


8-14-2013

# The World Trade Organization Dispute Over Genetically Modified Organisms: The Precautionary Principle Meets International Trade Law

David A. Wirth

*Boston College Law School*, [wirthd@bc.edu](mailto:wirthd@bc.edu)

Follow this and additional works at: <http://lawdigitalcommons.bc.edu/lspf>

 Part of the [Food and Drug Law Commons](#), [Health Law Commons](#), [International Law Commons](#), [International Trade Commons](#), and the [Science and Technology Commons](#)

---

## Recommended Citation

David A. Wirth. "The World Trade Organization Dispute Over Genetically Modified Organisms: The Precautionary Principle Meets International Trade Law." *Vermont Law Review* 37, no.4 (2013): 1153-1188.

This Article is brought to you for free and open access by Digital Commons @ Boston College Law School. It has been accepted for inclusion in Boston College Law School Faculty Papers by an authorized administrator of Digital Commons @ Boston College Law School. For more information, please contact [nick.szydowski@bc.edu](mailto:nick.szydowski@bc.edu).

# THE WORLD TRADE ORGANIZATION DISPUTE CONCERNING GENETICALLY MODIFIED ORGANISMS: PRECAUTION MEETS INTERNATIONAL TRADE LAW

David A. Wirth<sup>\*†</sup>

## I. INTRODUCTION

“Precaution” has been an important theme in international relations in recent years, especially in those related to the environment and public health. The concept of precautionary decision-making has received considerable attention in the context of such global environmental challenges as stratospheric ozone depletion, climate change, and bioengineered food. These issues share a common attribute of scientific uncertainty surrounding the likelihood, extent, and severity of future impacts.

An international exhortation to “precautious” decision-making counsels early policy action to avoid uncertain or poorly understood risks. Formulated in this manner, precaution as a decision-making paradigm has its roots in such common-sense maxims as: “an ounce of prevention is worth a pound of cure,” “a stitch in time saves nine,” “look before you leap,” and “better to be safe than sorry.” Extrapolated to the level of broad-gauge public policy, a precautionary perspective encourages prompt, vigorous governmental responses to suggestive, but perhaps inconclusive, indications of harm.

While a precautionary approach may facilitate goals associated with mission-oriented public policies designed to protect the environment and public health, from a trade perspective precaution as a public policy appears less salutary and, indeed, potentially corrosive. In an extreme case, operating on a theory of “any port in a storm,” a government unable to justify a measure any other way might find a safe harbor by reference to precaution. If a trade agreement’s test for the validity of a measure rests on science, then inevitably a trade-based inquiry engages the relationship between precaution and science.

International efforts in a variety of fora have further elaborated harmonized good practice standards for precautionary decision-making, and in some cases binding legal obligations. These developments in non-trade

---

\* Professor of Law and Director of International Studies, Boston College Law School.

† The author retains copyright to this work, and has granted a non-exclusive license to the *Vermont Law Review* to publish. The author gratefully acknowledges the assistance and comments of Jeffery Atik, Elizabeth Fisher, Zhanwen Que, Mark Sullivan, and Susan Vaughn in the preparation of this Article. The responsibility for all views expressed in this Article, however, is the authors’ own. This project was supported by a generous grant from the Dr. Thomas F. Carney ‘47 Gift Fund.

contexts in turn have played an important role in World Trade Organization (WTO) dispute settlement proceedings governed by the WTO Agreement on the Application of Sanitary and Phytosanitary Standards, most notably two disputes initiated against the European Communities concerning hormone-treated beef and genetically engineered foods and crops.

This Article explores the implications for international trade law of domestic and internationally harmonized attempts to respond to the problem of scientific uncertainty in public policy decision-making. Accordingly, the Article commences by scrutinizing the legal and policy status of precaution as a basis for governmental action. International efforts in a variety of fora have further elaborated harmonized good practice standards for precautionary decision-making, and in some cases, binding legal obligations. The Article then analyzes the unusual structural attributes when precaution plays a role in trade disputes. The Article goes on to assess the role of precaution in the WTO disputes over food safety and agricultural quarantines in which it has been litigated and its status adjudicated. Next, the Article examines the role of precaution in the WTO panel report on the transatlantic biotech dispute, which is unique in a number of ways. Last, the Article suggests an alternative principled approach to that taken by WTO panels and its Appellate Body, one that is more receptive to the role of precaution in governmental decision-making.

## II. PRECAUTION IN INTERNATIONAL POLICY AND LAW

Precautionary policies by definition involve situations of scientific uncertainty. Experience over time with a variety of public policy issues related to environment and public health has demonstrated that analytical techniques for collecting and interpreting empirical information about the natural world—the scientific method—may be less than fully adequate to predict the nature and magnitude of future risks.<sup>1</sup> The reasons for this are numerous. The data set upon which a public policy decision is based may be incomplete. More profoundly, the scientific techniques for fully assessing the risks presented by a particular scenario may not yet exist. Or the underlying nature of the problem itself may be poorly understood, frustrating attempts at characterizing either the mechanism or the effects.<sup>2</sup>

---

1. See, e.g., European Env't Agency, *Late Lessons From Early Warnings: The Precautionary Principle 1896–2000*, Environmental Issue Report No. 22, at 11 (2001), available at [www.eea.europa.eu/Publications/environmental\\_issue\\_report\\_2001\\_22/Issue\\_Report\\_No\\_22.pdf/View](http://www.eea.europa.eu/Publications/environmental_issue_report_2001_22/Issue_Report_No_22.pdf/View) (identifying as the purpose of the report seeing if the history discussed can help prevent or minimize the impacts of other harmful agents without stifling innovation or compromising science).

