> Therefore, unlike in the initial hormone dispute, the U.S. argument will likely fail to persuade the DSB that the risk assessment does not meet the second element of risk identification.

d. The Risk Assessment Is Specific to the Effects Caused by Increased
Exposure to Growth Hormone Residues Through the
Consumption of Treated Meats

Unlike the first E.C.—Hormones risk assessment and Japan's risk assessment in Japan—Apples, the risk assessment that supports Council Directive 2003/74/EC is specific to the adverse effects the

E.C.—Hormones dispute because the evidence the E.C. cited failed to specifically address the risk posed by the consumption of hormone residues).

<sup>158.</sup> See Press Release, Senate Comm. on Finance, Senator Chuck Grassley, European Announcements on Hormone-Treated Beef (Oct. 15, 2003), http://www.useu.be/Categories/BeefHormones/Grassleyprg101503.pdf [hereinafter Press Release, Grassley] (alleging that the E.C. still does not have the support of scientific evidence indicating a risk posed by the hormones other than Oestradiol 17β, yet maintains its unlawful ban on hormone-treated beef); see also 1999 SCVPH REPORT, supra note 16, at 73 (acknowledging that "the current state of [scientific] knowledge does not allow [for] a quantitative estimate of risk").

<sup>159.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 186 (rejecting the Panel's implication that a risk assessment must establish a "minimum magnitude of risk").

<sup>160.</sup> See supra note 32 (explaining the Appellate Body's rejection of the Panel's conclusion that adverse potential identification requires a showing that the adverse effects are *probable*).

<sup>161.</sup> See 1999 SCVPH REPORT, supra note 16, at 70-71, 73 (identifying possible "endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects" and specifically determining that there is a possible link between consumption of treated meat and prostate and breast cancer).

<sup>162.</sup> See id. at 72 (noting that the primary reason that the committee is unable to determine a quantifiable risk is the general lack of understanding of "critical development periods in human life").

Directive seeks to avoid and the potential for those effects to occur. Remedying the previous failure, the new risk assessment specifically evaluates the risk posed to human health by the consumption of meats contaminated with growth hormone residues. In conducting its evaluation the SCVPH examined (1) the level of residues humans would typically be exposed to through consuming treated meats; (2) what effect such exposure by itself would have upon human health; and (3) what adverse effects the exposure would have upon human health when considered in conjunction with other normal human environmental factors. In the second sec

Thus, in addition to identifying a risk of adverse effects on human health and the potential for those effects to occur, the assessment is valid because it is also specific to both the covered hormones and to the precise mode of exposure. Because the risk assessment fulfills the requirements of adverse effects identification and meets the additional specificity requirement, the DSB will find that the E.C. has met its burden of demonstrating the existence of a valid risk assessment. 167

<sup>163.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  200 (rejecting the idea that the E.C.'s cited studies should be considered valid risk assessments because they failed to address the specific risks identified by the E.C.).

<sup>164.</sup> See 1999 SCVPH REPORT, supra note 16, at 1 (identifying the mandate of this report by the committee as evaluating "the potential for adverse effects" from the consumption of residues from growth hormones used in meats). The mandate specifically identifies the hormones evaluated in the study as Oestradiol  $17\beta$ , progesterone, testosterone, Zeranol, trenbolone acetate, and melengestrol acetate. Id.

<sup>165.</sup> See id. at 1-3.

<sup>166.</sup> See supra notes 34-37 and accompanying text (discussing the imposition of a specificity requirement under the SPS Agreement and the relevant body of WTO case law interpreting the SPS Agreement).

<sup>167.</sup> See discussion supra Part I.B (outlining the requirements of a valid risk assessment and the specific elements of adverse risk identification); see also discussion supra Part I.C (asserting that once a Member demonstrates the existence of a valid risk assessment, the DSB will find the Member's SPS measures valid so long as the Member is able to demonstrate that the measures are based on the risk assessment).

## 2. Council Directive 2003/74/EC is Rationally Related to Its Supporting Risk Assessment

The SPS measures are based on a valid risk assessment because there is a rational and objective relationship between the measures and the assessment.<sup>168</sup> The United States maintains there is no objective or rational relationship because the E.C. is unable to support its SPS measures with evidence of sufficient quantifiable risks to human health.<sup>169</sup> Contrary to U.S. assertions, neither the SPS Agreement, nor the DSB, requires the E.C. to show a certain minimum degree of risk within its risk assessment to establish valid SPS measures.<sup>170</sup> Rather, the SPS measures meet the SPS Agreement and DSB requirements so long as the E.C. demonstrates a rational and objective relationship between the measures and the risk assessment.<sup>171</sup>

Council Directive 2003/74/EC demonstrates an objective and rational relationship between the SCVPH reports' findings and conclusions and the SPS Measure, an accomplishment that neither Directive 96/22/EC nor the Japanese varietal testing requirement could achieve.<sup>172</sup> The 1999 SCVPH Report found that a risk of

<sup>168.</sup> See discussion supra Part I.C (noting that in addition to the existence of a valid risk assessment, the DSB also requires a rational and objective relationship between the risk assessment and the Member's SPS measures).

<sup>169.</sup> See WTO HORMONE CASE, supra note 145 (commenting on the E.C.'s failure to adequately rebut the modern body of knowledge developed by the international scientific community, which concludes that the use of growth hormones in meat production presents no risk of adverse health effects to human consumers).

<sup>170.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 186 (criticizing the Panel Report, which in one part acknowledged that an "identifiable risk" can never be proven to a certainty while in another part indicated that a certain threshold level of risk should be demonstrated to show that a SPS measure is consistent with Article 5.1); see also supra note 159 and accompanying text (discussing the absence of a requirement of a minimum quantifiable risk under the SPS Agreement).

<sup>171.</sup> See supra note 37 and accompanying text (observing the lack of a rational and objective relationship between the E.C. hormone measures and the risk assessment in the initial *E.C.—Hormones* dispute).

