

Marcos A. Orellana, *Evolving WTO Law  
Concerning Health, Safety and Environmental  
Measures.*

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## EVOLVING WTO LAW CONCERNING HEALTH, SAFETY AND ENVIRONMENTAL MEASURES

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*With the advent of the World Trade Organization (WTO) in 1995, the international trading system faced a new challenge: reinventing its mandate under the light of the sustainable development challenges confronting the global community in the twenty-first century. This challenge has emerged central to the identity of the WTO, since the organization is no longer simply about removing obstacles to trade, like its predecessor – the GATT, 1947. Instead, the WTO is facing the loaded question of how far it will go in scrutinizing the exercise of governmental authority of Members, in regard to internal regulatory issues that relate to trade. Facing this question has been far from easy, especially in connection with disputes concerning health, safety and environmental (HSE) measures, since HSE-related disputes touch upon core environmental and human rights issues. The WTO's Appellate Body has approached the tensions that surface in the adjudication of these disputes by engaging in a process of dialogue among the various legal regimes that bear on HSE measures. This process of normative dialogue and interpretation has allowed the WTO to overcome the GATT's isolation by situating WTO law within the broader public international law universe. Normative dialogue has thus fundamentally transformed the evolving WTO law concerning HSE measures. This article explores the contours of this proposition, with a view to assessing the degree to which WTO law secures the quantum of policy space that governments need to realize human rights and protection of the environment.*

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## I. INTRODUCTION

The multilateral trading system, founded on the General Agreement on Tariffs and Trade (GATT) 1947<sup>1</sup> and continuing with the World Trade Organization (WTO), was established with a clear objective: To promote economic growth and prosperity in order to secure and maintain peace.<sup>2</sup> Through rounds of negotiations the GATT achieved a dramatic reduction in tariffs, thus expanding trade and concomitant economic growth.<sup>3</sup> It did not take long, however, for developing countries to realize that the non-tariff measures, including internal health, safety and environmental (HSE)

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<sup>1</sup> General Agreement on Tariffs and Trade, 30 October, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

<sup>2</sup> Debra Steger, *Lessons from History: Trade and Peace, in TRADE AS GUARANTOR OF PEACE, LIBERTY AND SECURITY? –CRITICAL, EMPIRICAL AND HISTORICAL PERSPECTIVES* 12, 12 (Padideh Ala'i, Tomer Broude & Colin Picker eds., 2006).

<sup>3</sup> However, these gains excluded textiles and agriculture, for example, where developing countries had comparative advantage. See Daniel Drache, *Dreaming Trade or Trading Dreams: The Limits of Trade Blocs, in INTERNATIONAL REGULATORY COMPETITION AND COORDINATION* 417, 417-418 (William Bratton, Joseph McCahery, Sol Picciotto & Colin Scott eds., 1996).

measures, could impose as much of an obstacle as tariffs to international trade, and would thus negate the economic benefits of trade negotiations. HSE measures have, therefore, been regarded with suspicion that at times reflects a deep North-South split. Further, the gradual expansion of the multilateral trading system, from its original focus on removing protectionist measures affecting trade in goods towards rules on services and intellectual property rights, has amplified its potential for friction with non-economic policies.

The advent of the WTO realigned and refined the objectives of the multilateral trading system by reference to sustainable development. The functions of the WTO are several and include the oversight, implementation, and administration of WTO covered agreements, as well as serving as a forum for negotiations and administering a dispute settlement mechanism. These functions serve the attainment of specific goals set out in the Preamble of the Agreement Establishing the WTO,<sup>4</sup> which include raising standards of living, ensuring full employment, ensuring large and steadily growing real incomes and demand, and expanding the production of and trade in goods and services. According to the Preamble of the Agreement Establishing the WTO, these objectives are to be achieved while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, and while seeking to protect and preserve the environment.<sup>5</sup>

In trying to mediate and reconcile the tensions between economic law and HSE measures, the approach of building mutually supportive regimes finds inspiration in the concept of sustainable development. Indeed, the World Summit on Sustainable Development (WSSD) recognized that trade and investment are necessary tools for achieving the goals of sustainable development.<sup>6</sup> While its exact legal nature and status remain the object of controversy, at a minimum, sustainable development requires the integration of environmental issues in decision-making regarding economic activities. Whereas the process of integration required by international law occurs mainly at the planning and implementation of projects and policies,

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<sup>4</sup> Marrakesh Agreement Establishing the World Trade Organization, Legal Instruments—Results of the Uruguay round, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) (hereinafter Agreement Establishing the WTO/WTO Agreement).

<sup>5</sup> Preamble, Agreement Establishing the WTO, *id.*

<sup>6</sup> *Id.*

the resolution of disputes concerning those economic activities also calls for an attempt to integrate the various relevant legal fields.

With the emergence of sustainable development as the overarching policy framework, the international community faces the challenge of finding channels for normative and institutional dialogue between economic and HSE regimes.<sup>7</sup> In this light, economic activities may contribute to the progressive realization of human rights and environmental protection by fostering economic development, employment, income, and general welfare. This potential contribution is not automatic, however, as non-sustainable investments, or unwarranted interpretations of trade and investment disciplines, may defeat such general welfare goals by exposing the population to health risks, causing environmental destruction, or reducing the policy space necessary for the adoption of HSE measures.

HSE measures can be directly affected by any of the three pillars of the WTO – goods, services, or intellectual property.<sup>8</sup> For example, a controversial aspect of the trade and health debate at the WTO has revolved around intellectual property rules and access to essential medicines.<sup>9</sup> In that context, the adoption of the Ministerial Declaration on the TRIPS Agreement and Public Health in Doha is a landmark in the debate, offering light on how to approach competing interests.<sup>10</sup> In the words of the Declaration:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while

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<sup>7</sup> Other terminological approaches are used indistinctly along the text, including: “mutually supportive,” “accommodation,” “coherence,” and “reconciliation.” See NICO SCHRIJVER, *THE EVOLUTION OF SUSTAINABLE DEVELOPMENT IN INTERNATIONAL LAW: INCEPTION, MEANING AND STATUS* (2008).

<sup>8</sup> See generally WHO SECRETARIAT, *INTERNATIONAL TRADE AND HEALTH*, EB116/4 (April 28, 2005); Carlos Correa, *Implementing National Public Health Policies in the Framework of WTO Agreements*, 34 J. WORLD TRADE 89 (2000).

<sup>9</sup> See Sandipto Dasgupta & Yamini Srivastava, “Public Health Safeguards” in *TRIPS: A Domestic Legal Response*, 43 INDIAN J. OF INT’L L. 661 (2003); see also Frederick Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317 (2005); Henning Grosse Ruse – Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1(1) TRADE L. & DEV. 56 (2009).

<sup>10</sup> See generally Larry DiMatteo et al., *The Doha Declaration and Beyond: Giving a Voice to Non-Trade Concerns Within the WTO Trade Regime*, 36 VAND. J. TRANSNAT’L L. 95 (2003).

reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.<sup>11</sup>

In addition, several cases involving HSE measures have stirred public attention, including *Thailand-Cigarettes*, *US-Reformulated Gasoline*, *EC-Asbestos*, and *EC-Biotech* case, as well as the *Hormones* saga of cases<sup>12</sup> and the *Brazil-Tyres* case. These high profile cases illustrate the tensions that surface in the application of WTO law to HSE measures.

This article explores how WTO law can approach complex disputes concerning HSE measures, with a focus on sanitary and phytosanitary (SPS) measures.<sup>13</sup> It begins with a sketch of WTO's dispute settlement process, showing how HSE measures may be implicated in WTO disputes. Against this background, the article analyzes the normative content of the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures<sup>14</sup> (SPS Agreement), with a view to identify how trade disciplines affect HSE measures. This analysis illuminates the subsequent review of WTO jurisprudence concerning SPS measures. Detailed attention is given to the *US-Hormones* case, because, *inter alia*, it involves contested scientific and technical issues, evidences greater openness by litigating parties to disclosing pleadings and conducting open hearings, and reflects decades of thinking about how WTO dispute settlement should address HSE measures.

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<sup>11</sup> World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, ¶4, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002); *see also* WTO General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 2, 2003).

<sup>12</sup> Appellate Body Report, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (16 January, 1998) (hereinafter Appellate Body Report, *EC – Hormones*). This case is the first of the *Hormones* saga, and it thus needs to be distinguished from United States – *Continued Suspension of Obligations in the EC-Hormones Dispute*, WT/DS320/AB/R (16 October, 2008) (hereinafter Appellate Body Report, *US-Hormones*), which concerns a challenge by the European Communities against the failure of the United States and Canada to lift their trade sanctions.

<sup>13</sup> The evolution of WTO Jurisprudence on Article XX of the GATT, particularly exceptions (b) and (g), is also relevant to health, and environmental measures, but is beyond the scope of this article.

<sup>14</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, 15 April, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1226 (1994) (hereinafter SPS Agreement).

Finally, the article concludes that the WTO Appellate Body has shown increasing sensitivity to the objectives and design of HSE measures, which has allowed for a more coherent and nuanced approach to the tensions apparent in the interplay between economic and non-economic goals. The Appellate Body has further sought channels of normative dialogue between the trading system and other international legal regimes bearing on the adjudication of HSE measures, thus placing the WTO in the broader public international law universe. As a result, the WTO has achieved a significantly greater degree of balance in respect of HSE measures than its predecessor, the GATT 1947, thereby contributing to secure the policy space necessary to ensure that governments retain their capabilities to realize human rights and environmental protection while reaping the benefits of international economic law.

## II. WTO DISPUTE SETTLEMENT

The WTO provides the institutional framework for governing the world trading system, including a powerful and compulsory dispute settlement mechanism. This marks a significant departure from the previous GATT regime, where the settlement of trade disputes was done through “diplomatic” rather than “legal” means of adjudication.<sup>15</sup> Indeed, the reforms introduced in establishing the WTO provide for an integrated and comprehensive dispute settlement system, where the rule of law plays a fundamental role.<sup>16</sup> The legalization of the Panel procedures is complemented by a tight schedule for dispute resolution, appellate review procedures, surveillance of implementation of ruling and recommendations, and specific remedies for non-compliance, including compensation and the suspension of concessions. These features of the WTO’s dispute settlement system strengthen the institution’s abilities to achieve its mandate.