2. See generally ELIZABETH FISHER, RISK REGULATION AND ADMINISTRATIVE CONSTITUTIONALISM 39–46 (2007) (discussing implementation of precautionary principle);

A large number of international instruments of a normative nature now articulate expectations for precautionary decision-making. All those instruments identify circumstances under which it is desirable for governmental decisions to reflect a preference for precautionary action under conditions of uncertainty. Textual formulations vary in response to the requirements of, and variations in, specific substantive contexts, such as global warming or marine pollution.<sup>3</sup> To that extent, these instruments can be interpreted both individually and collectively as establishing harmonized, consensus good practice standards for the application of precautionary methodologies to address a wide variety of threats to health and the environment.

So, too, these instruments demonstrate variations in their institutional context and legal force. Because the products from multilateral deliberations are driving so much of the debate over precautionary perspectives on governmental decision-making, this section examines some of the salient international contexts in which precaution has been articulated as an approach to formulating public policy. Because of the sheer number of references to precaution in international practice, the instruments analyzed in this section were chosen to be illustrative as opposed to exhaustive.<sup>4</sup>

#### A. *Precaution as Non-Binding Guidance*

The most generally applicable admonition to apply a precautionary perspective in governmental decision-making processes appears in Principle 15 of the Rio Declaration on Environment and Development,<sup>5</sup> a set of non-binding recommendations adopted at the United Nations Conference on Environment and Development (UNCED), attended by over a hundred heads of state or government in 1992. The text of that instrument provides

---

JACQUELINE PEEL, *THE PRECAUTIONARY PRINCIPLE IN PRACTICE: ENVIRONMENTAL DECISION-MAKING AND SCIENTIFIC UNCERTAINTY* 1–2 (2005) (“The complexities of the systems involved and the difficulties often encountered in applying conventional scientific methodologies to health and environmental problems, mean that it may be impossible to estimate the likelihood and potential seriousness of harm with accuracy”).

3. See Elizabeth Fisher, *Precaution, Precaution Everywhere: Developing a ‘Common Understanding’ of the Precautionary Principle in the European Community*, 9 MAASTRICHT J. OF EUR. & COMP. L. 7, *passim* (2002) (demonstrating the flexibility of the precautionary principle across varying legal cultures).

4. See generally HARALD HOHMANN, *PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW* (1994) (analyzing precautionary duties and principles used in international law).

5. United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, Principle 15, U.N. Doc. A/Conf.151/5/Rev. 1, 31 ILM. 876, 879 (June 13, 1992).

as follows:

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>6</sup>

This statement, while not legally binding, is not confined to a particular subject matter and is therefore quite broad in application. Consequently, Rio Principle 15 is probably the most widely accepted benchmark for international standards for precautionary decision-making.

Other non-binding multilateral instruments address precaution as a public policy in specific situations or as applied to specific groups of states. The final communiqué of the G-8 summit held in Okinawa in 2000, endorses the Codex Alimentarius Commission's "efforts . . . to achieve greater global consensus on how precaution should be applied to food safety in circumstances where available scientific information is incomplete or contradictory."<sup>7</sup> A number of non-binding recommendations adopted by the Organization for Economic Cooperation and Development (OECD) contain references to precaution. Among those is a 1990 recommendation on integrated pollution prevention and control, which in an appendix entitled "Guidance on integrated pollution prevention and control" contains the following language under the heading "Essential Policy Aspects": "Certain policies, common to all aspects of environmental protection, are essential to an effective integrated approach. These include that . . . [t]he absence of complete information should not preclude precautionary action to mitigate the risk of significant harm to the environment."<sup>8</sup>

### *B. Precaution as Binding Obligation*

In contrast to the Rio Declaration and other non-binding instruments, statements concerning precautionary decision-making in treaties establish norms that are legally enforceable under international law. As treaties in international law are formed on a consensual theory, their obligations apply

---

6. *Id.*

7. The G8 Summit, Okinawa, Japan, July 21–23, 2000, *G8 Communique Okinawa 2000, Kyushu-Okinawa Summit Meeting*, ¶ 56 (July 23, 2000) <http://www.g8.utoronto.ca/summit/2000okinawa/finalcom.htm>.

8. Organization for Economic Cooperation and Development [OECD], *Recommendation of the Council on Integrated Pollution Prevention and Control*, OECD Doc. C(90)164 (Jan. 31, 1991).

only to those states party to the treaty in question. Second, such statements, like the treaties in which they are embedded, tend to be confined to relatively discrete subject matter. The number of treaty references to precautionary decision-making—of which those set out in this section are representative—is now quite large.

Significant multilateral conventions adopted alongside the Rio Declaration and addressing serious global environmental threats also articulate precautionary obligations. The 1992 United Nations Framework Convention on Climate Change, the cornerstone of the potentially universal regime for addressing the “greenhouse” effect, states that:

The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.<sup>9</sup>

While not mentioning precaution by name, the 1992 United Nations Convention on Biological Diversity (Biodiversity Convention) in its preamble notes that “where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat . . . .”<sup>10</sup>

Because the subject matter covered by that agreement is more or less coextensive with the WTO dispute on biotech foods and crops, the Cartagena Protocol on Biosafety,<sup>11</sup> an ancillary agreement to the Biodiversity Convention, is of particular interest in this context. The language on precaution was fiercely contested during the negotiations,<sup>12</sup> which produced a compromise result. Article 1, entitled “Objective,” specifies as follows:

In accordance with the precautionary approach contained in

---

9. U.N. Framework Convention on Climate Change, May 9, 1992, 31 I.L.M. 849, 854 (1992).

10. U.N. Convention on Biological Diversity, May 22, 1992, 31 I.L.M. 822 (1992) [hereinafter Biodiversity Convention].

11. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 [hereinafter Cartagena Protocol on Biosafety].