<sup>172.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 197 (affirming the Panel's determination that the risk assessment could not "rationally support" the E.C. measures, especially when considering the "difficulty raised by the Panel's use of the term 'identifiable risk'"); see also Panel Report, Japan—Agriculture

increased exposure to residues from growth hormones exists through the consumption of treated meats.<sup>173</sup> The Report further determined that this increase results in exposure beyond normal levels.<sup>174</sup> The Report finally concluded that this increased exposure beyond normal levels has the potential to result in adverse effects on human health.<sup>175</sup> A multitude of studies contained within all three SCVPH reports, including studies from various international scientific bodies, support these findings and conclusions, thus meeting the "sufficient scientific evidence" requirement to establish a rational and objective link between hormone residue exposure and adverse health effects.<sup>176</sup>

By prohibiting the use of the disputed growth hormones in meats intended for human consumption, and preventing the importation of such meats, Council Directive 2003/74/EC is rationally and objectively related to the valid supporting risk assessment.<sup>177</sup> The goal of the Directive is to prevent adverse health effects by preventing the increased exposure to hormone residues. Eliminating the presence of the hormone residues from consumable meats will necessarily prevent this type of increased exposure. Accordingly, the DSB must conclude that the new Directive is consistent with E.C. obligations under the SPS Agreement.

- 173. See 1999 SCVPH REPORT, supra note 16, at 36, 47, 52, 57, 63-64, 67.
- 174. See id. (discussing the levels of increased exposure presented by each of the hormones in dispute).
- 175. See supra notes 132-49 and accompanying text (describing the various possibilities of adverse health effects and emphasizing a particular risk to prepubertal children posed by the increased level of exposure to growth hormone residues from the consumption of treated meats).
- 176. See Appellate Report, Japan—Agricultural Products, supra note 40, ¶ 73 (maintaining that "sufficiency" merely requires a showing that there is an "adequate relationship" between the scientific evidence and the risk assessment).
- 177. See Directive 2003/74, supra note 60, pmbl. ¶¶ 11-12 (recognizing that while there is a risk posed to human health from the increased exposure to residues from growth-promoting hormones in consumable meats, especially in light of the potential for the misuse of such hormones, there are certain legitimate uses for these hormones other than for growth promotion that should continue to be authorized, though only for well-defined purposes and under strict supervision).

*Products*, *supra* note 41,  $\P$  8.42 (finding that the United States offered sufficient evidence for the panel to conclude that there was never an instance where a treatment for one variety of a certain agricultural product had to be modified in order to be effective on another variety of the same product, thus contradicting a rational relationship between Japan's measures and its purported risk assessment).

### 3. The E.C. SPS Measures Are Valid Even Without a Demonstration of Sufficient Scientific Evidence

Perhaps the one weakness in the E.C.'s argument is the fact that the SCVPH reports do not quantify the risk adverse effects. The reports state that there is insufficient data, though several adverse effects "could be envisaged." The United States argues that this fact alone should render the Directive inconsistent with the requirements of a valid risk assessment because the scientific evidence does not rationally support the measures. However, the lack of knowledge or data does not automatically lead to the DSB invalidating the Directive. Rather, Article 5.7 of the SPS Agreement specifically allows for situations such as this, in which the scientific data is not fully developed to allow for a full conclusion on the level of risk posed to human health.

In the initial *E.C.—Hormones* dispute, the E.C. never invoked Article 5.7 to support Council Directive 96/22/EC.<sup>183</sup> However, the manner in which the E.C. enacted Council Directive 2003/74/EC

<sup>178.</sup> See supra note 169 and accompanying text (noting the U.S. assertion that a lack of quantifiable risk negates the validity of the Directive).

<sup>179.</sup> See 1999 SCVPH REPORT, supra note 16, at 73 (concluding that the report identifies a risk to consumer health "with different levels of conclusive evidence," but the current state of knowledge and the data available do not "allow for a quantitative estimate of the risk").

<sup>180.</sup> See WTO HORMONE CASE, supra note 145, at 2 (stating that the E.C.'s justification relies only on the findings of the SCVPH Report regarding the potential for adverse health effects posed by Oestradiol 17 $\beta$  alone and does not substantially discuss the effects of the other hormones at issue).

<sup>181.</sup> See Jan Bohanes, Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle, 40 COLUM. J. TRANSNAT'L L. 323, 329, 388-89 (2002) (commenting on the so-called "precautionary principle" as embodied in Article 5.7 of the SPS Agreement and explaining that positive action, like a ban on particular products, may occur before a risk is scientifically established).

<sup>182.</sup> See supra note 47 and accompanying text (demonstrating that Article 5.7 of the SPS Agreement allows Members to provisionally adopt SPS measures in these situations).

<sup>183.</sup> See Panel Report, E.C. Measures, supra note 21, ¶ 8.249.

leads to the conclusion that it has considered possible invocation of Article 5.7 to support the validity of the Directive.<sup>184</sup>

Though the United States claims that the provisional nature of the prohibition only supports its assertions of invalidity, <sup>185</sup> the DSB should find that Council Directive 2003/74/EC meets all four requirements necessary to invoke Article 5.7. <sup>186</sup> First, the E.C. imposed the Directive where the scientific information was insufficient. <sup>187</sup> Second, the E.C. adopted the Directive based on the pertinent information contained within the 1999 SCVPH Report and two follow-up reports, <sup>188</sup> both of which affirmed the conclusions of the first report. <sup>189</sup> The E.C. also meets the third requirement, as the

<sup>184.</sup> See Directive 2003/74, supra note 60, art. 1(1) (implying that the provisions contained within the Directive banning certain substances may be applied on a provisional basis). However, the provisional nature of the Directive does not apply to the prohibition on Oestradiol 17 $\beta$ , the restriction of which is actually increased with the aim of terminating all use by October 14, 2006. *Id.* art. 1(1), 1(4).