The breach of any of the obligations contained in the agreements included in Appendix 1 of WTO’s Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU)<sup>17</sup> is enforceable through the

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<sup>15</sup> ERNST-ULRICH PETERSMANN, *THE GATT/WTO DISPUTE SETTLEMENT SYSTEM: INTERNATIONAL LAW, INTERNATIONAL ORGANIZATIONS AND DISPUTE SETTLEMENT* 66-70, 177-194 (1997) (hereinafter PETERSMANN).

<sup>16</sup> *Id.*

<sup>17</sup> Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2,

WTO's binding dispute settlement mechanism. DSU Appendix 1 includes the multilateral agreements concerning trade in goods, such as the GATT and the SPS Agreement. Accordingly, by virtue of the DSU, HSE measures implicated by the WTO covered agreements can give rise to a WTO dispute.

The DSU contains *lex specialis* rules that contract out from the general system of secondary norms of state responsibility and that operate on the basis of cessation and countermeasures. In short, a country found in breach of its WTO obligations will be responsible for bringing its measures into conformity with the relevant agreement in a reasonable period (cessation). If a country fails to bring itself into conformity, an arbitrator will determine the amount of retaliation authorized to induce compliance (countermeasures). This scheme has played out in *EC-Hormones*, for example, where the EU has preferred to suffer trade retaliation from the United States and Canada rather than removing its ban on hormone-grown beef and exposing its population to potential health risks.

The emphasis in the DSU on cessation, *i.e.* removing the offending measures, has a direct linkage with the content of the primary obligations and exceptions. For example, both the GATT and the SPS agreement allow measures that are "necessary" to achieve a country's level of HSE protection. The term "necessary" has been interpreted as requiring the adoption of less inconsistent, reasonably available alternative measures. If a Panel and/or the Appellate Body decided that a country's HSE measures are inconsistent with its WTO obligations because a less-WTO inconsistent alternative measure is reasonably available, the country can bring itself into compliance and resolve the dispute by removing the offending measures and adopting the alternative measure.

While the DSU provides the hook that may bring a dispute involving an HSE measure before the WTO, it is only where a covered agreement affects an HSE measure that such a dispute arises.

### III. THE AGREEMENT ON SPS MEASURES

WTO law can envelope HSE measures by virtue of the normative content of its covered agreements. This section will study how HSE measures can be implicated in WTO law, with a particular focus on the SPS Agreement.

The SPS Agreement addresses one of the most protectionist fields in international economic law, namely agricultural trade. In fact, behind the discourse and rhetoric of free trade lies the practice of tariff and other barriers to market access, especially against developing countries.<sup>18</sup> Against this protectionist background in agricultural trade, it should come as no surprise that the trading system has established stringent tests to screen out non-tariff barriers to market access, including with respect to HSE measures.<sup>19</sup>

According to its Preamble, the SPS Agreement elaborates the rules for the application of the GATT exceptions pertaining to human, animal and plant life and health.<sup>20</sup> The SPS Agreement deals generally with measures taken to protect public health from diseases, pests, and other food-borne hazards. The following paragraphs, rather than attempting a comprehensive discussion of the SPS Agreement, will highlight key points relevant for the adjudication of HSE-related disputes.

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<sup>18</sup> See Sara Larrain, *Trade and Environment: Latin American Issues and the FTAA*, in TRADE, ENVIRONMENT, AND SUSTAINABLE DEVELOPMENT: VIEWS FROM SUB-SAHARAN AFRICA AND LATIN AMERICA 230, (P. Könz, ed., UNU/ICTSD, 2000). For example, the inability of industrialized countries to dismantle their agricultural subsidies not only contributed significantly to derailing the WTO 2003 Cancun Ministerial and delaying the Doha agenda of negotiations, but has also brought about harmful consequences for small economies dependent on agricultural commodities; See, e.g., OXFAM, BRIEFING PAPERS, 50 *Dumping Without Borders: How US agricultural policies are destroying the livelihoods of Mexican corn farmers* (August 2003); 59 *The Rural Poverty Trap: Why agricultural trade rules need to change and what UNCTAD XI could do about it* (June 2004); *A little blue lie: harmful subsidies need to be reduced, not redefined* (July 2005); See also, 3D > TRADE – HUMAN RIGHTS – EQUITABLE ECONOMY & INSTITUTE FOR AGRICULTURE AND TRADE POLICY, PLANTING THE RIGHTS SEED: A HUMAN RIGHTS PERSPECTIVE ON AGRICULTURE TRADE AND THE WTO (March 2005).

<sup>19</sup> See generally Gretchen Stanton, *A review of the Operation of the Agreement on Sanitary and Phytosanitary Measures*, in AGRICULTURE AND THE NEW TRADE AGENDA 101 (Merlinda Ingco & Alan Winters, eds., 2004).

<sup>20</sup> Preamble, SPS Agreement, *supra* note 14.



The SPS Agreement is one of the WTO covered agreements on trade in goods and by virtue of express savings clauses it prevails over the GATT<sup>21</sup> and the Technical Barriers to Trade Agreement<sup>22</sup> in respect of SPS measures. The SPS Agreement is limited in scope, however, applying only to food safety and plant and animal measures that affect international trade. That is, health measures, standards, or technical regulations other than SPS measures will be covered by the GATT and the TBT Agreement. In turn, SPS measures are defined by their purpose: “Measures applied to protect” from pests and diseases and food borne hazards. In other words, measures other than those defined in the SPS Agreement, either for environmental or health protection, consumer interests or animal welfare, are not covered by the SPS Agreement. The limited scope of the SPS Agreement is critical to determining whether particular HSE measures are covered by its disciplines.

The role of purpose and intent as the defining feature of SPS measures may render the objective characteristics of the measure of secondary importance. Whether this emphasis on the purpose of the measure may justify a departure from more objective tests to determining discrimination with respect to trade in goods, as in *Japan – Alcoholic Beverages*<sup>23</sup> and *Chile – Taxes on Alcoholic Beverages*,<sup>24</sup> remains an open question. Further, the SPS Agreement’s emphasis on purpose raises difficulties in situations where measures have more than one purpose.<sup>25</sup> This dual-purpose situation is all the more troubling when legitimate and illegitimate motives coexist within a measure. In such cases of motives in close proximity, it may be impossible for the WTO to remove the protectionist element of the measure without also affecting the ability of the State to address HSE risks.

Whilst the SPS Agreement explicitly recognizes that the protection of health must take priority over trade, it requires that measures not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination. This dual construction of the SPS Agreement reflects the

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<sup>21</sup> WTO Agreement, *supra* note 4, Interpretative Annex A.

<sup>22</sup> SPS Agreement, *supra* note 14, art. 1.4.

<sup>23</sup> Appellate Body Report, *Japan – Alcoholic Beverages*, ¶ 29, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Nov. 1, 1996).

<sup>24</sup> Appellate Body Report, *Chile – Taxes on Alcoholic Beverages*, ¶ 62, WT/DS87/AB/R, WT/DS110/AB/R, (Dec. 13, 1999).

<sup>25</sup> See Gabrielle Marceau & Joel Trachtman, *GATT, TBT, and SPS: A Map of WTO law of Domestic Regulation of Goods*, in *THE WTO DISPUTE SETTLEMENT SYSTEM 1995-2003*, 275, 328 (Federico Ortino & Ernst-Ulrich Petersmann eds., 2004).

sometimes opposing terms, interests, and values underlying HSE measures. On the one hand, the SPS Agreement affirms the right of Members to adopt SPS measures, and on the other, it contains several rules to prevent abuse of such fundamental right. Although these terms may sometimes appear in contradiction, their reconciliation does not necessarily involve a cost-benefit balancing exercise<sup>26</sup> because such test could annihilate the right of Members to determine their level of protection.<sup>27</sup> Rather, the question of the interplay between health protection and market access for agricultural products is better framed as a double-pronged inquiry into disguised discrimination and the scientific basis of measures.

Indeed, the SPS Agreement contains two baskets of rules: Science-based and trade-based. Though these two baskets interact, their existence is separate. This duality became clear in the *EC-Hormones* case, where the Appellate Body decided against the European Communities not because of a breach of trade rules, but because the measure at issue was not supported by a proper risk assessment. The trade rules mainly address issues of harmonization and non-discrimination, but also introduce considerations of necessity and consistency, much in line with GATT Article XX(b), including its *chapeau*. In contrast, the science rules require that measures be based on scientific principles and cannot be maintained without sufficient scientific evidence. A risk assessment is the tool envisaged by the SPS Agreement to operationalize its science-based rules.

The SPS Agreement's architecture and particular emphasis on risk assessment and international standards influence its methodology for evaluating HSE measures.<sup>28</sup> The first question is whether the measure is based on international standards. If it is, it will be presumed to be consistent with the SPS Agreement. This presumption is rebuttable, however, it is not clear to what extent it provides a safe harbor.<sup>29</sup> Second, is the measure temporary or

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<sup>26</sup> Alan Sykes, *Regulatory Protectionism and the Law of International Trade*, 66 U. CHI. L. REV. 1, 31-5 (1999).

<sup>27</sup> In addition, it could be argued that the right to determine the level of protection (and in this context the ability to protect human rights and the environment), on the one hand, and the trade costs of HSE measures do not operate at the similar axiological level.

<sup>28</sup> See Mitsuo Matsushita, *Some Issues of the SPS Agreement*, in WORLD TRADE FORUM 2000, THE ROLE OF THE JUDGE IN INTERNATIONAL TRADE REGULATION: EXPERIENCE AND LESSONS FOR THE WTO 193, 197-98 (Thomas Cottier & Petros Mavroidis eds., 2003).

<sup>29</sup> Steve Charnovitz, *Improving the Agreement on Sanitary and Phytosanitary Measures*, in TRADE, ENVIRONMENT, AND THE MILLENNIUM 171, 182-83 (Gary P. Sampson & W. Bradnee Chambers eds., 1999).

permanent? If it is a temporary SPS measure, the requirements of Article 5.7 will apply; else, Article 5.1 will require a proper risk assessment. Third, if the measure is permanent and based on a risk assessment, is it discriminatory or arbitrary or does it constitute a disguised restriction on trade? And finally, is the otherwise consistent measure necessary or excessive? The approach of the Appellate Body to these questions is examined further below in the analysis of evolving WTO jurisprudence concerning HSE measures.