12. See, e.g., CHRISTOPH BAIL ET AL., *European Union, in The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development* 166, 176 (Christoph Bail, Robert Falkner & Helen Marquard eds., 2002) (describing some of the issues the EU had in drafting the protocol).

Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.<sup>13</sup>

This instrument also contains a preambular reference “reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.”<sup>14</sup>

The Stockholm Convention on Persistent Organic Pollutants,<sup>15</sup> is among the more recent major multilateral agreements to be motivated by a precautionary approach. In the preamble to that instrument, the parties declare that they “[a]knowledge[e] that precaution underlies the concerns of all Parties and is embedded within this Convention.”<sup>16</sup> Article 1, entitled “Objective,” provides that “[m]indful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants.”<sup>17</sup> Article 8, addressing the listing of additional chemicals governed by the agreement at the initiative of one of the parties, states in paragraph 9 that the Conference of the Parties shall act on such a proposal “in a precautionary manner.”<sup>18</sup> An annex directs parties to take into account considerations of “precaution and prevention” in considering best available techniques for preventing or reducing releases of chemicals regulated by the agreement.<sup>19</sup>

On a multilateral level, express articulation of precautionary principles originated in the context of protection of the marine environment.<sup>20</sup> Now that it has entered into force, the Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (London Convention) supersedes the earlier 1972 instrument for parties to

---

13. Cartagena Protocol on Biosafety, *supra* note 11.

14. *Id.*

15. Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 2256 U.N.T.S. 119 (entered into force May 17, 2004).

16. *Id.* at pmb1.

17. *Id.* at art. 1.

18. *Id.* at art. 8.

19. *Id.* at Annex C.

20. *See, e.g.,* Lothar Gündling, *The Status in International Law of the Principle of Precautionary Action*, 5 INT'L. ESTUARINE & COASTAL L. (SPECIAL ISSUE) 23 (1990) (discussing the considerable role the principle of precautionary action played in the protection policy for the North Sea).

both agreements.<sup>21</sup> Article 3, paragraph 1 of the Protocol specifies that:

In implementing this Protocol, Contracting Parties shall apply a precautionary approach to environmental protection from dumping of wastes or other matter whereby appropriate preventive measures are taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects.<sup>22</sup>

The Protocol is constructed around a precautionary theory of regulation expressly articulated in the text which, in contrast to the 1972 London Convention, prohibits ocean dumping altogether unless the activity is specifically authorized by the new agreement.

### *C. Precaution as a Principle*

Over time the concept of “general principles” has come to play an increasingly prominent role in international environmental law and policy:

Although they have an analytical significance beyond any one international instrument, many of these principles are collected and codified in the Rio Declaration on Environment and Development from the 1992 U[nited] N[atations] Conference on Environment and Development. Unlike some other non-binding authorities, principles of international environmental law are not primarily intended expressly to establish normative standards. Rather, these principles are overarching aspirational precepts identified as part of a comprehensive and unifying architecture that identifies the direction in which international law should progressively evolve. Principles of international environmental law consequently are equally relevant to the development of treaties, customary law, and non-binding norms.<sup>23</sup>

As the term is used in the field, principles are not necessarily binding customary law nor are they mandatory treaty obligations, although under some circumstances they could be either or both. Rather, principles of

---

21. Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, Nov. 7, 1996, 36 I.L.M. 1 (1997).

22. *Id.* at 9.

23. David A. Wirth, *Hazardous Substances and Activities*, in OXFORD HANDBOOK OF INTERNATIONAL ENVIRONMENTAL LAW 394, 398 (Daniel Bodansky et al. eds., 2007).



international environmental law are widely accepted thematic postulates that inform more substantive, operative norms, whether obligatory or non-binding in character. To that extent, principles of international environmental law operate to shape or inform particularized substantive decisions or more specific rules. While some of these axioms may have matured to the point of acceptance as binding custom, the status of others as *lex ferenda* in theory does not attenuate their applicability as meta-level principles. The utility of a principle in this sense is independent of its precise legal status; its power, rather, derives from widespread acceptance of the principle and its potential for broad application to a variety of more particularized circumstances.

There is considerable scholarly commentary concerning the utility of general principles of international environmental law.<sup>24</sup> Principles in this sense play an important role in non-binding declarations such as the Rio Declaration and have been incorporated into a number of prominent multilateral treaties in recent years.<sup>25</sup> The Treaty on European Union expressly includes a provision articulating principles of supranational environmental law.<sup>26</sup> Principles of international environmental law have featured prominently in decisions of international tribunals<sup>27</sup> and in a number of judicial opinions from a variety of jurisdictions.<sup>28</sup> An established canon of principles of international environmental law and policy can now be identified, including: (1) a duty to refrain from causing transboundary environmental harm; (2) a principle of preventive action; (3) a principle of cooperation; (4) a principle of sustainable development; (5) the polluter-

---

24. See, e.g., PHILIPPE SANDS ET AL., *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW* 187 (3d ed. 2012) (enumerating and discussing general principles); Alexandre Charles Kiss & Dinah Shelton, *International Environmental Law* 86–88 (3rd ed. 2004) (discussing “General Principles” of international law); Daniel Bodansky, *The United Nations Framework Convention on Climate Change: A Commentary*, 18 *YALE J. INT’L L.* 451, 501 (1993) (contrasting developing countries’ views with those of developed countries such as the United States).