<sup>185.</sup> See GAIN REPORT I, supra note 89, at 2 (concluding that the 'provisional' nature of the new growth hormone ban in the 2003 Directive provides no justification for the DSB to consider the ban valid because there is no real change in the status of the banned hormones from the 1996 Directive).

<sup>186.</sup> See supra note 54 and accompanying text (outlining the requirements that a Member must meet to comply with Article 5.7 and emphasizing that each of the requirements must be met for the Member's SPS measure to be consistent with Article 5.7's mandate).

<sup>187.</sup> See supra note 179 and accompanying text (discussing the inability of the SCVPH report to come to a full conclusion as to the risks associated with the hormones due to a lack of current scientific knowledge); see also 1999 SCVPH REPORT, supra note 16, at 72-73 (concluding that despite not being able to identify a quantitative level of risk, the 1999 SCVPH Report does in fact identify the potential for adverse effects to human health posed by all of the six disputed hormones).

<sup>188.</sup> See Directive 2003/74, supra note 60, pmbl. ¶¶ 5-8 (outlining the studies that the E.C. relied on to support the new Directive, which supported the original hypothesis of the 1999 Report).

<sup>189.</sup> See id. ¶ 8 (suggesting that the two follow-up SCVPH reports were influenced in part by the U.K. Veterinary Products Committee's findings in a 1999 report, which, along with two other contemporaneous reports, provided more scientific information to be included in the SCVPH's evaluation of the risk posed by growth hormone residues). The SCVPH noted the findings of three major committees, including the U.K. Veterinary Products Committee, and concluded that they did not provide convincing evidence sufficient to warrant changing the 1999 SCVPH Report's conclusions. *Id.* The SCVPH affirmed this determination again in 2002. *Id.* 

follow-up reports indicate that the E.C. continues to search for available scientific evidence to allow for a more objective risk assessment. Furthermore, unlike Japan in Japan—Agricultural Products II, 191 the E.C. seeks information directly relevant to the validity of maintaining its SPS measure. Finally, unlike the provision in Australia—Salmon that Australia had in place for more than twenty years, 193 the E.C. reviews the efficacy of its provisions every couple of years, allowing for enough time in between reviews for pertinent scientific developments, without ignoring its responsibilities to the international community. 194

Therefore, even if the DSB concludes that the E.C. maintains the SPS measures without sufficient scientific evidence, the DSB will find that the E.C.'s SPS measures meet the four requirements to establish the Directive's validity under Article 5.7. 195

<sup>190.</sup> See supra note 189 and accompanying text (indicating the E.C.'s willingness to review its measures and modify them accordingly, as it required the SCPVH to review its original 1999 report twice).

<sup>191.</sup> See supra note 55 and accompanying text (discussing the Panel and Appellate Body determinations that Japan failed to meet the requirements of Article 5.7 of the SPS Agreement by not continuing to review its SPS measures through relevant scientific evidence to produce a more objective risk assessment).

<sup>192.</sup> See European Comm'n, Scientific Committee On Veterinary Measures Relating to Public Health, Review of Specific Documents Relating to the SCVPH Opinion of 30 April 99 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products 2-3 (2000), http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/sci\_opinion\_en.htm [hereinafter 2000 SCVPH Report] (commenting that the SCVPH undertook this review primarily based on the U.K. Veterinary Products Committee's findings regarding the use of Oestradiol 17 $\beta$  in cattle for therapeutic and zootechnical purposes, which showed a "lack of correlation" between the use of such hormones and "carcinogenic potencies").

<sup>193.</sup> See supra notes 50-52 and accompanying text (discussing the DSB's rejection of Australia's ability to assert that the measure at issue, which had been in place for two decades, was provisional and thus within the scope of Article 5.7).

<sup>194.</sup> See Directive 2003/74, supra note 60, pmbl. ¶¶ 8, 10 (indicating that the SCVPH conducted the relevant studies and reviews in 2000 and 2002 and will continue to evaluate "more complete scientific information from any source" that will allow the E.C. to draw full conclusions on the safety of the individual hormones).

<sup>195.</sup> See discussion supra Part I.D (observing that SPS measures lacking the support of sufficient scientific evidence are valid under certain situations as governed by Article 5.7 of the SPS Agreement).

## B. THE ACTION OF THE UNITED STATES CONSTITUTES UNILATERAL ACTION INCONSISTENT WITH ITS OBLIGATIONS UNDER THE DISPUTE SETTLEMENT UNDERSTANDING

The U.S. refusal to withdraw the suspension of concessions is fueled by its misperception of the new Directive as fundamentally the same as the previous invalidated Directive.<sup>196</sup> The DSB will ultimately find this constitutes unilateral action under the DSU, because (1) Council Directive 2003/74/EC is a "measure taken to comply" with the DSB rulings and recommendations and (2) the U.S. action is meant to redress the existence or inconsistency of that measure.<sup>197</sup>

The United States must abide by DSU rules and procedures if the Directive constitutes a new measure that the E.C. took to comply with the DSB. However, the United States vigorously maintains that because the E.C. policy remains unchanged the Directive is not a new measure, but one the DSB has already considered and determined to be invalid. 199

It is possible the DSB might conclude that the new Directive is not distinct from the measures deemed inconsistent with WTO obligations,<sup>200</sup> which led to the Arbitration Panel's authorization for

<sup>196.</sup> See supra note 82 and accompanying text (discussing the E.C.'s notification of compliance to the DSB and the United States in October 2003 and the U.S. reaction to the notification).

<sup>197.</sup> See discussion supra Part I.F.1 (explaining the prohibition under the DSU against Members acting unilaterally in resolving disputes with other WTO Members).

<sup>198.</sup> See DSU, supra note 22, art. 22.8 (providing that the suspension of concessions is intended as a temporary measure and must be terminated upon compliance by the offending Member).