#### IV. EVOLVING WTO JURISPRUDENCE CONCERNING HSE MEASURES

The jurisprudence concerning HSE measures by the WTO can be said to chronicle the efforts to overcome a crisis of legitimacy, where an insider network of like-minded technocrats could no longer impose its trade liberalization ideology above other legitimate public policies.<sup>30</sup> In this regard, finding bridges to overcome WTO's isolation and engage in normative dialogue with other international law regimes seems to have become a distinctive quest for the WTO's Appellate Body.<sup>31</sup>

This section examines jurisprudential developments in the adjudication of HSE-related disputes at the WTO. It focuses on issues relating to science and risk assessment, as well as uncertainty and the precautionary principle, as these are critical to the proper adjudication of HSE measures. Further, given that they reflect the culmination of more than a decade of discussions as to how HSE measures should be approached by WTO dispute settlement, the *US-Hormones* dispute is discussed at length.

##### *A. Science and Risk Assessment*

The need for rational HSE measures in the face of pervasive hostility between certainty and uncertainty in scientific evidence has led to the emergence of two approaches: Risk assessment and the precautionary

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<sup>30</sup> See Robert Howse, *From Politics to Technocracy—and Back Again: The Fate of the Multilateral Trading System*, 96 AM. J. OF INT'L L. 94, 94-117 (2002); see also Jeffrey Dunoff, *The Death of the Trade Regime*, 10 EUR. J. OF INT'L L. 733 (1999).

<sup>31</sup> Already in its first decision, the *US-Gasoline* case involving measures to address air pollution, the Appellate Body marked a radical departure from the GATT by noting "that the [GATT 1994] is not to be read in clinical isolation from public international law". Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, 17, WT/DS2/AB/R, (29 April, 1996).

principle.<sup>32</sup> The former refers to a methodology for identifying risks; the latter seeks legal and economic responses to serious situations, in the face of uncertainty. Both approaches intersect at the point of uncertainty, which allows for their complementary operation.

This section focuses on risk assessment as the tool of choice in the SPS Agreement for operationalizing its science-based rules. The particular questions addressed include: Value judgments in risk assessments; linkage between uncertainty and scientific evidence in respect of risk assessment requirements; content of a risk assessment; relationship between an SPS measure and a risk assessment; and specificity of risk assessments. The analysis of these questions shed light on how the WTO has addressed cases involving HSE measures.

### 1. Value Judgments in Risk Assessment

As much as policy makers seek *objective* answers from science, risk assessment as a tool for identifying risks is not altogether devoid of value judgments and other meta-science considerations.<sup>33</sup> The SPS Agreement incorporates non-scientific considerations in risk assessment, such as relevant processes and production methods, ecological and environmental conditions, existence of pest – or disease – free areas, etc.<sup>34</sup>

By introducing extra-scientific considerations – such as societal values and concerns – into risk assessment, the distinction between risk assessment and risk management is somewhat blurred. Risk assessment refers generally to determining levels of risk according to science-based processes, while the latter refers to the acts of governments with a view to protect health, safety and the environment on the basis of scientific evidence.<sup>35</sup>

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<sup>32</sup> Konrad von Moltke, *The Relationship Between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle*, in THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION 97, 99 (David Freestone & Ellen Hey eds., 1996).

<sup>33</sup> Gavin Goh & Andreas Ziegler, *A Real World Where People Live and Work and Die—Australian SPS Measures after the WTO Appellate Body's Decision in the Hormones Case*, 32 J. WORLD TRADE 271, 279 (1998).

<sup>34</sup> SPS Agreement, *supra* note 14, art. 5.2.

<sup>35</sup> William Ruckelhaus, *Risk, Science, and Democracy*, in FOUNDATIONS OF ENVIRONMENTAL LAW AND POLICY 48 (Richard Revesz ed., 1997). This distinction

In regard to this distinction, the Appellate Body emphatically noted that risk management does not appear in the text of the SPS Agreement,<sup>36</sup> and thus focused on risk assessment, broadly conceived. Expanding from a strictly scientific or laboratory assessment of quantitative risks, the Appellate Body noted that:

It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.<sup>37</sup>

Introducing value judgments and other societal preferences to a risk assessment carries potentially conflicting implications. It has been argued that by expanding the scope of risk assessment to include qualitative elements, science as a tool loses some of its objective character and could potentially allow abuse of SPS measures for protectionist purposes.<sup>38</sup> In contrast, it has also been argued that a broad reading of risk assessment may allow regulators to consider consumer concerns and anxieties when evaluating risks, thereby expressing democratically adopted choices and achieving public welfare – the ultimate goal of the trading system.<sup>39</sup> This latter argument appears to better appreciate the nature of risk as influenced by a myriad of factors, including societal perceptions and cultural preferences, as well as the limitations of the scientific enterprise in addressing uncertainty.

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between assessment and management has been criticized, however, as impeding public deliberation on important issues of expert judgment regarding scientific and regulatory issues, see Lawrence Busch et al. [academics], *Amicus Curiae* Brief in the case of European Communities - Measures Affecting the Approval and Marketing of Biotech Products 12-13 (30 April, 2004), available at [http://www.ecolomics-international.org/biosa\\_ec\\_biotech\\_amicus\\_academic2\\_ieppp\\_lancasteru\\_coord\\_0404.pdf](http://www.ecolomics-international.org/biosa_ec_biotech_amicus_academic2_ieppp_lancasteru_coord_0404.pdf) (last visited 20 July, 2009).

<sup>36</sup> This textual feature led the Appellate Body to reverse the Panel's analysis in the *Hormones* case, which had adopted the assessment/management distinction.

<sup>37</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, ¶ 187.

<sup>38</sup> Reinhard Quick & Andreas Bluthner, *Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case*, 2 J. INT'L ECON. L. 603, 618 (1999).

<sup>39</sup> Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323 (2002).

## 2. Link Between Uncertainty & Scientific Evidence

Can scientific uncertainty render scientific evidence insufficient for the purposes of risk assessment? The particular architecture and text of the SPS Agreement has notoriously influenced the Appellate Body's approach to this question. The SPS Agreement distinguishes between permanent and temporary SPS measures on the basis of whether "sufficient scientific information" is available to the regulator. Permanent measures are subject to risk assessment requirements, while temporary measures reflecting the precautionary principle are not. However critical the meaning of "sufficient scientific information", it is not defined in the SPS Agreement. Does insufficiency refer to the lack of quantitative data, to the lack of quality reports, to inconclusive scientific evidence, or to a certain degree of uncertainty? Some of these issues are addressed below in the discussion on the precautionary principle.

## 3. Content of a Risk Assessment

An important distinction in the SPS Agreement relates to the content of risk assessment. The distinction pertains to whether the risks effect human or animal health and arise from food borne dangers, on the one hand, or whether risks effect plant and animal health and occur from the entry, establishment, or spread of pests or diseases, on the other.<sup>40</sup>

This distinction carries important consequences for the requirements of risk assessment and the relevance of efficiency considerations. When confronting risks to human health, a risk assessment needs to evaluate the *potential* for adverse effects. In contrast, when animal or plant life or health is concerned, a risk assessment needs to evaluate the likelihood of entry, establishment, or spread of a disease, and of the associated potential biological and economic consequences. In other words, economic considerations are only required in respect of risks effecting plant and animal health, while risk assessments evaluating potential adverse effects on human health are subject to considerably less stringent requirements. As the Appellate Body emphasized in *Australia-Salmon*, the substantial differences between these two types of risk assessments cannot be diminished.<sup>41</sup>

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<sup>40</sup> SPS Agreement, *supra* note 14, Annex A, art. 4.

<sup>41</sup> Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, ¶¶ 123 & note 69, WT/DS18/AB/R, (20 October, 1998) (hereinafter Appellate Body Report, *Australia – Salmon*).

#### 4. Relationship between an SPS Measure and a Risk Assessment

The SPS Agreement requires that a Member's measures must be "based on" a risk assessment. The *EC-Hormones* Panel reading of the "based on" requirement was procedural, in the sense that a Member had to adduce evidence that it had taken the risk assessment into account when adopting a measure. This procedural reading would make a contribution to good governance and the quality of democratic dialogue in a society. However, given that the SPS Agreement applies to measures adopted before its entry into force, such reading would automatically have rendered most SPS measures around the world in breach of WTO law and open to challenge. The Appellate Body reversed the Panel ruling and read "based on" as a determination of whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment.<sup>42</sup>

In this vein, in *EC-Hormones* the Appellate Body implicitly accepted a role for the precautionary principle in its assessment of whether permanent SPS measures are "based on" a risk assessment,<sup>43</sup> in the following terms:

We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources....<sup>44</sup>

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<sup>42</sup> *Id.* at ¶¶ 186, 193.

<sup>43</sup> HOWARD MANN & STEVE PORTER, CTR. FOR INT'L ENVTL. LAW/INT'L INST. FOR SUSTAINABLE DEV., STATE OF TRADE AND ENVIRONMENT LAW 2003: IMPLICATIONS FOR DOHA AND BEYOND 30 (2003), available at [http://www.iisd.org/pdf/2003/trade\\_enviro\\_law\\_2003.pdf](http://www.iisd.org/pdf/2003/trade_enviro_law_2003.pdf) (last visited 20 July, 2009) (hereinafter STATE OF TRADE AND ENVIRONMENT LAW).

<sup>44</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, ¶ 194.

As much as the Appellate Body recognized a role for minority scientific opinions in a risk assessment,<sup>45</sup> the actual weight of such opinions in establishing a “reasonable relationship” between the assessment and the measure imports consideration of a number of additional factors. These factors may include, for example, the character of the threat (irreversible or life threatening) and the quality of the evidence (qualified and respected sources).<sup>46</sup> The fact that these variables interact and the fact that their evaluation devolves into a question of degree, amplify the difficulties associated in passing judgment on whether regulators have established a reasonable relationship between the HSE measure and its underlying risk assessment. All in all, the Appellate Body has not excluded that WTO Panels and itself may be up to the task.

What is clear from the foregoing is that the mandate of the WTO, in accordance with the SPS Agreement and the DSU, does not extend to determining whether the science is true or the findings of risk of a risk assessment are correct. Instead, the WTO will evaluate the relationship between the findings of risk in the risk assessments and the measures adopted to address those risks. The scope of this scrutiny raises the question of the specificity of scientific studies to determine whether a purported risk assessment qualifies as such.