25. E.g., U.N. Framework Convention on Climate Change, *supra* note 9, at 854–55; Biodiversity Convention, *supra* note 10, at 824; Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area art. 2, Apr. 9–Sept. 24, 1992, 1507 U.N.T.S. 167 (entered into force Jan. 17, 2000); Convention on the Protection and Use of Transboundary Watercourses and International Lakes art. 2, Mar. 17, 1992, 1936 U.N.T.S. 269; Convention on the Transboundary Effects of Industrial Accidents pmbl., Mar. 17 1992, 2105 U.N.T.S. 457.

26. Treaty on European Union, art. 21(2)(d), 2012 O.J. (C83) 29.

27. See generally International Tribunal for the Law of the Sea: Southern Bluefin Tuna Cases (New Zealand & Australia v. Japan), 38 *I.L.M.* 1624, 1638, 1643 (1999) (discussing international environmental law in separate opinions); Case Concerning the Gabčíkovo-Nagymaros Project (Hungary v. Slovakia), 1997 *I.C.J.* 7, 88 (Sept. 25, 1997) (separate opinion of Vice-President Weeramantry) (discussing sustainable development and its relation to international law and environmental disputes).

28. E.g., *M.C. Mehta v. Union of India and Ors.*, (2002) 2 *S.C.R.* 963 (India); *Leatch v Nat’l Parks & Wildlife Serv.* [1993] 81 *NSWLEC* 270 (Austl.); Case C-2/90, *Re Imports of Waste: EC Comm’n v. Belgium* 1992 *E.C.R. I-4431* (Eur. Union).

pays principle; and (6) a principle of common but differentiated responsibilities.<sup>29</sup> The “precautionary principle” understood in this manner occupies a prominent position in the hierarchy.<sup>30</sup>

### III. PRECAUTIONARY POLICIES AND INTERNATIONAL TRADE

Precaution as a principle or approach to addressing international environmental and public health threats is clearly intended to expand the “toolbox” of methodologies intended to accomplish salutary public policy goals—whether at the domestic level or as an international strategy—in laying the foundation for unilateral or coordinated multilateral governmental action. In the context of international trade law and policy, however, precaution appears in a different posture that may be considerably less beneficial, to the point of potentially undermining the mission-oriented goal of trade liberalization.

#### A. *Precaution as a Structural Challenge to Trade Liberalization*

Trade liberalization, like policies that promote environmental protection, is intended to enhance human welfare. Free trade agreements achieve this goal in a manner that is structurally different from the international environmental instruments identified above. The form of international legal requirements for trade on the one hand and environment on the other mirror these disparate policy approaches. Trade agreements encourage liberalized or free trade by limiting governmental intrusion into what otherwise would be a free market. International obligations on trade are consequently almost exclusively “negative” in the sense that they place constraints on governmental action. From an environmental point of view, this phenomenon is the equivalent of deregulation—in the sense of reducing the level of governmental intrusion in the market—and trade agreements by virtue of their negative obligations are inherently deregulatory.

Environmental protection, by contrast, anticipates affirmative governmental interventions in the marketplace to offset market failures. Obligations in trade agreements *proscribe* certain governmental behaviors that impede trade, while environmental agreement regulations *prescribe*

---

29. SANDS ET AL., *supra* note 24.

30. Peter Sand, *The Precautionary Principle: A European Perspective*, 6 HUMAN & ECOLOGICAL RISK ASSESSMENT 445–46 (2000) (quoting David Freestone, *The Precautionary Principle*, in INTERNATIONAL LAW AND GLOBAL CLIMATE CHANGE 36 (Robin Churchill & David Freeman eds., 1991)). *But see* Christopher D. Stone, *Is There a Precautionary Principle?* 31 ENVTL. L. REP. 10790, 10799 (2001) (discussing problems with “the precautionary principle” in that there is no one principle).

governmental actions to protect public health and ecosystems. It is important to note that international trade agreements, by their terms, do not mandate any minimum standards for protection of the environment or human health. Rather, these instruments define zones of appreciation in which states are free to act if they choose to regulate in these areas, and establish constraints designed to prohibit regulatory choices that do not conform to minimum requirements.

At a more specific level, trade agreements focus on environmental measures as potential impediments to international trade. The task from the point of view of trade policy is consequently to distinguish between those measures ostensibly intended to promote environmental or public health goals that are legitimate exercises of governmental regulatory powers and those that are, by contrast, pretexts for protectionism. Free trade agreements accomplish this goal by articulating rules designed to clarify the line dividing these two categories. The dispute settlement process then operates as an adversarial, quasi-adjudicatory setting in which to apply those rules, requiring the respondent state to justify its exercise of governmental authority in response to an assertion of inconsistency by the challenging state. This is a very different posture from a multilateral negotiation on an issue such as climate change, which is designed to overcome collective action problems by reference to at least some minimal level of international agreement about the nature of the underlying threats. In the area of climate change, for instance, the scientific predicate for action might be established by the Intergovernmental Panel on Climate Change (IPCC), whose mandate is to synthesize available policy-relevant science in a manner intended to support and inform the policy debate.