<sup>199.</sup> See GAIN REPORT II, supra note 134, at 3 (conveying the U.S. belief that the E.C. has not presented a "new risk assessment based on scientific information and reasoning" that would warrant the consideration of the Directive as a measure taken to comply with the DSB's prior ruling).

<sup>200.</sup> See DSU, supra note 22, art. 22.8 (providing that the suspension of concessions may continue where a measure has not been removed, DSB recommendations or rulings have not been implemented, or a "mutually satisfactory solution" has not been reached); see also supra notes 82, 89 and accompanying text (recounting the U.S. belief that E.C. Directive 2003/74/EC was

the initial suspension of concessions.<sup>201</sup> In this situation, the United States would be well within its right to maintain the suspension of concessions, as the WTO would have already determined a violation.<sup>202</sup>

However, the evidence in this case makes clear that the temporary suspension of concessions must end because the suspension no longer has legitimate DSB authorization, as the DSB has not yet ruled on the validity of the new Directive.<sup>203</sup> In this situation, DSU Article 23 requires the United States to seek recourse through the dispute settlement process exclusively.<sup>204</sup> Without such recourse the alleged violation remains merely perceived, not DSB-determined, and the DSB will consider the U.S. response as unilateral.<sup>205</sup>

not a new measure that warranted treatment as a measure enacted to comply with the recommendations and rulings of the DSB).

- 201. See Decision by the Arbitrators, Hormones, supra note 86, ¶¶ 83-84 (indicating that after reviewing the relevant submissions, the arbitration panel determined that the appropriate level of suspension of concessions in consideration of the E.C. measures involved would be \$116.8 million per year). See generally Request by the European Communities for Arbitration Under Article 22.6 of the DSU, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/20 (June 9, 1999) [hereinafter E.C. Request for Arbitration, E.C.—Hormones] (noting that the E.C. disputed the initial amount of the suspension requested by the United States and sought review of that award by an arbitration panel).
- 202. See DSU, supra note 22, art. 22.8 (declaring that the suspension of concessions is a temporary measure granted by the DSB under certain conditions and can be maintained when the offending Member has not taken measures to comply with the DSB's rulings and recommendations).
- 203. See id. art. 22.1 (providing that the DSB only authorizes the suspension of concessions when an offending Member fails to bring its inconsistent measures into compliance with the DSB's rulings and recommendations within a reasonable period of time). The DSB determines whether the offending Member has failed to comply prior to granting authorization for the suspension of concessions. Id.
- 204. See supra note 95 and accompanying text (discussing the requirement of Article 23.1 of the DSU, which mandates that Members have recourse to the DSU's procedures exclusive of all other processes to resolve conflicts that fall under the jurisdiction of the WTO Agreement).
- 205. See Panel Report, U.S.—Section 301 Trade Act, supra note 95,  $\P$  7.43 ("This . . . 'exclusive dispute resolution clause', is an important new element of Members' rights and obligations under the DSU.").

## 1. Council Directive 2003/74/EC is a "Measure Taken to Comply" with the DSB Rulings

The DSB will find that Council Directive 2003/74/EC is a measure that the E.C. took to comply with the DSB rulings and recommendations from the initial dispute.<sup>206</sup> The United States argues that the new Directive is different from the previously invalidated Directive in name only.<sup>207</sup> However, Council Directive 2003/74/EC is distinct from Council Directive 96/22/EC and is meant to correct the inconsistencies of the DSB-invalidated Directive.<sup>208</sup> As the DSB has noted, when a Member implements a measure on the basis of bringing a previously invalidated measure into compliance with DSB rulings and recommendations, the DSB will view the newly implemented measure as one "taken to comply with [its] recommendations and rulings."<sup>209</sup>

The phrase "measure taken to comply" thus implies (1) DSB invalidation of a certain measure and (2) action on the part of the Member, whose measure the DSB has invalidated, to either remove the invalidated measure or *correct* the previous inconsistencies to ensure WTO compliance.<sup>210</sup> In the present case, the DSB first invalidated Council Directive 96/22/EC because it lacked the support of sufficient scientific evidence demonstrated by a valid risk

<sup>206.</sup> See generally Debra Herz, Effects of International Arbitral Tribunals in National Courts, 28 N.Y.U. J. INT'L L. & POL. 217, 246 (1995-1996) (observing that "prior to the establishment of the WTO, the preferred method of resolution [of an adverse ruling] was the phasing out of the challenged measure," but that the WTO has changed its procedures to provide Members with time to bring their measures into compliance).

<sup>207.</sup> See Nov. 7, 2003 DSB Meeting Minutes, supra note 80, ¶ 30.

<sup>208.</sup> See discussion supra Part II.A (outlining the steps that the E.C. took in developing the new Directive, discussing why the E.C. took these steps to comply with the previous DSB rulings and recommendations, and explaining why these actions do comply with the DSB's previous rulings and recommendations).

<sup>209.</sup> Appellate Report, Canada—Civil Aircraft, supra note 118, ¶ 36 (asserting that, in principle, a measure "taken to comply" is distinguishable from "the measure which was the subject of the original dispute").

<sup>210.</sup> See id. (emphasizing that the phrase 'measure taken to comply' refers to those measures that the Member takes in reaction to the DSB's rulings and recommendations on a previous measure, thus making the two measures "separate and distinct").

assessment.<sup>211</sup> In response, the E.C. sought more relevant scientific evidence.<sup>212</sup> Once the E.C. obtained valid scientific evidence demonstrating a risk to human health, the European Parliament and Council amended Directive 96/22/EC and enacted Directive 2003/74/EC with provisions that were more consistent with the relevant scientific findings.<sup>213</sup>

This evidence demonstrates that the DSB's rulings regarding Directive 96/22/EC influenced the E.C. to implement Directive 2003/74/EC to ensure WTO consistency.<sup>214</sup> Therefore, the DSB will reject the U.S. claims and conclude that Directive 2003/74/EC is a measure taken to comply with the DSB rulings.