## 5. Specificity of Risk Assessments

Finally, the specificity and exhaustiveness of scientific studies adduced as evidence has become an issue in the resolution of several WTO cases concerning HSE measures. In *EC-Hormones*, the studies presented by the EC were dismissed because they showed the carcinogenic potential of hormones *in general*, but not specifically as residues in hormone-grown beef.<sup>47</sup> Likewise, in *Japan-Apples*, involving quarantine requirements to address the risk of transmission of fire blight (*Erwinia amylovora*) from mature, symptomless apples from infested orchards, the risk assessment

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<sup>45</sup> KARINE FOUCHER, PRINCIPE DE PRECAUTION ET RISQUE SANITAIRE 425 (2002).

<sup>46</sup> Joost Pauwelyn, *Does the WTO Stand for “Deference To” or “Interference With” National Health Authorities When Applying the Agreement on Sanitary and Phytosanitary Measures*, in *THE ROLE OF THE JUDGE IN INTERNATIONAL TRADE REGULATION* 175, 180-81 (Thomas Cottier & Petros Mavroidis eds., 2003).

<sup>47</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, at ¶¶ 199-200 (emphasis in original).



presented by Japan was dismissed because it did not specifically evaluate the likelihood of entry, establishment or spread of fire blight in Japan through apple fruit.<sup>48</sup> In *Australia-Salmon*, involving Australia's prohibition on the importation of untreated fresh, chilled or frozen salmon to address the introduction of disease agents, the issue arose as to the exhaustiveness of a risk assessment; the Appellate Body emphasized that *some* evaluation of the likelihood of entry or spread of diseases is not enough and concluded that Australian studies were not a proper risk assessment.<sup>49</sup>

Such strict requirements for risk assessments may become a barrier to the adoption of effective HSE measures because financial and human resources will be lacking in many developing countries.<sup>50</sup>

### B. *Science and the Precautionary Principle*

In trying to screen real risks from imaginary risks, much like the early philosophers tried to distinguish causation from mythology, science provides an imperfect tool that incrementally assists human understanding of planet earth and the universe. Prominent among the shortcomings in scientific inquiry is its inability to produce conclusive evidence on nature and magnitude of risk in every situation. Thus, policy makers are often confronted with the pressing need to take effective action to avert, control, or mitigate HSE emergencies or risks in situations where science is disputed or inconclusive. The precautionary principle has been developed to aid policy makers in facing such difficult situations of inconclusive science, not in disregard of science, but in recognition of its limitations.

This section explores how uncertainty and the precautionary principle have been dealt with in WTO jurisprudence relating to HSE measures, with a particular focus on the SPS Agreement. It is divided into four subsections, first introducing the precautionary principle and then exploring three salient issues: The precautionary principle in *EC-Hormones*, which set first principles on the matter; uncertainty and sufficient scientific evidence; and the precautionary principle and the level of protection.

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<sup>48</sup> Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, ¶¶ 202-03, WT/DS245/AB/R, (26 November, 2003) (hereinafter Appellate Body Report, *Japan – Apples*).

<sup>49</sup> Appellate Body Report, *Australia-Salmon*, *supra* note 41, at ¶¶ 124, 128, 134, 136 (the Appellate Body does note that the risk can be assessed in quantitative or qualitative terms).

<sup>50</sup> STATE OF TRADE AND ENVIRONMENT LAW, *supra* note 43, at 35.

## 1. The Precautionary Principle: An Introduction

While formulations vary, a common element of the precautionary principle is its reliance on science as a tool for HSE protection. Stated differently, the precautionary principle does not dismiss science as irrelevant in the regulatory decision-making process, nor does it pretend to justify measures devoid of any scientific or rational basis. Rather, the precautionary principle attempts to provide a legitimate basis for HSE regulation in situations where scientific uncertainties render available scientific evidence inconclusive.

Perhaps the most authoritative general formulation of the precautionary principle is found in the Rio Declaration on Environment and Development:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.<sup>51</sup>

In the particular context of human health, the precautionary principle can provide that in cases of serious threats to public health, lack of conclusive evidence should not deter – or render illegitimate – actions to eliminate, control, or abate environmental disturbances underlying the public health hazards.

Despite the fact that the precautionary principle is often included in Multilateral Environmental Agreements (MEAs), and that the legislation of numerous countries reflects it, there is persistent debate as to the exact status of the precautionary principle as a rule of customary law or a general principle of international law.<sup>52</sup> The *EC-Biotech* Panel, for example, noted that the question of whether the precautionary principle is a general

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<sup>51</sup> United Nations Conference on Environment and Development, Rio Declaration on Environment and Development, Principle 15, 31 I.L.M. 874, 879 (1992).

<sup>52</sup> Arie Trouwborst, EVOLUTION AND STATUS OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW (2002); Owen McIntyre & Thomas Mosedale, *The Precautionary Principle as a Norm of Customary International Law*, 9 J. ENV. L. 221 (1997); James Cameron, *The Status of the Precautionary Principle at the International Level*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE 262 (Timothy O’Riordan & James Cameron eds., 1995).

principle of international is a complex and unsettled one.<sup>53</sup> This inconclusive debate has influenced WTO jurisprudence on HSE measures. A review of the relevant cases decided by the WTO sheds further light on the relationship between science and the precautionary principle.

## 2. The Precautionary Principle in *EC-Hormones*

In the *EC-Hormones* case, the Appellate Body established the basic contours of its approach to the relationship of the precautionary principle with the SPS Agreement. First, the Appellate Body rejected the precautionary principle as a defense or justification for a breach of obligations under the SPS agreement.<sup>54</sup> The Appellate Body reached this conclusion without determining the exact status of the precautionary principle in international law and without applying a conflict of norms analysis to the interplay between WTO law and customary law.<sup>55</sup> The Appellate Body's reluctance to decide issues of non-trade law,<sup>56</sup> such as the status of the precautionary principle, may have been inspired by its decided attempt to establish meaningful normative dialogue between the WTO and other international regimes.<sup>57</sup>

Second, the Appellate Body accepted that the precautionary principle finds reflection in Article 5.7 (on temporary SPS measures), and noted that such a provision did not exhaust the relevance of the principle. Article 5.7, however, is far away from providing *carte blanche* based on the precautionary principle. In *Japan-Agricultural Products II*, for example, the Appellate Body emphasized that Article 5.7 establishes a stringent test with cumulative

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<sup>53</sup> Panel Report, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*, ¶ 7.89, WT/DS291, WT/DS292, WT/DS293 (29 September, 2006) (hereinafter Panel Report, *EC-Biotech*).

<sup>54</sup> Appellate Body Report, *EC - Hormones*, *supra* note 12, ¶¶ 124-25.

<sup>55</sup> JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW 481-82 (2003). See further Adarsh Ramanujan, *Conflicts over "Conflict": Preventing Fragmentation of International Law*, 1(1) TRADE L. & DEV. 172 (2009).

<sup>56</sup> In this sense and by analogy, the WTO's Committee on Trade and Environment recorded its preference for environmental disputes arising under MEAs to be decided by the dispute settlement of the respective MEA. WTO, Committee on Trade and Environment, *Report to the Singapore Ministerial*, WT/CTE/1 (12 November, 1996), ¶178.

<sup>57</sup> Perhaps it could also reflect judicial restraint on behalf of the Appellate Body, in implicit recognition of its inherent powers as an international tribunal.

requirements,<sup>58</sup> and that whenever one of the four requirements is not met the measure at issue is inconsistent with Article 5.7.<sup>59</sup>

Finally, while the Appellate Body has accepted a role for the precautionary principle in the HSE regulatory process, it has emphasized that SPS measures should address “ascertainable” risks.<sup>60</sup> In this sense, the Appellate Body has excluded that a minimum level of risk is a pre-requisite for action, but has indicated that theoretical uncertainty is not the type of risk to be assessed. By resorting to the concept of “ascertainable risks”, the Appellate Body thus seems to be struggling between two polarities: On the one hand a probabilistic, quantified determination of risk, and on the other a conjectural, hypothetical risk.<sup>61</sup>

The Appellate Body in *EC-Hormones* also discussed other issues relating to the precautionary principle, such as the question of uncertainty and sufficient scientific evidence, where we now turn.

### 3. Uncertainty and Sufficient Scientific Evidence

The Appellate Body appeared to link the question of sufficient scientific evidence with precaution in the face of irreversible risks, in the following terms:

.... [A] Panel charged with determining, for instance, whether “sufficient scientific evidence” exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of

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<sup>58</sup> Article 5.7 requires that: (i) the measure is imposed in respect of a situation where “relevant scientific evidence is insufficient”; (ii) the measure is adopted “on the basis of available pertinent information”; (iii) the Member which adopted the measure “seek[s] to obtain the additional information necessary for a more objective assessment of risk”, and (iv) the Member which adopted the measure “review[s] the ... measure accordingly within a reasonable period of time.” SPS Agreement art. 5.7.

<sup>59</sup> Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, ¶ 89, WT/DS76/AB/R (22 February, 1999) (hereinafter Appellate Body Report, *Japan – Agricultural Products II*).

<sup>60</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, ¶¶ 186-87.

<sup>61</sup> Michael Trebilcock & Julie Soloway, *International Trade Policy and Domestic Food Safety Regulation: The Case for Substantial Deference by the WTO Dispute Settlement Body Under the SPS Agreement*, in *THE POLITICAL ECONOMY OF INTERNATIONAL TRADE LAW* 537, 565 (Daniel Kennedy & James Southwick eds., 2002).

prudence and precaution where risks are irreversible, e.g., life-terminating, damage to human health are concerned.<sup>62</sup>

The Appellate Body's approach to the precautionary principle in SPS cases has been strongly influenced by the difficulties associated with incorporating uncertainty into the operation of scientific principles. In this regard, Article 2.2 of the SPS Agreement requires that permanent SPS measures must be based on scientific principles and not maintained without sufficient scientific evidence, except as provided in Article 5.7 regarding temporal measures. Consequently, the operative question is whether the precautionary principle can inform the reading of "scientific principles" in this provision. Here, it would appear that a science-based risk assessment process is capable of taking into account unknown or uncertain elements, as scientific principles allow for uncertainty to be weighed and considered.<sup>63</sup> This proposition finds echo in the *EC-Biotech* Panel, which noted:

Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g., uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any to be taken.<sup>64</sup>

Accordingly, the precautionary principle would allow for a measure to be based on "scientific principles" in a situation of scientific uncertainty, after a risk assessment has been performed. Could the precautionary principle also allow for a permanent measure to be based on "sufficient scientific evidence", thereby satisfying Article 2.2, in a situation of scientific uncertainty?