Although these structural features are common to all trade-based challenges to environmental, health, and safety regulations, the tension is particularly acute for those based on a theory of precaution. To the extent that a challenged measure appears to be the result of inferences that are less, as opposed to more, susceptible to validation by reference to objective tests of legitimacy, the vulnerability of the measure to criticism as motivated by protectionist intent increases. More specifically, from a trade point of view the precautionary exhortation to anticipate and prevent harm in response to uncertain science appears to be an invitation to overregulation and hence abuse. This concern plays out in parallel fashion in the dispute settlement process, in which a precautionary justification regulation gives the appearance of an argument of last resort for a respondent state that cannot justify a measure by reference to “hard” or ostensibly “sound” science.

*B. Precaution in Transatlantic Relations*

The genetically modified organism (GMO) debate is but one instance of the extent to which precaution has been a particularly delicate question in transatlantic relations, particularly those concerning disparities in regulatory approaches. Trade disputes over non-tariff barriers frequently arise from differences in national regulatory approaches.<sup>31</sup> From this point of view, international responses of various kinds, including regulatory instruments such as the Cartagena Protocol on Biosafety<sup>32</sup> to the United Nations Convention on Biological Diversity,<sup>33</sup> can be considered consequences or artifacts of attempts by national governments to harmonize domestic regulatory strategies.<sup>34</sup> Trade in, and market access for, genetically engineered products can then be understood as one of the principal driving forces behind much of the international debate.<sup>35</sup> In the case of GMOs, this feature is particularly pronounced, as the European Union has probably the strictest regime for pre-market approval of genetically engineered foods and crops,<sup>36</sup> whereas the United States' regulatory approach is relatively less rigorous.<sup>37</sup>

Especially in the field of environment and public health, there has been extensive legislative and policy activity at the Community level over the past quarter century or so.<sup>38</sup> At the same time, the United States has had

31. See, e.g., Michael Cardwell, *Introduction*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 1, 2–3 (Luc Boddiguel & Michael Cardwell eds., 2010) (providing examples of trade disputes arising from differing regulatory schemes); Ilona Cheyne, *Precaution and International Trade in Food and Other Agricultural Products*, 2009 EUR. FOOD & FEED L.REV. 47 (2009) (examining international trade disputes arising from restrictions based on the precautionary principle).

32. See Cartagena Protocol on Biosafety, *supra* note 11, at 1030–33 (requiring parties to obtain “advance informed agreement” in the form of the express consent of the government of a state of import before exportation of living modified organisms can take place).

33. Biodiversity Convention, *supra* note 10.

34. See Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L. J. 47, 48 (2001) (“assess[ing] the strengths and limits of existing international law and structures in this area, and . . . suggest[ing] a means for augmenting the current structures to make them more effective”).

35. See generally MARK A. POLLACK & GREGORY C. SHAFFER, *WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS* (2009) (discussing the difference in approach taken by the US and EU with respect to GMOs).

36. See generally MARIA LEE, *EU REGULATION OF GMOS: LAW AND DECISION-MAKING FOR A NEW TECHNOLOGY* (2008) (discussing the difference in approach taken by the US and EU with respect to GMOs).

37. See generally Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. R. 2167 (2004) (identifying several lapses in the U.S. regulatory regime).

38. See, e.g., *Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (Feb. 2, 2000); see also Sand, *supra* note 30, at 449 (describing how “precautionary policies also made their appearance in the emerging quasi-federal law of the European Union”).

more of a deregulatory orientation, relying on existing policies or even rolling back some environmental and public health protections.<sup>39</sup> As the European Union has progressively expanded to twenty-seven Member States, it has become more of an alternative power center in the area of environmental regulation.<sup>40</sup> Regulatory divergences, which naturally tend to metamorphose into trade disputes, are consequently increasingly common and less amenable to diplomatic pressure, especially with the advent of greater transparency and more formal procedures at the Community level, such as the Parliamentary co-decision process. The stage has consequently been set for a series of flash points over regulatory policies, with precaution not infrequently at the center of the storm.<sup>41</sup>

The situation is doubly confounded by widespread international agreement on the utility of precautionary approaches in overcoming collective action problems at the multilateral level on such global environmental and public health threats as depletion of the stratospheric ozone layer. In situations characterized by a multilateral consensus, precaution is viewed as a salutary perspective, as evidenced by Rio Principle 15. As a result, the problem is largely confined to a single state's reliance on precaution as a regulatory theory to justify unilateral, domestic measures—or, as in the case of the European Community (EC), supranational policies and legislation. One might think of this as precaution's potentially corrosive alter ego, which invites trade disputes. This cognitive dissonance is clear in a White House Declaration on Environment and Trade, adopted during the Clinton presidency:

Precaution is an essential element of the US regulatory system given that regulators often have to act on the frontiers of knowledge and in the absence of full scientific certainty. . . . We will insist that this ability to take precautionary action be maintained in order to achieve our environmental objectives. At

---

39. See, e.g., Ragnar E. Lofstedt & David Vogel, *The Changing Character of Consumer and Environmental Regulation: A Comparison of Europe and the United States*, 21 RISK ANALYSIS 399, *passim* (2001) (hypothesizing "flip-flop" in positions of U.S. and EC with respect to regulatory rigor between 1970s and present).