#### 2. The Continued Suspension of Concessions Constitutes Unilateral Action Taken to Redress a Violation or Existence of the E.C. SPS Measures

The DSB will find that Council Directive 2003/74/EC is a measure taken to comply.<sup>215</sup> Therefore, by maintaining the suspension of concessions, the United States seeks to redress what can only be viewed as a perceived violation.<sup>216</sup> Such action is unilateral under the

<sup>211.</sup> See discussion supra Part I.A (analyzing the findings and conclusions of the DSB Panel and Appellate Bodies in the initial E.C.—Hormone dispute).

<sup>212.</sup> See Directive 2003/74, supra note 60, pmbl.  $\P$  3 (noting that the E.C. undertook the new risk assessment beginning in February 1998, immediately following the release of the recommendations for compliance by the DSB).

<sup>213.</sup> See id.  $\P$  13 (outlining the E.C.'s belief that the measures embodied in the new Directive "are necessary to achieve the chosen level of health protection" based on its own scientific information). "Moreover, there is no other means that is reasonably available at present, taking into account technical and economic feasibility, which is significantly less restrictive of trade and can achieve equally effectively the chosen level of health protection." Id.

<sup>214.</sup> See Press Release, E.U. Complies with Hormone Beef Ruling, supra note 60 (explaining the background of the DSB ruling on Council Directive 96/22/EC and how the E.C. worked to amend that Directive to bring its measures into compliance with the DSB rulings and recommendations).

<sup>215.</sup> See discussion supra Part II.B.1 (outlining the DSB's interpretation of a measure taken to comply and arguing that the new Directive fits within that interpretation).

<sup>216.</sup> See generally Panel Report, U.S.—Certain E.C. Products, supra note 105, ¶ 6.22 (commenting that a Member can seek to redress either a "perceived or WTO determined violation").

DSU until the United States obtains the DSB's determination as to whether the measure actually does comply with the DSB rulings.<sup>217</sup>

The United States asserts that the Arbitration Body authorized the current suspension of concessions and it is not seeking to redress a new violation or the existence of a measure taken to comply.<sup>218</sup> This argument is based on the premise that the DSB has already reviewed the E.C. SPS measures and found them to be incompatible with WTO obligations.<sup>219</sup> What the argument fails to acknowledge is that Directive 2003/74/EC is a measure taken to comply with the previous invalidated Directive and as such the DSB must consider it as separate from the old Directive.<sup>220</sup>

Furthermore, the United States places too much emphasis on the notion that the language and policy of the Directive remains largely the same as the invalidated directive, thereby evidencing an indisputable lack of change. This argument misinterprets the DSB ruling in the initial *E.C.—Hormones* Panel Report.<sup>221</sup> The DSB did not determine that the E.C. measures were per se invalid.<sup>222</sup> Rather, the DSB concluded that the E.C. lacked the support of a valid risk assessment to legitimately enact its measures.<sup>223</sup> Consequently, bringing the E.C. measures into compliance does not necessarily require changing the language or policy of the Directive, it merely

<sup>217.</sup> See id. ¶¶ 6.23, 6.26 (indicating that when a violation is merely perceived, the Member asserting the violation has recourse to the DSU alone).

<sup>218.</sup> See GAIN REPORT II, supra note 134, at 3 (suggesting that the United States is still operating under the WTO's authorization for the suspension of concessions stemming from the initial hormone dispute).

<sup>219.</sup> See WTO HORMONE CASE, supra note 145 (stating that the current measures remain inconsistent with WTO obligations because of the lack of sufficient supporting scientific evidence).

<sup>220.</sup> See discussion supra Part II.B.1 (arguing that the E.C. enacted the new Directive with the purpose of bringing its measures into compliance with the rulings and recommendations of the DSB in the initial hormones dispute).

<sup>221.</sup> See supra notes 27-29 and accompanying text (recounting the DSB's findings and conclusions on the consistency of Council Directive 96/22/EC with the SPS Agreement).

<sup>222.</sup> See Appellate Report, E.C. Measures, supra note 22, ¶ 246 (rejecting the Panel's contention that the E.C. acted in an "arbitrary and unjustifiable" manner in enacting the Directive solely as a means to create a discriminatory trade practice).

<sup>223.</sup> See id.

requires that the E.C. support the measures with a valid risk assessment, which the E.C. has accomplished with the SCVPH reports.<sup>224</sup>

Therefore, the Directive no longer contains the invalidated deficiencies, thereby rendering the continued suspension of concessions simply a response to a measure taken to comply.<sup>225</sup> Just as the *U.S.-Certain E.C. Products* Panel concluded, the DSB in the present case will conclude that the current E.C. measure is a measure taken to comply,<sup>226</sup> the alleged violation is merely a result of U.S. perception,<sup>227</sup> and the United States must seek the DSB's determination as to whether the measure actually does comply with its rulings.<sup>228</sup>

## 3. The Continued Suspension of Concessions Is Unilateral Action in Violation of WTO Obligations Regardless of When the United States First Initiated the Suspension

The U.S. action is unilateral even though the DSB initially authorized the suspension of concessions.<sup>229</sup> In the present case, the U.S. actions are similar to its response to E.C. measures in U.S.—

<sup>224.</sup> See discussion supra Part II.A.1 (outlining the exact steps that the E.C. took to ensure that its risk assessment would meet the requirements established by the DSB to demonstrate a valid risk assessment).

<sup>225.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96,  $\P$  6.26 (concluding that the United States acted unilaterally when it imposed additional obligations on certain E.C. products because the United States perceived the E.C. to be in violation of its WTO obligations when it did not comply with the DSB's rulings and recommendations within a reasonable time period, even though the E.C. took measures to comply that the DSB itself had not yet evaluated).

<sup>226.</sup> Cf. Appellate Report, Canada—Civil Aircraft, supra note 108, ¶ 36 (remarking that Canada presented a revised measure as a measure taken to comply and the DSB was required to consider it accordingly).