This question arose in the *Japan – Agricultural Products* case, where the Appellate Body concluded that "sufficiency" is a relational concept to be determined on a case-by-case basis, including the quality and quantity of the scientific evidence.<sup>65</sup> In the words of the Appellate Body, "the obligation in Article 2.2 that an SPS measure not be maintained without sufficient scientific evidence requires that there be a rational or objective relationship

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<sup>62</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, ¶ 124.

<sup>63</sup> STATE OF TRADE AND ENVIRONMENT LAW, *supra* note 43, at 31.

<sup>64</sup> Panel Report, *EC – Biotech*, *supra* note 53, at ¶ 7.1518 (citations omitted).

<sup>65</sup> Appellate Body Report, *Japan – Agricultural Products II*, *supra* note 59, at ¶ 73.

between an SPS measure and the scientific evidence.”<sup>66</sup> By characterizing “sufficiency” as a relational concept, the Appellate Body seems to acknowledge the difficulties of *a priori* quantifying the degree or amount of scientific evidence, as well as its quality. Rather, the Appellate Body chose to preserve its authority to make final determinations on the matter on a case-by-case basis, thereby leaving the door open to including the precautionary principle in the determination of what constitutes sufficient scientific evidence in the context of Article 2.2. and permanent measures.

Could the precautionary principle allow SPS measures absent a risk assessment? This question goes to the requirement in Article 2.2, in relation to Article 5.1 and 5.2, that permanent measures not be maintained without “sufficient scientific evidence” and a risk assessment. In this regard, what constitutes “sufficient scientific evidence”, and how does uncertainty play into that determination? Is there a role for the precautionary principle in this context? The answer to these questions involves a discussion on temporary measures under Article 5.7.

The *Japan-Apples* case confronted the question of uncertainty and the sufficiency of scientific evidence in the context of temporary measures under Article 5.7. On appeal, Japan argued that relevant scientific evidence was insufficient to perform a risk assessment and thus its measures were covered by Article 5.7 of the SPS Agreement. The Appellate Body disagreed, noting that “relevant scientific evidence” will be insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks.<sup>67</sup> The Appellate Body also observed that the Panel had found a voluminous quantity of high quality evidence describing the risk of transmission of fire blight through apple fruit as “negligible”. Nevertheless, the Appellate Body did not exclude cases from the purview of Article 5.7 where the available evidence is more than minimal in quantity,

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<sup>66</sup> *Id.* at ¶ 84.

<sup>67</sup> Appellate Body Report, *Japan – Apples*, *supra* note 48, at ¶ 179. The Appellate Body then noted that the Panel had found a voluminous quantity of high quality evidence describing the risk of transmission of fire blight through apple fruit as “negligible.” Japan, however, also argued that despite accumulated evidence, there was unresolved uncertainty about certain aspects of transmission of fire blight. The Appellate Body again disagreed, focusing on the text of Article 5.7, which refers not to scientific uncertainty but to insufficient evidence.

but has not led to reliable or conclusive results.<sup>68</sup> In other words, where the science is inconclusive, the precautionary principle, as reflected in Article 5.7, could be used as a basis for temporary measures.

#### 4. Precautionary Principle and the Level of Protection

Another important dimension in the relationship between science and the precautionary principle is the sovereign right of a country to determine its level of HSE protection. In the *Australia-Salmon* case, the Appellate Body emphasized the distinction between the evaluation of risk in a risk assessment and the determination of the appropriate level of protection. The Appellate Body noted that no provision of the DSU or the SPS Agreement entitles the Panel or the Appellate Body to “substitute its own reasoning about the implied level of protection for that expressed consistently by Australia”.<sup>69</sup> In that sense, the Appellate Body confirmed that a Member could determine its own appropriate level of protection to be “zero risk”.<sup>70</sup> Further, the Appellate Body noted that:

The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as “the level of protection deemed appropriate by the member establishing a sanitary ...measure”, is a *prerogative* of the Member concerned and not of a Panel or of the Appellate Body.<sup>71</sup>

Besides categorically affirming the *right* of Members to adopt their level of protection, the Appellate Body also observed in *Australia-Salmon* that the SPS Agreement contains an implicit *obligation* to determine the appropriate level of protection.<sup>72</sup> The Appellate Body’s view of the level of protection both as a right and an obligation may be instrumental to the operation and dynamics of the provisions of the SPS Agreement. Such characterization of the level of protection could also open channels for dialogue, for instance between trade norms and human rights norms. Further, such reading could open a role for the precautionary principle, not only as a right in health, safety, and environmental policy, but also as a duty in the determination of the appropriate level of protection.

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<sup>68</sup> *Id.* at ¶ 185.

<sup>69</sup> *Id.* at ¶ 199.

<sup>70</sup> *Id.* at ¶ 125.

<sup>71</sup> *Id.* at ¶ 199 (emphasis in original).

<sup>72</sup> Appellate Body Report, *Australia – Salmon*, *supra* note 41, at ¶¶ 205-07.

C. *Concluding Remarks on the Evolving WTO Jurisprudence Concerning HSE Measures*

As the cases examined above show, the WTO Appellate Body's approach to the precautionary principle in HSE-related cases has oscillated between acceptance and rejection. Such an approach is due partly to strict textual readings of rights, obligations, and exceptions in the WTO covered agreements. At a more systemic level, the Appellate Body's approach to the certainty/uncertainty conundrum seems to reflect an attempt to preserve for itself as much room for deliberation as possible. In other words, the Appellate Body often resorts to ambiguous tests and formulas, perhaps in the deliberate attempt not to foreclose future options and tools available to reason and resolve challenging disputes involving both scientific uncertainty and important public health objectives. Finally, the Appellate Body seems to have struggled with the tension arising from the limited terms of reference of Panels under the DSU and the need to find channels for normative dialogue with other international law regimes.

The Appellate Body's approach, as refined in the cases examined above, has culminated in its application in the *US-Hormones* case, analyzed next.

## V. US – HORMONES

The *Hormones* saga is a long-standing trade dispute that predates even the creation of the WTO and the negotiations of the SPS Agreement. The *Hormones* disputes pit the United States and Canada's use of hormones in stimulating beef growth against the EC's ban on the use of hormones in treating beef. In the mix fall a range of issues relevant to the interaction between economic law, environmental law and human rights law, including: Scientific evidence and risk assessment; the precautionary principle and temporary measures; and the standard of review and the degree of deference to regulators. Broader systemic implications of the *Hormones* saga involve: Compliance determinations in the operation of the DSU; determinations on the burden of proof; and the due process implications of the selection of experts advising a WTO Panel. All in all, the *Hormones* cases reveal the difficulties placed upon the trading system in threading dialogue with other branches of international law and finding ways to account for the value of non-trade interests.



The latest chapter of the *Hormones* sequel opened with a complaint by the EC against the United States and Canada, in connection with their refusal to lift their respective sanctions on EC products after the EC had communicated to the WTO the adoption of its new directive on hormones, Directive 2003/74/EC.<sup>73</sup> According to the EC, the adoption of its new directive on hormones in beef brought it into compliance with WTO law, thus making the continued suspension of concessions illegal. According to the United States and Canada, in contrast, the EC had not modified its measure, as the ban on meat and meat products from cattle treated with hormones for growth-promotion purposes continued in effect.

It may be useful to recall that in 1999 the DSB had authorized trade retaliation by the United States and Canada against the EC as a result of the 1998 *EC – Hormones* decision of the Appellate Body. In that case the Appellate Body concluded that the EC ban on beef treated with hormones was not based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement, because the scientific studies supporting the ban did not focus on and address the particular carcinogenic and genotoxic potential of the residues of hormones found in meat derived from cattle treated with hormones.<sup>74</sup>

In response, the EC undertook seventeen new scientific studies to evaluate the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of hormones in cattle for growth-promotion purposes, including the risks associated with inadequate veterinary practices. The results of these studies were reviewed by the Scientific Committee on Veterinary Measures relating to Public Health of the European Commission (SCVPH), which also reviewed available information from the Codex Alimentarius Commission (Codex) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). On this basis, the SCVPH published a scientific opinion in 1999 and reviewed it in 2000 and 2002. These scientific studies were the basis for the adoption of Directive 2003/74/EC by the EC in September 2003.

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<sup>73</sup> Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, 2003 O.J. (L 262) 17 (14 October 2003).

<sup>74</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, at ¶ 200.

According to the EC, the new scientific evidence demonstrated that the use of oestradiol-17 $\beta$  in treating beef for growth-promotion purposes posed a risk to humans, and especially to pre-pubertal children and menopausal women, and thus *permanently* banned the import of beef treated with this hormone. The EC also argued that it had determined the need for a higher level of protection than that which would be achieved under Codex's standard for oestradiol-17 $\beta$ .<sup>75</sup> In addition, the EC argued that the science was insufficient to conduct a risk assessment in respect of the other five hormones, namely progesterone, testosterone, trenbolone acetate, zeranol, and melengestrol acetate, and *provisionally* banned the import of beef treated with these hormones under SPS Agreement Article 5.7.<sup>76</sup>

In *US – Hormones*, the Panel and the Appellate Body confronted two clusters of issues. First, how the DSU provides for the termination of retaliation; second, whether the EC was in compliance with the SPS Agreement. On most issues falling under these clusters, the Appellate Body reversed the findings of the Panel, and for this reason the analysis that follows will focus on the Appellate Body's decision. However, in respect of whether the EC was in compliance with the SPS Agreement, as much as the Appellate Body reversed the Panel's findings of non-compliance, it did not complete the analysis, thus inviting the parties to engage in a new dispute that will scrutinize afresh the compatibility of the new EC Directive on hormones in beef with the SPS Agreement.

#### *A. On the Broader Systemic Implications of US – Hormones*

The recent decisions by the Panel and the Appellate Body in *US – Hormones* implicate several systemic issues in the operation of the DSU. For example, the use of experts by the Panel raised due process considerations; and the notification by the EC of its new risk assessment to the WTO raised the issues relating to the cessation of retaliation. While the broader issue of trade retaliation is important for the operation of the DSU, this section will focus on the issue of experts, since it directly concerns HSE measures.