40. David A. Wirth, *The EU's New Impact on American Environmental Regulation*, FLETCHER F. WORLD AFF., Summer 2007, at 91, 97–98.

41. See generally PEEL, *supra* note 2 (discussing the embrace of the precautionary principle in the US); DAVID VOGEL, THE POLITICS OF PRECAUTION: REGULATING HEALTH, SAFETY, AND ENVIRONMENTAL RISKS IN EUROPE AND THE UNITED STATES 1–2 (2012) (listing and describing several examples of differing U.S. and European regulations); Jonathan B. Wiener, *The Rhetoric of Precaution*, in THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE UNITED STATES AND EUROPE 4 (Jonathan B. Wiener et al. eds., 2011) (discussing controversies precaution has caused between the United States and Europe).

the same time, precaution must be exercised as part of a science-based approach to regulation, not a substitute for such an approach. In this connection, the term precaution must not be used as a guise for trade protectionist measures as this would have the effect of casting doubt upon, and even undermining, environmental as well as trade policy objectives.<sup>42</sup>

At the level of principled regulatory policy, this tension has played out against the background of the familiar risk assessment/risk management distinction.<sup>43</sup> Both the United States and the European Union agree that precaution is appropriate as a risk management tool. In other words, it is appropriate for public officials to choose a “precautious” or highly protective risk management measure in response to a scientific analysis contained in a risk assessment. The EC has tended to expand this perspective into the risk assessment stage as well.<sup>44</sup> The United States, in

---

42. Press Release, The White House, White House Policy Declaration on Environment and Trade (Nov. 16, 1999), *available at* <http://clinton6.nara.gov/1999/11/1999-11-16-fact-sheet-on-policy-declaration-on-environment-and-trade.html>.

43. An influential publication has described the distinction as follows:

We use *risk assessment* to mean the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

The term *risk assessment* is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with *quantitative risk assessment* and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. Broader uses of the term than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions—functions that we assign to risk management.

NATIONAL RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 18 (1983).

44. See, e.g., *Communication from the Commission on the Precautionary Principle*, ¶ 4, COM (2000) 1 final (Feb. 2, 2000) (“The precautionary principle is particularly relevant to the management of risk.”).

response, has insisted on “sound” science in the risk assessment stage.<sup>45</sup> This debate leaves unresolved the question of whether precaution can be accommodated within the framework of a risk assessment/risk management approach to regulation, or whether it is an alternative decision model.<sup>46</sup> Even the language used to characterize precaution’s role in policymaking has become fraught, with the United States objecting to Europeans’ use of the word “principle,” and insisting instead that precaution is an “approach.”<sup>47</sup> Not coincidentally, these differences in perspective track the disciplines in the principal WTO authority on the subject, the Agreement on the Application of Sanitary, and Phytosanitary standards (SPS Agreement).<sup>48</sup>

#### IV. PRECAUTION IN WTO RULES AND JURISPRUDENCE

The SPS Agreement<sup>49</sup> is the most readily apparent setting in which precaution would be expected to play a role in WTO jurisprudence. Indeed, precaution has either explicitly or implicitly played a role in each of the five major disputes initiated under that agreement in which precaution was litigated, including that addressing GMOs.<sup>50</sup>

##### A. Text of the SPS Agreement

The SPS Agreement governs measures applied to protect the life or health of humans, animals, or plants from pests, disease-causing organisms,

---

45. Ludwig Krämer, *The Roots of Divergence: A European Perspective*, in GREEN GIANTS?: ENVIRONMENTAL POLICIES OF THE UNITED STATES AND THE EUROPEAN UNION 68 (Norman J. Vig & Michael G. Faure eds., 2004).

46. See generally PRECAUTION, ENVIRONMENTAL SCIENCE AND PREVENTIVE PUBLIC POLICY xv (Joel Tickner ed., 2002) (examining how environmental science relates to precautionary preventive decisions).

47. Krämer, *supra* note 45, at 63.

48. World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

49. *Id.* See generally LUKASZ GRUSZCZYNSKI, REGULATING HEALTH AND ENVIRONMENTAL RISKS UNDER WTO LAW: A CRITICAL ANALYSIS OF THE SPS AGREEMENT (2010) (questioning the relevance of the precautionary principle under the SPS Agreement); JOANNE SCOTT, THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY (2007) (examining the relationship between the precautionary principle and the SPS agreement).

50. Science and precaution feature as well in the basic principles of nondiscrimination set out in GATT 1994, although to date less explicitly than in the SPS Agreement. See David A. Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT’L L.J. 818, 839 (1994) (noting that “the Uruguay Round may well have incorporated the precautionary principle into the international trade regime more generally”).

additives, contaminants, and toxins. Consequently, the agreement disciplines or governs both food safety measures and agricultural quarantines. The core of the SPS text is a series of science-based disciplines. An SPS measure that is not based on international standards must be supported by “a scientific justification” (Article 3.3).<sup>51</sup> A challenged measure must be “based on scientific principles” (Article 2.2), must not be “maintained without sufficient scientific evidence” (Article 2.2), and the regulatory process leading to the measure must “take into account available scientific evidence” (Article 5.2).<sup>52</sup> A central feature of the SPS Agreement, found in Article 5.1, is a requirement for a risk assessment, and the principal operative test in the agreement is the need for the measure to be “based on” that risk assessment.<sup>53</sup> The SPS Agreement consequently codifies requirements for an approach to regulation roughly commensurate with the risk assessment/risk management duality.<sup>54</sup>

The word “precaution” does not appear in the text of the SPS Agreement. If precaution might be acceptable as a public policy within the framework of the regulatory approach established in the Agreement, then precaution likely would be considered acceptable within the architecture of the regulatory approach set out in the Agreement. In other words, to the extent that precaution is consistent with the SPS Agreement’s disciplines on domestic regulatory activity, at least in principle there is no need for the Agreement expressly to authorize a precautionary approach. Alternatively, precautionary formulations such as Rio Principle 15 might serve as an additional source of law or an aid to interpretation of the SPS Agreement.