<sup>227.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96,  $\P$  6.22 (explaining that a Member can seek to redress a violation that is "perceived," meaning that the WTO has not yet found that the violation actually exists).

<sup>228.</sup> See id. ¶ 6.26 (indicating that when a violation is merely perceived and not WTO determined, the Member asserting the violation must have recourse to the DSU alone, otherwise its actions are unilateral under the DSU).

<sup>229.</sup> See supra note 106 and accompanying text (observing that the DSB granted the United States authorization to suspend concessions after the E.C. failed to bring its measures within a reasonable period of time).

Certain E.C. Products, where the Panel concluded that the U.S. action was unilateral because the violation the United States sought to redress was merely perceived.<sup>230</sup> The United States is likely to argue that a key difference between the two cases is that here, unlike in U.S.—Certain E.C. Products, the DSB authorized the U.S. action prior to initiation of the suspension of concessions.<sup>231</sup>

However, the U.S. argument fails for two important reasons. First, regardless of when the United States took the action in this case, it did so to redress a perceived violation or question the existence of a measure taken to comply.<sup>232</sup> The DSB makes no distinction between actions taken to redress a perceived violation after the authorization to suspend concessions and those taken before the DSB grants authorization.<sup>233</sup> The language of Article 21.5 explicitly and simply states that Members must resort to the dispute settlement procedure when there is a question as to the validity or existence of a measure taken to comply with a DSB ruling.<sup>234</sup>

Second, the U.S. argument fails because Article 22.8 and the Arbitration Body's prior holdings make clear that the authorized suspension of concessions is a temporary remedy.<sup>235</sup> The determining

<sup>230.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96, ¶ 6.26 (concluding that the U.S. imposition of additional liabilities on certain E.C. products amounted to an addition of tariffs above that which the DSB authorized, violating the DSU's rules and procedures).

<sup>231.</sup> See id. ¶¶ 2.11-2.14 (indicating that the United States implemented its retaliatory measures prior to the final ruling of the arbitration body, which ultimately did authorize the United States to suspend concessions); see also discussion supra Part I.F.2 (suggesting that the DSB authorized the United States to suspend concessions after the E.C. failed to bring its measures into compliance within the fifteen month reasonable period of time set by the Arbitration Body).

<sup>232.</sup> See discussion supra Part II.B.1-B.2 (arguing that the New Directive is a measure taken to comply and that the DSB view the U.S. maintenance of the suspension of concessions as action to redress the Directive's perceived violation).

<sup>233.</sup> See DSU, supra note 22, art. 21.5.

<sup>234.</sup> See id.; see also Jason E. Kearns & Steve Charnovitz, Adjudicating Compliance in the WTO: A Review of DSU Article 21.5, 5 J. INT'L ECON. L. 331, 342 (2002) (arguing that because Article 21.5 does not explicitly state that it applies to post-retaliation situations to compel non-offending Members to resort to such proceedings, an effective use in such situations is for the previously offending Member to initiate proceedings under the Article 21.5).

<sup>235.</sup> See DSU, supra note 22, art. 22.8 (providing that the suspension of concessions should last only so long as the measure found to be inconsistent

factor is the offending Member's implementation of a measure taken to comply with the DSB's rulings and recommendations.<sup>236</sup> Here, the E.C. implemented a new Directive intended to comply with the DSB.<sup>237</sup> The DSU rules and procedures obligated the United States to withdraw its suspension of concessions upon E.C. notification of the new measure.<sup>238</sup> From that point, the United States could have freely exercised its right to bring the matter before the DSB.<sup>239</sup> However, the United States acted unilaterally, a move that the DSB will find inconsistent with U.S. obligations under the DSU.<sup>240</sup>

#### III. RECOMMENDATIONS

A. THE DSB SHOULD USE THE U.S.—CONTINUED SUSPENSION OF OBLIGATIONS CASE TO DECLARE THE IMPORTANCE OF THE "PRECAUTIONARY PRINCIPLE"

The DSB should use this latest case in the hormone dispute to acknowledge the importance of the so-called "precautionary principle," which nations often use to support health and safety

remains); see also Decision by the Arbitrators, Hormones, supra note 86,  $\P$  40 (agreeing with the Panel from E.C.—Bananas III that the principle behind imposing suspension of concession is "to induce compliance" from Members with respect to the rulings and recommendations of the DSB (emphasis in original)).

<sup>236.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96, ¶ 6.93 (concluding that "the term 'measure found to be inconsistent" assumes an adjudicating process and must be read together with Article 23.2(a), which also mandates WTO adjudication to determine whether a WTO violation has occurred). Here the DSB found Council Directive 96/22/EC inconsistent with the SPS Agreement, not Council Directive 2003/74/EC. See Panel Report, E.C. Measures, supra note 21. Council Directive 2003/74/EC seeks to comply with the prior DSB rulings and recommendations, but has not yet been subjected to adjudication by the DSB.

<sup>237.</sup> See discussion supra Part II.A (noting that the E.C. promulgated Directive 2003/74/EC only after seeking sufficient scientific evidence to rationally and objectively support its SPS measures in accordance with the rulings and recommendations of the DSB in E.C.—Hormones).

<sup>238.</sup> See DSU, supra note 22, art. 22.1.

<sup>239.</sup> See id. art. 21.5.