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<sup>75</sup> Codex Alimentarius Commission, *Maximum Residue Limits for Veterinary Drugs in Foods*, updated as at the 29<sup>th</sup> Session of the Codex Alimentarius Commission (July 2006), CAC/MRL 2. See Appellate Body Report, *US – Hormones*, *supra* note 12, at ¶ 200.

<sup>76</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, ¶ 493.

A critical element of the *US – Hormones* case concerning broad systemic implications relates to the use of certain experts by the Panel. The EC complained that certain experts appointed by the Panel suffered a conflict of interest because, *inter alia*, they had participated in earlier assessments by JECFA and had made public statements on the dispute, and thus they were being asked to evaluate and comment on their own work. The Panel had considered that the use of six experts in their individual capacity, including two who had participated in JECFA's work, could provide a "more complete picture both of the mainstream scientific opinion and of any divergent views".<sup>77</sup> Rather than being a source of concern, the Panel considered that the participation in JECFA's work of the two experts would make them more valuable as experts.

The Appellate Body, however, noted that precisely because JECFA's risk assessments have such a prominent role in the dispute, the Panel should have exercised particular caution before appointing persons with institutional links to JECFA as experts.<sup>78</sup> Moreover, the Appellate Body observed that the Panel asked the experts to evaluate the EC's risk assessment, and relied on the two experts' advice in its assessment of the consistency of Directive 2003/74/EC with Articles 5.1 and 5.7 of the SPS Agreement. Finally, the Appellate Body concluded that the appointment of, and consultations with, these two experts "compromised the adjudicative independence and impartiality of the Panel",<sup>79</sup> in violation of DSU Article 11 mandating the Panel to conduct an objective assessment of the facts.

The Appellate Body's decision on the use of experts and due process also relates to the role of scientific evidence in WTO dispute settlement.<sup>80</sup> The Panel heavily relied on the expert testimonies to determine whether the SPS measures adopted by the EC were compatible with its WTO obligations. Stated differently, the Panel conducted its review on the basis of the expert views on the correct science relating to the use of hormones in beef. And since the two scientists in question had already concluded that the use of hormones was safe in the Codex assessment, the EC faced an uphill road in persuading the Panel that its new Directive 2003/74/EC

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<sup>77</sup> Panel Report, United States – *Continued Suspension of Obligations in the EC-Hormones Dispute*, ¶ 7.418, WT/DS320/R (31 March, 2008) (hereinafter Panel Report, *US – Hormones*).

<sup>78</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, at ¶ 462.

<sup>79</sup> *Id.* at ¶ 481.

<sup>80</sup> See Joost Pauwelyn, *The Use of Experts in WTO Dispute Settlement*, 51 I.C.L.Q. 325

permanently banning oestradiol-17 $\beta$  and temporarily banning the other five hormones, was a legitimate SPS measure to address the risks associated to the use and misuse of hormones. Along these lines, the Appellate Body's decision can be read as an indication to Panels to conduct their own review and analysis, without asking experts to determine the legality of a country's measure. This reading is directly related to the standard of review formulated by the Appellate Body in relation to the level of deference to be accorded by WTO Panels to regulators, addressed in turn.

*B. On Risk Assessment and Qualified Deference to Regulators*

The Panel in *US – Hormones* determined that Directive 2003/74/EC was an SPS measure within the meaning of the SPS Agreement, and thus sought to determine whether the permanent ban on meat treated with oestradiol-17 $\beta$  was based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement. The Panel applied a four-part test to this question, examining in particular whether the SCVPH scientific opinions:

1. Took into account risk assessment techniques of the relevant international organizations;
2. Took into account the factors listed in Article 5.2 of the *SPS Agreement*;
3. Satisfied the definition of “risk assessment” contained in Annex A, paragraph 4, of the *SPS Agreement*; and
4. Were supported by the scientific evidence evaluated.<sup>81</sup>

The *US – Hormones* Panel concluded that the SCVPH Opinions satisfied parts 1 and 2 of this test, but failed parts 3 and 4. In respect of the definition of a risk assessment (part three of the test), the Panel observed that:

[A]lthough the EC has evaluated the association between excess hormones and neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity, and carcinogenicity, ... it has not evaluated specifically the possibility that these adverse effects come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-7 $\beta$  as a result of the cattle being treated with the hormone for growth promotion purposes.<sup>82</sup>

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<sup>81</sup> Panel Report, *US – Hormones*, *supra* note 77, at ¶ 7.445.

<sup>82</sup> *Id.* at ¶ 7.537.

And in respect of the fourth element of its test, the Panel concluded that the scientific evidence referred to in the SCVPH Opinions did not support the conclusion that the genotoxicity of oestradiol-17 $\beta$  has been demonstrated and that residue of oestradiol-17 $\beta$  in meat and meat products lead to increased risk of cancer or adverse immunological and developmental effects.<sup>83</sup>

The EC appealed, arguing, *inter alia*, that the Panel failed to conduct an objective assessment of the facts because it applied an improper standard of review to the evidence, by seeking to determine the correct scientific conclusions. This argument brought the issue of science and scientific evidence before the Appellate Body, and it is perhaps in this respect that the *US – Hormones* case may make a lasting contribution to the development of HSE jurisprudence at the WTO.

At this point it may be useful to recall the long-lasting doctrinal controversy surrounding the use of science in the SPS Agreement as a mechanism to determine legality of internal SPS measures.<sup>84</sup> This discussion identifies the tension between the prerogative of WTO Members to determine their own levels of protection, on the one hand, and the obligation to adopt HSE measures on the basis of a risk assessment, where science plays a central role, on the other. This tension is amplified in situations of scientific uncertainty, where science does not offer conclusive evidence regarding causal connections between particular risks and particular substances or processes.

In addressing this tension, the Appellate Body in *US – Hormones* traversed a course that emphasized the process of production of scientific evidence, and in this way avoided the snare of seeking to determine the

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<sup>83</sup> *Id.* at ¶ 7.572.

<sup>84</sup> See generally David Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines* 27 CORNELL INT'L L.J. 817 (1994); Vern Walker, *Keeping the WTO from Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute* 31 CORNELL INT'L L.J. 251 (1998); Robert Howse, *Democracy, Science and Free Trade: Risk Regulation on Trial at the World Trade Organization* 98 MICH. L. REV. 2329 (2000); Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle* 40 COLUM. J. TRANSNAT'L L. 323 (2002); CATHERINE BUTTON, *THE POWER TO PROTECT: TRADE, HEALTH AND UNCERTAINTY IN THE WTO* (2004); and Alan Sykes, *Domestic Regulation, Sovereignty and Scientific Evidence: A Pessimistic View*, in *TRADE AND HUMAN HEALTH AND SAFETY* 257-270 (George Berman & Petros Mavroidis eds., 2006).

*correct* science underlying the use of hormones in beef for growth-promotion purposes. The Appellate Body's approach thus affords deference to regulators adopting HSE measures on the basis of divergent and minority opinions from qualified and reputable scientific sources, thereby restoring the policy space that had been lost as a result of the narrow and strict interpretation of Article 5.1 by the Panel. As argued in this article, this policy space is central to ensure that governments retain their capabilities to realize human rights and environmental protection.

The Appellate Body began its path by restating certain key elements of its jurisprudence: First, the results of the risk assessment must sufficiently warrant the SPS measures – that is, there must be a “rational relationship” between the SPS measure and the risk assessment. Second, governments may act on the basis of divergent opinion coming from qualified and respected sources. Third, the risk assessment supporting the measure may be performed by the WTO Member, and also by a relevant international organization or by another WTO Member. Fourth, the risk assessment can be quantitative or qualitative in nature. Fifth, the risk to be assessed must be an “ascertainable risk”, thus excluding “theoretical uncertainty” as the kind of risk to be assessed under Article 5.1. Sixth, the assessment must be “sufficiently specific” in terms of the harm concerned and the precise agent that may possibly cause the harm. Seventh, WTO Members have the right to introduce or maintain an SPS measure which results in a higher level of protection than would be achieved by international standards. Finally, the SPS Agreement does not attach a more exacting burden of proof to a WTO Member establishing a higher level of protection.<sup>85</sup>

The Appellate Body next reasoned that the risk assessment cannot be entirely isolated from the appropriate level of protection.<sup>86</sup> In this vein, a higher level of protection than, for example, the level of protection embodied in an international standard, may require particular research that is different from the parameters considered underlying the international standard. The Appellate Body, while recalling that the scientific process must not be understood narrowly as being strictly confined to matters susceptible to quantitative analysis by empirical or experimental laboratory methods, nevertheless cautioned that “the chosen level of protection must not affect the rigour or objective nature of the risk assessment, which must

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<sup>85</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, at ¶ 528-29 *et seq.*

<sup>86</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, at ¶ 534.

remain, in its essence, a process in which possible adverse effects are evaluated using scientific methods”.<sup>87</sup>

The Appellate Body also addressed the distinction between “risk management” and “risk assessment”. The Appellate Body noted that while it had not provided a clear demarcation of the factors that may be considered in a risk assessment, there is no closed list of factors and, in particular, that abuse or misuse and difficulties of control in the administration of hormones may be considered in the context of a risk assessment.<sup>88</sup> In this regard, the Appellate Body concluded that the Panel incorrectly applied Article 5.1 by “summarily dismissing the evidence on the misuse or abuse in the administration of the hormones and the consequent conclusions in the SCVPH Opinions”.<sup>89</sup>

This finding regarding abuse or misuse in the administration of the hormones is of particular importance to developing countries in connection with HSE measures, as they often lack effective mechanisms of control to ensure adequate veterinary practices. This finding also resonates with *Brazil – Tyres*, in that risks need to be ascertained not as they exist in fictitious scenarios of flawless management practices, but as they exist in the real world.<sup>90</sup> Responsible governments respond to risks as they exist beyond laboratories and the consideration of such real-world risks brings to a sharper focus the policy measures adopted to address them. Consequently, by avoiding narrow notions of the risks to be assessed, the Appellate Body restores the policy space that governments need in order to face real risks.

Another crucial finding relevant to the policy space available to governments in *US – Hormones* concerns the standard of review. On appeal, the EC claimed that the Panel erred when it decided to become a jury on the correct science. The US and Canada disagreed with the EC’s contention and maintained that the Panel did not exceed the bounds of its discretion as the trier of facts when assessing the weight and determining the credibility to be attributed to the opinions of the scientific experts.