Without identifying it as expressly precautionary, Article 5.7 of the SPS Agreement incorporates policies similar to those underlying precautionary approaches:

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

---

51. SPS Agreement, *supra* note 48, at 70.

52. *Id.* at 71.

53. *Id.*

54. *Id.* at 69. *But see* FISHER, *supra* note 2, at 187 (Appellate Body in *EC-Hormones*, *infra* note 56, rejected strict compartmentalization rejected strict compartmentalization of risk assessment/risk management distinction accepted by panel).



assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.<sup>55</sup>

While expressing a somewhat different formulation than the standard precautionary exhortation found in Rio Principle 15, Article 5.7, depending on its interpretation, could serve as a vehicle for introducing a precautionary element into the SPS Agreement's decision rubric.

### B. *The Beef Hormones Dispute*

The relationship between precaution and the SPS Agreement was expressly litigated in the first dispute initiated under the SPS Agreement, a challenge by the United States and Canada to the European Communities' prohibition on the sale of imported and domestically manufactured meat and meat products derived from cattle treated with three natural and three synthetic growth-promoting hormones.<sup>56</sup> This dispute was hardly a surprise, coming as it did after years of transatlantic tensions over the hormone ban. Indeed, the inclusion of the SPS Agreement as a component of the Uruguay Round was motivated in large measure as a generic effort to address the EC's across-the-board hormone ban, which did not appear to be susceptible to challenge by reference to the non-discrimination tests in General Agreement on Tariffs and Trade (GATT) 1947.<sup>57</sup> In the process, the WTO adopted rules addressing not just this situation, but a variety of others including both food safety measures and agricultural quarantines.

In response to the challenging parties' accusation that the hormone ban suffered from a flimsy scientific justification, the EC relied in part on the precautionary principle to defend the challenged measure. As discussed in section III.A above, this is precisely the structural and procedural posture in which one would expect to encounter precaution in a free trade agreement designed to identify and eliminate unjustified barriers to market access. This argument consequently presented first the panel, and subsequently the Appellate Body, with the need to articulate the relationship between the precautionary principle and the SPS Agreement.

The Appellate Body might have attempted to harmonize normative standards for precautionary decision-making with the SPS Agreement, giving life to both by interpreting the Agreement in light of those standards.

---

55. *Id.* at 72.

56. Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products*, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) (adopted Feb. 13, 1998) [hereinafter EC-Hormones].

57. *Id.* ¶ 15.

If precaution were understood as having matured to binding custom, then the SPS Agreement and the customary norm could exist simultaneously as sources of law to be applied in the WTO dispute settlement process.

Alternatively, if precaution is a principle of law, but is not *a fortiori* binding on the parties to the dispute, the precautionary principle might still have been applied as a guiding precept. Consistent with that status, the SPS Agreement could be interpreted in a manner consistent with the principle. Even if precaution were nothing more than an international good practice standard—consistent with a view of precaution as *lex ferenda*—that non-binding guidance could still be available as an aid to interpretation of the SPS Agreement, especially to the extent that precaution is an appropriate component of domestic regulatory processes disciplined by the Agreement.

WTO objectives and principles also could serve as an entry point for harmonizing the science-based principles of the SPS Agreement and precautionary approaches. The preamble to the Agreement Establishing the World Trade Organization refers to “the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so . . . .”<sup>58</sup> “Sustainable development” was the central theme around which the 1992 United Nations Conference on Environment and Development (UNCED) meeting was organized only a few years before the conclusion of the Uruguay Round and at which the Rio Declaration was adopted.<sup>59</sup> Precautionary decision-making is a component of strategies for sustainable development.<sup>60</sup> Trade liberalization, as indicated by the Agreement Establishing the WTO, is consequently but one facet of a global agenda of sustainable development, which includes both market access and precautionary decision-making as part of the larger strategy.

In any event, the Appellate Body’s report in the dispute<sup>61</sup> adopted a contrary approach.<sup>62</sup> The Appellate Body first distinguished between precaution as a principle of international environmental law on the one hand and general international law on the other. Regardless of its status in

---

58. Marrakesh Agreement Establishing the World Trade Organization pmb. ¶ 1, Apr. 15, 1994, 1867 U.N.T.S. 154, *reprinted in* 33 I.L.M. 15 (1994).

59. *Rio Declaration on Environment and Development*, *supra* note 5, at 876.

60. *See, e.g.*, M.C. Mehta v. Union of India and Ors., (2002) 2 S.C.R. 963, 965 (India) (“The two essential features of sustainable development are (a) the precautionary principle and (b) the polluter pays principle.”).