<sup>240.</sup> See discussion supra Part I.F.1 (outlining the DSU and DSB's prohibition against unilateral action to redress a perceived WTO violation).

policies upon grounds other than just strict scientific evidence.<sup>241</sup> This important principle recognizes the need for Members to maintain sovereignty over their measures, even though such decisions are partly based on public policy considerations.<sup>242</sup> However, the WTO has become increasingly reluctant to allow Members to interject public policy into the evaluation of a measure's validity, focusing instead on strict harmonization of standards.<sup>243</sup>

The *E.C.—Hormones* case is perhaps the perfect example of a dispute arising from the intersection between the need for establishing international harmonization and the need for Members to maintain their sovereign right to acknowledge public policy goals within their health and safety measures.<sup>244</sup> Few would dispute the importance of working toward eliminating arbitrary and unjustified trade barriers.<sup>245</sup> However, the WTO must not do so at the expense of a Member's right to consider more than just hard scientific evidence when developing health and safety measures to protect their citizens.<sup>246</sup>

<sup>241.</sup> See SPS Agreement, supra note 13, pmbl. ("[N]o Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health . . . ."); see also John S. Applegate, The Taming of the Precautionary Principle, 27 Wm. & MARY ENVIL. L. & POL'Y REV. 13, 51-52 (2002) (acknowledging that the precautionary principle is an element of SPS Agreement Article 5.7, but is only accepted after a demonstration of scientific uncertainty).

<sup>242.</sup> See Regine Neugebauer, Note, Fine-Tuning WTO Jurisprudence and the SPS Agreement: Lessons from the Beef Hormone Case, 31 LAW & POL'Y INT'L BUS. 1255, 1258 (2000) (stating that the drafters of the SPS Agreement intended for the determination of acceptable levels of risk to be an exclusively political decision that is the right of Members to decide for themselves).

<sup>243.</sup> See Lori M. Wallach, Accountable Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization Standards, 50 U. KAN. L. REV. 823, 829 (2002) (observing that a major principle behind the concept of standardizing policies is "maximizing economic efficiency" of international trade).

<sup>244.</sup> See discussion supra Introduction (commenting on the various motivations behind the actions of the E.C. and United States).

<sup>245.</sup> See Kevin C. Kennedy, The Illegality of Unilateral Trade Measures to Resolve Trade-Environment Disputes, 22 Wm. & MARY ENVTL. L. & POL'Y REV. 375, 398 (1998) (suggesting that the SPS Agreement is supposed to be a mechanism to distinguish between measures designed to protect domestic industry and those legitimately designed to ensure health and safety).

<sup>246.</sup> See Benjamin L. Brimeyer, Note, Bananas, Beef, and Compliance in the World Trade Organization: The Inability of the WTO Dispute Settlement Process

The DSB has in fact acknowledged that the SPS agreement embodies this important principle.<sup>247</sup> Yet the principle remains an afterthought within DSB jurisprudence, with the DSB choosing instead to place the greatest emphasis on whether Members follow the strict process that ensures the harmonization of health and safety measures affecting trade among WTO Members.<sup>248</sup>

To properly acknowledge the importance of the precautionary principle, the DSB must place greater emphasis on whether Members are acting arbitrarily or unjustifiably discriminatory when enacting SPS measures.<sup>249</sup> For example, the DSB acknowledged the universal nature of the E.C. hormone ban.<sup>250</sup> However, the fact that the E.C. measures were not arbitrary or unjustifiably discriminatory was not dispositive in the DSB's evaluation.<sup>251</sup> Now that the E.C. is in a prime position to invoke Article 5.7, the DSB should make a clear declaration that it will give deference to Members' sovereign right to determine appropriate levels of safety for their citizens so long as Members do not act arbitrarily or in an unjustifiably discriminatory manner.<sup>252</sup>

to Achieve Compliance from Superpower Nations, 10 MINN. J. GLOBAL TRADE 133, 167 (2001) (explaining that noncompliance with WTO decisions will become more prevalent if the WTO continues to ignore the need for Members to maintain a certain level of sovereignty in developing their health and safety measures).

<sup>247.</sup> See, e.g., Appellate Report, E.C. Measures, supra note 22,  $\P$  124 (affirming that the precautionary principle is embodied within SPS Agreement Articles 5.7 and 3.3, as well as the Preamble).

<sup>248.</sup> See id. ¶ 125 (upholding the Panel's conclusion that SPS Agreement Articles 5.1 and 5.2 were the primary considerations in this case).

<sup>249.</sup> See Alan O. Sykes, Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View, 3 CHI. J. INT'L L. 353, 359 (2002) (suggesting that the E.C. had legitimate reasons for banning the use of growth hormones and did not impose the ban as a disguised trade barrier).

<sup>250.</sup> See Appellate Report, E.C. Measures, supra note 22,  $\P$  244 (observing that the ban not only affected U.S. exports to Europe, but it also impacted European exports to the United States).

<sup>251.</sup> See id. ¶¶ 246, 253-55 (reversing the Panel's conclusion that the E.C. acted arbitrarily or in an unjustifiably discriminatory manner, but affirming the conclusion that the hormone measures were invalid).

<sup>252.</sup> See Mystery Bridgers, Comment, Genetically Modified Organisms and the Precautionary Principle: How the GMO Dispute Before the World Trade Organization Could Decide the Fate of GMO Regulation, 22 TEMP. ENVIL. L. & TECH. J. 171, 184 (remarking that many nations incorporate the precautionary

# B. THE DSB SHOULD USE THE U.S.—CONTINUED SUSPENSION OF OBLIGATIONS CASE TO ESTABLISH THAT MEMBERS WHO REFUTE ANOTHER MEMBER'S COMPLIANCE WITH THE DSB MUST RESORT TO ARTICLE 21.5 PROCEEDINGS

The DSB should take this opportunity to bring clarity to the scope of DSU Article 21.5 by declaring that original complainants must initiate Article 21.5 proceedings when contesting an offending Member's compliance with the DSB.<sup>253</sup> The DSB should state unequivocally that original complainants must adhere to this process regardless of whether the DSB already granted authorization to suspend concessions.<sup>254</sup> This would force the original complainant to engage in the dispute and work toward an expedient resolution under DSB observation rather than hiding behind the DSB's previous grant of suspension authorization.<sup>255</sup>

Under current DSU jurisprudence there is no enforcement mechanism compelling a Member, who the DSB previously authorized to suspend concessions, to resort to Article 21.5 proceedings when it disputes the validity of measures taken to comply.<sup>256</sup> Rather, such Members can easily stand by and maintain the suspension of concessions, forcing the previously offending Member to initiate such proceedings if it wishes to end the

principle within their own domestic law, and arguing that it is a part of customary international law).