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<sup>87</sup> *Id.* at ¶ 534.

<sup>88</sup> *Id.* at ¶ 535.

<sup>89</sup> *Id.* at ¶ 553.

<sup>90</sup> Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS/332/AB/R, (3 December, 2007) (hereinafter Appellate Body Report, *Brazil – Tyres*).

The Appellate Body once again approached this issue recalling its earlier decision in *EC – Hormones*, to the effect that the applicable standard is “neither de novo review as such, nor ‘total deference’, but rather the “objective assessment of facts”.<sup>91</sup> The Appellate Body went further in *US – Hormones*, elaborating its views on the applicable standard of review, noting that the Panel’s mandate under Article 5.1 is to review the risk assessment performed by the WTO Member:

Where a Panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own scientific judgment for that of the risk assessor and making a *de novo* review and, consequently, would exceed its functions under Article 11 of the DSU. Therefore, the review power of a Panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.<sup>92</sup>

In discharging this discrete task, the Panel may and should rely on the advice of experts, in accordance with Article 11.2 of the SPS Agreement and Article 13.1 of the DSU. However, the role of experts is not to determine whether they would have conducted the risk assessment in the same way and would have reached the same conclusions as the risk assessor. Rather, the assistance of the experts is constrained by the kind of review that the Panel is required to undertake.<sup>93</sup> To remove ambiguities from the kind of review attached to Article 5.1, the Appellate Body clarified that a Panel must:

... first, identify the scientific basis upon which the SPS measure was adopted. This scientific basis need not reflect the majority view within the scientific community but may reflect divergent or minority views. Having identified the scientific basis underlying the SPS measure, the Panel must then verify that the scientific basis comes from a respected and qualified source. Although the scientific basis need not represent the majority view within the scientific community, it must nevertheless have the necessary scientific and methodological rigour to be considered reputable science. In other words, while the correctness of the views need not have been accepted by the broader scientific community, the views must be considered to be legitimate science according to the standards of the relevant scientific community. A Panel should also assess whether the reasoning articulated on

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<sup>91</sup> Appellate Body Report, *EC – Hormones*, *supra* note 12, at ¶ 117.

<sup>92</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, at ¶ 590.

<sup>93</sup> *Id.* at ¶ 592.



the basis of the scientific evidence is objective and coherent. In other words, a Panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon. Finally, the Panel must determine whether the results of the risk assessment “sufficiently warrant” the SPS measure at issue. Here, again, the scientific basis cited as warranting the SPS measure need not reflect the majority view of the scientific community provided that it comes from a qualified and respected source.<sup>94</sup>

This formulation of the standard of review and the role of experts is critical in articulating the balance between the rights and obligations of WTO Members in respect of SPS measures having an impact on trade. First, the Appellate Body clearly notes that experts are not to substitute the Panel in deciding the case, but rather are to assist the Panel by providing it with advice in connection with its limited mandate. Second, the Appellate Body places the emphasis of the Panel’s task in conducting an objective assessment of the facts not on whether the science underlying the SPS measure is correct, but on whether the science is legitimate, in accordance with the standards employed by the relevant scientific community.

On the basis of this comprehension of the standard of review, the Appellate Body reviewed the Panel’s approach to the EC’s risk assessment generally, and the genotoxicity of oestradiol-17 $\beta$  in particular. The Appellate Body observed that the Panel conducted a survey of the advice presented by the scientific experts and based its decisions on whether the majority of the experts agreed with the EC’s risk assessment.<sup>95</sup> The Appellate Body also noted that the Panel’s reasoning revealed flaws, for example in connection with the Panel’s conclusion regarding lack of scientific evidence to support the genotoxicity of oestradiol-17 $\beta$ , on the one hand, and minority views that revealed some acceptance of the EC’s position, on the other.<sup>96</sup> Further, a similar flaw was identified with respect to the EC’s contention that a threshold, that is a level below which intakes from residue should be considered to be safe, could not be established for oestradiol-17 $\beta$ .<sup>97</sup> Ultimately, the Appellate Body concluded that:

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<sup>94</sup> *Id.* at ¶ 591 (citations omitted).

<sup>95</sup> *Id.* at ¶ 598.

<sup>96</sup> *Id.* at ¶¶ 603-606.

<sup>97</sup> *Id.* at ¶¶ 599, 607-609.

We have identified above how the Panel approached its task without proper regard to the standard of review and the limitations this places upon the appraisal of expert testimony. Ultimately, the Panel reviewed the scientific experts' opinions and somewhat peremptorily decided what it considered to be the best science, rather than following the more limited exercise that its mandate required.<sup>98</sup>

On this basis, the Appellate Body found that the Panel failed to conduct an objective assessment of the facts of the case, as required by Article 11 and reversed the Panel's findings that the EC had not satisfied the requirements of Article 5.1. The Appellate Body, however, determined that it could not complete the analysis by reviewing the consistency of the EC's risk assessment relating to oestradiol-17 $\beta$  with Article 5.1, given the "numerous flaws" found in the Panel's analysis, and "the highly contested nature of the facts".<sup>99</sup> As the Appellate Body made no findings with respect to the consistency or inconsistency of the EC's import ban, it thus set the stage for a new Panel dispute on those issues.

In the end, on a more general note, the formulation of the standard of review adopted by the Appellate Body in *US – Hormones* stresses the importance of the scientific method in the production of scientific evidence. This is the key criterion to ascertain whether scientific evidence comes from a respected and qualified source. By resorting to the scientific standards of the relevant scientific community to define legitimate science, the Appellate Body avoids the snare not only of having to decide on the *correct* science, but also of having to articulate substantive criteria to define science. In other words, scientific evidence derives from the scientific method, including peer review, and is recognized as such by the relevant scientific community even when the correctness of the views have not been accepted by the mainstream.<sup>100</sup>

The Appellate Body's formulation thus avoids transforming the WTO into a science court empowered to resolve scientific disputes, and preserves the scientific domains to the relevant scientific communities. This

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<sup>98</sup> *Id.* at ¶ 612.

<sup>99</sup> *Id.* at ¶ 620.

<sup>100</sup> *See, e.g.*, RICHARD CLAUDE, SCIENCE IN THE SERVICE OF HUMAN RIGHTS (2002); Marcos Orellana, *The Role of Science in Investment Arbitrations Concerning Public Health and the Environment*, in Yearbook of International Environmental Law 48 (Ole Fauchald & David Hunter eds., 2006).

formulation also properly defines the scope of the task facing Panels reviewing risk assessments by WTO Members; it affords qualified deference to regulators, thereby avoiding artificially narrow interpretations that unduly restrict the policy space necessary for responsible governments to safeguard human rights and the environment.

### C. *On Temporary Measures and Paradigm Shifts*

The question of when scientific evidence is sufficient to conduct an adequate assessment of risks figured prominently in *US – Hormones*, in the discussion surrounding Article 5.7 of the SPS Agreement. The complexities involved in this question were compounded in this case by the existence of international standards adopted by CODEX, on the basis of assessments conducted by JEFCA, on the five hormones in question. Thus, the interplay between international standards and more stringent SPS measures, in the context of scientific uncertainties and changing scientific evidence was a central issue in *US – Hormones*.

The *US – Hormones* Panel had decided that available scientific information concerning the five hormones provisionally banned by the EC was not insufficient to conduct a risk assessment.<sup>101</sup> Consequently, the EC was not justified in resorting to Article 5.7 to enact provisional measures regarding these five hormones. The Panel reached this conclusion after examining the relationship between insufficiency of evidence and the existence of an international standard. The Panel's reasoning on the international standard can be summarized in two points: First, the presumption of consistency of SPS measures conforming to international standards established in the SPS Agreement implies that these standards are based on risk assessments. Second, the existence of international standards meant that there was sufficient evidence to undertake appropriate risk assessments.

The matter did not end there, however, as the Panel recognized that “science continuously evolves”.<sup>102</sup> The Panel thus articulated a test to determine whether scientific evidence had become insufficient, in the meaning of Article 5.7 of the SPS Agreement:

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<sup>101</sup> Panel Report, *US – Hormones*, *supra* note 77, ¶ 7.719

<sup>102</sup> *Id.* at ¶ 7.645

[T]here must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient. In the present case where risk assessment have been performed and a large body of quality evidence has been accumulated, this would be possible only if it put into question existing relevant evidence *to the point that* this evidence is no longer sufficient to support the conclusions of existing risk assessments.<sup>103</sup>

Pursuant to this test, the Panel examined the insufficiencies presented by the EC regarding the scientific evidence, both in connection to issues common to the five hormones as well as insufficiencies alleged for each hormone. The Panel concluded that the “critical mass” standard had not been reached.<sup>104</sup>

The EC appealed this finding, arguing that the Panel erred in its interpretation and application of Article 5.7 of the SPS Agreement. In particular, the EC argued that: The Panel erred in finding that its chosen level of protection was not relevant for the determination of whether the relevant scientific evidence was insufficient; the presumption of consistency that applies to measures that conform to international standards does not necessarily mean that the international standards themselves are based on a risk assessment; and the critical mass standard imposed an excessively “high quantitative and qualitative threshold” with respect to the new scientific evidence that is required to render the relevant scientific evidence insufficient. The United States, in contrast, agreed with the Panel on all these points.

Before examining the approach by the Appellate Body to these issues, it is useful to recall some of the elements upon which the EC argued that available scientific evidence is insufficient to adequately assess the risks associated with the five hormones subject to the provisional ban. The EC noted that “the development of more sensitive detection methods had identified lower endogenous levels of oestradiol in pre-pubertal children than previously assumed by the detection methods referred to in JECFA’s risk assessments.”<sup>105</sup> This suggested that pre-pubertal children, as well as post-menopausal women, might be at an increased risk of adverse health

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<sup>103</sup> *Id.* at ¶ 7.648 (emphasis in original).

<sup>104</sup> *Id.*

<sup>105</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, ¶ 722.

effects resulting from exposure to exogenous sources of hormones. Moreover, the new methods capable of detecting lower levels of endogenous production of hormones in humans, on the one hand, and uncertainties in the estimates of endogenous hormone production rates and metabolic clearing capacities, on the other, led the EC to conclude that no safe threshold level could be established for any of the six hormones assessed.<sup>106</sup> Consequently, according to the EC, previous scientific evidence had become insufficient to adequately assess the risks associated with the hormones in question, and thus the provisional ban was justified under SPS Article 5.7.

The Appellate Body began its analysis by recalling its jurisprudence on provisional SPS measures, and in so doing took the opportunity to clarify certain key points, such as the relationship between sufficient scientific evidence and scientific uncertainty. In this respect, the Appellate Body noted that under Article 5.1 Members are allowed to base SPS measures on divergent or minority views provided they are from a respected and qualified source, and thus “the existence of scientific controversy in itself is not enough to conclude that the relevant scientific evidence is “insufficient.”<sup>107</sup> In this light, the Appellate Body clarified that Article 5.7 is concerned with situations where deficiencies in the body of scientific evidence does not allow a WTO Member to arrive at a “sufficiently objective conclusion in relation to risk”.<sup>108</sup>

This general proposition led to a more focused examination of the key issues on appeal. First, on the relationship between insufficiency and the acceptable level of protection, the Appellate Body reasoned that where the chosen level of protection is higher than would be achieved by a measure based on an international standard, this may have some bearing on the scope and method of the risk assessment.<sup>109</sup> Still, the Appellate Body emphasized that “whatever the level of protection a WTO Member chooses does not pre-determine the outcome of its determination of the sufficiency of the relevant scientific evidence”.<sup>110</sup> In this regard, the determination of

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<sup>106</sup> *Id.* at ¶¶ 722-730.

<sup>107</sup> *Id.* at ¶ 677

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at ¶ 685

<sup>110</sup> *Id.* at ¶ 686.

“sufficiency” in the context of Article 5.7 remains in essence a “rigorous and objective process”.<sup>111</sup>

This reading of the relation between the level of protection and the sufficiency of scientific evidence informed the Appellate Body’s approach to a second issue: Whether the existence of an international standard demonstrated sufficiency of scientific evidence to perform a risk assessment? In this connection, the Appellate Body reasoned that the presumption of consistency with the SPS Agreement of SPS measures which conform to international standards does not apply where a member has adopted an SPS measure that reflects a higher level of protection than that embodied in the international standard.<sup>112</sup> This is partly because this presumption of consistency cannot be interpreted to imply that there is sufficient scientific evidence to perform a risk assessment where a Member chooses a higher level of protection than embodied in the international standard. Moreover, as science evolves, the scientific evidence supporting an international standard at a certain point of time may no longer be valid. Consequently, the existence of a risk assessment performed by JEFCA does not mean that the scientific evidence underlying it must be considered sufficient within the meaning of Article 5.7.<sup>113</sup>

The third element of the Appellate Body’s decision regarding Article 5.7 relates to the “critical mass” test presented by the Panel for determining when scientific information that was previously considered sufficient becomes insufficient. In this context, the Appellate Body observed that the nature of scientific inquiry is such that it is always possible to conduct more research or obtain additional information, and thus that this possibility does not mean that the relevant scientific evidence is insufficient. Moreover:

... [A]s the Panel noted, science continuously evolves. It may be useful to think of the degree of change as a spectrum. On one extreme of this spectrum lies the incremental advance of science. Where these scientific advances are at the margins, they would not support the conclusion that previously sufficient evidence has become insufficient. At the other extreme lie the more radical scientific changes that lead to a paradigm shift. Such radical change is not frequent. Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too

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<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at ¶ 694

<sup>113</sup> *Id.* at ¶ 695.

inflexible an approach. WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. We are referring to circumstances where new scientific evidence casts doubts as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk.<sup>114</sup>

In this light, the Appellate Body considered that the critical mass test could be understood as requiring “a paradigm shift, which is too high a threshold”,<sup>115</sup> as well as too inflexible an approach. For these reasons, the Appellate Body rejected the *US – Hormones* Panel’s critical mass test.

In the end, after examining the Panel’s application of Article 5.7, including its critical mass test and its use of JEFCA as a benchmark, the Appellate Body concluded that “the Panel erred in its interpretation and application of Article 5.7 of the SPS Agreement by adopting an incorrect legal test to assess the EC’s explanations concerning the insufficiencies in the relevant scientific evidence.”<sup>116</sup> As noted previously, the Appellate Body did not complete the analysis involved in these issues, thereby setting the stage for fresh proceedings, before the original *EC – Hormones* Panel if possible, regarding EC compliance with the SPS Agreement.

The Appellate Body’s reading of Article 5.7 is also to be welcomed, as it ensures that provisional measures remain a tool available to governments facing the need to enact SPS measures, in situations where scientific evidence regarding risks is inconclusive. The Panel’s approach, by contrast, had in effect limited the potential use of provisional measures to situations where international standards were not available. This limitation significantly eroded Members prerogatives to determine their level of protection, since standards exist with respect to numerous products, substances and processes.

In addition, the Panel’s approach based on the use of presumptions and the critical mass test had effectively transformed international standards into benchmarks of legality. Given the difficulty of many countries, and developing countries in particular, to participate in the elaboration of

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<sup>114</sup> Appellate Body Report, *US – Hormones*, *supra* note 12, ¶ 703 (citations omitted).

<sup>115</sup> *Id.* at ¶ 706.

<sup>116</sup> *Id.* at ¶ 731.

international standards, clarification on the probative role of international standards as “available pertinent information” – in contrast to a dispositive role – is to be welcomed for ensuring that countries retain the space to adopt measures reflecting a higher level of protection than international standards.

Finally, the critical mass test has been rejected for imposing a standard too onerous, high and inflexible. In its stead, the formulation proposed by the Appellate Body hinges on two elements: First, the new information must come from qualified and respected sources. Second, the new evidence should “put into question” the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. While still imposing a discipline on governments adopting provisional SPS measures, these two elements nevertheless enable the operation of Article 5.7 insofar as the test is not insurmountable to the point of requiring a paradigm shift.

## VI. CONCLUSION

The international trading system has had to confront the fact that countries adopt HSE measures that at times restrict trade because it is the role of government to regulate to protect the population from HSE risks. Given the trading system’s emphasis on removing obstacles to trade so as to increase trade volumes and achieve the economic gains of trade, national measures that restrict trade cause a naturally allergic effect on it. This allergy is augmented by the potential for HSE measures to disguise illegitimate goals, such as the use of overly stringent sanitary measures to secure protection for a domestic economic sector or sham environmental measures employed to protect a specific industry.

While the normative substratum of the trading system has always recognized the importance of HSE objectives and has allowed HSE measures to derogate from substantive trade rules, for many decades since the original GATT 1947 the psychology of those oiling the wheels of the trading system placed its economic goals above the attainment of non-economic values. In this context, there was an unwritten presumption that considered HSE measures to be *a priori* discriminatory or disguised restrictions to market access, and thus incompatible with the goals of the trading system.



This vision of a trading system living in splendid isolation, oblivious of the emergence of a whole new branch of international and comparative environmental law, could not last. A crisis of legitimacy ensued as a result of both the secrecy in negotiations and dispute settlement, as well as the inability of GATT Panels to adequately consider the values and objectives embodied in HSE measures.

The advent of the WTO and the consequent judicialization of trade disputes has allowed for a more coherent, balanced, and nuanced approach to the tensions apparent in the interplay between economic and non-economic goals.<sup>117</sup> In this vein, the Appellate Body has embarked upon a definite quest toward normative dialogue between the trading system and other international legal regimes bearing on the adjudication of HSE measures. And while certain elements of its jurisprudence may be criticized for not adequately safeguarding the ability of Members to establish their level of protection, for the most part the WTO has achieved a significantly greater degree of balance than its predecessor – GATT 1947.

Notable in the Appellate Body's approach to HSE measures is the role of science. The evolving WTO jurisprudence underscores the importance of a risk assessment as the tool to operationalize the SPS Agreement's requirement that SPS measures be based on scientific principles. In this regard, the Appellate Body's recognition of the flexibilities involved in the risk assessment, and particularly the legitimate role of minority scientific opinions, preserve the function of the trade norm imposing a discipline to prevent abuse, while at the same time allowing policy space for Members to adopt HSE measures.

Similarly, the Appellate Body's elaboration of the standard of review in *US – Hormones* clarifies the role of the judge *vis-à-vis* HSE measures: Panels lack the authority to decide which is the correct or valid science, but instead their role as the trier of fact is to determine whether the science used by the Member as the basis for its HSE measures originates from respected sources, even if not reflecting the mainstream consensus. This clarification of the position of adjudicators in respect of the role of science is key to avoid transforming the WTO into a science court.

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<sup>117</sup> See Padideh Ala'i, *Free Trade or Sustainable Development? An Analysis of the WTO Appellate Body's Shift to a More Balanced Approach to Trade Liberalization*, 14 AM. U. INT'L L. REV. 1129 (1999).

The approach to ascertaining risk is another area where significant progress has been made. Succinctly, risk can be established by qualitative and quantitative evidence, thus increasing the tools available to WTO Members to demonstrate the existence of risk. Further, risks are to be approached as they exist in the real world, and not just in laboratory conditions or in relation to idealized scenarios where technical management standards are fully implemented. This finding is of particular consequence to developing countries, often lacking the financial resources to ensure adequate implementation of technical standards.

Moreover, the Appellate Body has recognized that the precautionary principle finds reflection in the SPS Agreement, particularly in Article 5.7 concerning temporal measures. In this vein, the Appellate Body has also clarified that a paradigm shift is not necessary to consider previously sufficient scientific evidence as insufficient, where new and credible scientific studies question the methodologies or conclusions of previously accepted science.

Further, WTO's HSE jurisprudence has firmly stated that WTO Members have the right to determine the level of HSE protection that they consider appropriate in a given situation. Given the lack of textual basis for this right in Article XX(b), it has been imported by the Appellate Body from the SPS Agreement.<sup>118</sup> It is also notable in this regard that the Appellate Body has considered this right to be both a prerogative of WTO Members and an obligation.

The distillation of the WTO's HSE jurisprudence reflects a greater degree of sensitivity and awareness by the Appellate Body to the particular features of HSE measures. In this regard, greater nuance and balance in the adjudication of HSE measures by the WTO is central to securing the policy space necessary to ensure that governments retain their capabilities to realize human rights and achieve environmental protection.

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<sup>118</sup> Jeffery Atik, *Health*, in OXFORD HANDBOOK OF INTERNATIONAL TRADE LAW 597, 614 (Daniel Bethlehem, Donald McRae, Rodney Neufeld and Isabelle Van Damme, eds., 2009).