<sup>253.</sup> See discussion supra Part II.B.3 (contending that the absence of specific language indicating that the article only applies within the designated "reasonable period of time" should be construed to mean the article applies to all measures taken to comply).

<sup>254.</sup> See Panel Report, U.S.—Certain E.C. Products, supra note 96,  $\P$  6.92 (emphasizing that Article 21.5 includes a substantive requirement, similar to that of Article 23.2(a), imposing on Members the obligation of exclusive use of the WTO dispute settlement process).

<sup>255.</sup> See Kearns & Charnovitz, supra note 234, at 341-42 (proposing that the availability of Article 21.5 to original defendants may be the only realistic way for the withdrawal of retaliatory measures under current DSB jurisprudence).

<sup>256.</sup> See DSU supra note 22, art. 22.8 (providing that an authorized suspension of concessions lasts until an offending Member complies with the DSB, but providing no indication regarding who makes the determination of compliance).

suspension of concessions.<sup>257</sup> This inherently allows original complainants to make unilateral decisions while placing the full burden on the previously offending Member to initiate an action, which is against fundamental DSB principles.<sup>258</sup>

To correct this procedural flaw, the DSB should require the original complainant to postpone its suspension of concessions when an offending Member notifies the DSB and the original complainant that the previously inconsistent measures are in compliance with the DSB rulings. Such a requirement ensures that original complainants seek expedient resolution of the dispute. If the DSB finds the measures are in compliance then it would no longer authorize the suspension of concessions. If, however, the DSB concludes that the measures do not comply then the original complainant could resume the suspension, applying it retroactively to the date of postponement and thus eliminate the potential for Members to reap benefits from bad faith notifications. In the end, this procedure mirrors the current WTO dispute settlement process

<sup>257.</sup> See Kearns & Charnovitz, supra note 234, at 333 (emphasizing that the primary purpose of Article 21.5 is to ensure prompt compliance in order promote expeditious resolution of trade disputes).

<sup>258.</sup> See Panel Report, U.S.—Section 301 Trade Act, supra note 95, ¶ 7.43 (stating that the force of the DSU is of a dual nature whereby it grants Members the right to have recourse to the dispute settlement process, while obligating them at the same time to abide by the very same process); see also Seung Wha Chang, Taming Unilateralism Under the Multilateral Trading System: Unfinished Job in the WTO Panel Ruling on U.S. Sections 301-310 of the Trade Act of 1974, 31 LAW & POL'Y INT'L BUS. 1151, 1196 (2000) (arguing that Members of the WTO agreement have a certain expectation of enjoying the procedural benefits embodied within the DSU and that violations of the DSU most certainly nullify those benefits).

<sup>259.</sup> See discussion supra Part I.F (observing that the United States has consistently refused to remove or postpone the suspension of concessions, claiming a right to do so under the DSB award).

<sup>260.</sup> See Kearns & Charnovitz, supra note 234, at 341-42 (commenting on the propensity for a Member to be content with the "status quo" once the DSB awards a suspension of concessions and suggesting that this propensity may not be advantageous in the course of finding a resolution to the dispute).

<sup>261.</sup> See DSU, supra note 22, art. 22.8 (providing that the suspension of concessions is intended as a temporary measure and must be terminated upon compliance by the offending Member).

<sup>262.</sup> See id.

whereby Members must prove the validity of their measures only after a complaining Member initiates an action, and the DSB authorizes the suspension of concessions only after a full review of the measures in dispute.<sup>263</sup>

In the current dispute, this would mean that the United States should have postponed the suspension of concessions in October 2003.<sup>264</sup> Whether they should resume or be withdrawn completely will necessarily depend on the final DSB determination.

#### CONCLUSION

E.C. Council Directive 2003/74/EC is a measure taken to comply, and in fact does comply, with the DSB's rulings and recommendations. <sup>265</sup> The E.C. hormone measures are now consistent with the SPS Agreement because they are rationally and objectively supported by sufficient scientific evidence from a valid risk assessment. <sup>266</sup> Further, the United States is acting unilaterally by refusing to acknowledge the new Directive as a measure taken to comply and by maintaining its suspension of concessions. <sup>267</sup> Accordingly, the WTO should use this case to state unequivocally that DSU Article 21.5 applies universally whenever one Member questions the validity of another's measure. <sup>268</sup> In deciding this case and those like it in the future, the WTO should ensure that the precautionary principle becomes an important element of future DSB

<sup>263.</sup> See generally Brimeyer, supra note 246, at 143-46 (summarizing the WTO dispute settlement process).

<sup>264.</sup> See E.C. Communication 22, supra note 80.

<sup>265.</sup> See discussion supra Part II.A.1 (outlining the important role of the SCVPH reports in providing scientific support for the E.C. SPS measures).

<sup>266.</sup> See discussion supra Part II.A.2 (demonstrating that it is rational to prohibit the use of growth hormones where the scientific evidence shows a risk of adverse health effects from the increased exposure to the residues of such hormones).

<sup>267.</sup> See discussion supra Part II.B (demonstrating that the Directive is a measure taken to comply with the rulings and recommendations of the DSB and that by maintaining the suspension of concessions the United States is seeking to redress what it merely perceives to be the absence of a measure taken to comply).

<sup>268.</sup> See discussion supra Part III.B (proposing a process for the DSB to ensure that original complaining Members adhere to DSU Article 21.5, even after the DSB authorizes the suspension of concessions).

jurisprudence by granting more importance to whether a measure is arbitrary or unjustifiably discriminatory.<sup>269</sup>

<sup>269.</sup> See discussion supra Part III.A (arguing that the precautionary principle is an important element of a Member's health and safety measure development that the WTO should acknowledge in addition to harmonization of standards).