61. EC-Hormones, *supra* note 56, ¶¶ 186–87.

62. *Cf.* 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, 624 (1999) (analyzing the Appellate Body’s decision not to apply the precautionary principle as binding customary international law).

international environmental law, stated the Appellate Body, the precautionary principle's vigor as a matter of general international law was uncertain.<sup>63</sup> The Appellate Body then noted that precaution "finds reflection" in Article 5.7 of the SPS Agreement.<sup>64</sup> Precautionary elements also appear in Article 3.3, permitting a Member to adopt standards more rigorous than those in multilaterally agreed minima, consistent with a Member's own chosen appropriate level of protection.<sup>65</sup> The Appellate Body observed, moreover, that the SPS Agreement's test of scientific sufficiency itself reflects the wide acceptance of governmental regulation to protect the public from "risks of irreversible, e.g. life-terminating, damage to human health."<sup>66</sup> Last, the Appellate Body noted the need to apply the SPS Agreement consistently with ordinary approaches to treaty interpretation.<sup>67</sup> Without necessarily closing the door to an approach in a future case that might harmonize the SPS Agreement's scientific disciplines with the precautionary principle, particularly if it were to acquire greater international legal force, the Appellate Body invited the inference that WTO members had contracted out of such a standard in the SPS Agreement.<sup>68</sup>

A preliminary analytical question, indirectly alluded to by the Appellate Body, is the extent to which sources of law or other non-binding authorities extrinsic to WTO agreements are available as aids to interpretation of WTO rules. At the time this was, and to some extent still is,<sup>69</sup> a controversial approach. Subsequent to the *EC-Hormones* report, the

---

63. *EC-Hormones*, *supra* note 56, ¶ 123.

64. The Appellate Body also noted that "there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3." *Id.* ¶ 124. The Appellate Body has since elaborated its interpretation of Article 5.7 to a considerably greater extent with an interpretation that diverges to a considerable extent from a standard formulation of precaution. *See, infra*, Section IV.C.

65. *EC-Hormones*, *supra* note 56, ¶ 124.

66. *Id.*

67. *Id.* The Vienna Convention on the Law of Treaties, for instance, directs that a treaty should be interpreted according to the plain meaning of its terms, consistent with the agreement's objects and purposes. Vienna Convention on the Law of Treaties art. 31, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter Vienna Convention].

68. At least one commentator has argued that measures based on a public policy of precaution should survive scrutiny under the WTO Agreement on Technical Barriers to Trade, whose structure is similar to that of the SPS Agreement. JOAKIM ZANDER, *THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN PRACTICE* 45 (2010).

69. *See, e.g.*, Joel P. Trachtman, *The Domain of WTO Dispute Resolution*, 40 HARV. INT'L L.J. 333, 342 (1999) ("The mandate to WTO dispute resolution panels, to the Appellate Body, and to the Dispute Settlement Body is clear: apply (directly) only WTO law."). *Contra* JOOST PAUWELYN, *CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW* 1 (2003) (discussing the extrinsic sources of law cited by the defense in the *US-Shrimp* and *EC-Hormones* disputes and the need to maintain unity and a secure framework in international trade). *See also* Jan McDonald, *Tr(e)ading Cautiously: Precaution in WTO Decision-*

Appellate Body in a number of disputes has relied on both binding and non-binding sources of international law in a similar context. Most notably in the environmental context, the Appellate Body in its report on the *U.S.-Shrimps* dispute<sup>70</sup> cited the United Nations Convention on the Law of the Sea and the Biodiversity Convention to frame its interpretation of the term “natural resources” in Article XX(g). The Appellate Body also referenced Agenda 21, a non-binding action program adopted at the Rio conference.<sup>71</sup>

Perhaps most importantly, it is by no means apparent that Article 5.7 of the SPS Agreement embodies policies that track international standards for precaution. That provision applies “[i]n cases where relevant scientific evidence is insufficient.”<sup>72</sup> Particularly in countries in which governmental regulation is subject to judicial review, a scientific predicate for regulation characterized as “insufficient” generally would suggest that the measure would not withstand scrutiny by a neutral third party such as a court.<sup>73</sup> Presumably for reasons like this, Rio Principle 15 and other authorities speak of “lack of full scientific certainty,”<sup>74</sup> the “absence of complete information” as in the 1990 OECD recommendation,<sup>75</sup> or “no conclusive evidence to prove a causal relation” as in the London Protocol.<sup>76</sup> Phrased in these terms, the justification for policy action is considerably clearer.

Assuming that it applies, Article 5.7 authorizes only provisional application of a precautionary measure while the Member “seek[s] to obtain the additional information necessary for a more objective assessment of risk.”<sup>77</sup> Here the SPS Agreement and the precautionary principle plainly diverge. While precaution may be applicable to situations in which research is ongoing, the intent of the precautionary principle is broader than that

---

*Making, in* IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: PERSPECTIVES AND PROSPECTS 160, 166 (Elizabeth Fisher et al. eds., 2006) (discussing the role of the precautionary principle in WTO proceedings). See generally Jeffrey Lagomarsino, *WTO Dispute Settlement and Sustainable Development: Legitimacy Through Holistic Treaty Interpretation*, 28 PACE ENVTL. L. REV. 545 (2011) (pointing out that public international law is sometimes used to fill gaps in WTO treaties).

70. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, art. 55 ¶ 130 (Oct. 12, 1998) [hereinafter *U.S.-Shrimps*].

71. *Id.*

72. SPS Agreement, *supra* note 48, at 72.

73. See, e.g., *Int'l Harvester Co. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973) (denial of waiver for new motor vehicle emissions reduction standards in U.S. invalidated after deferential review of substance of scientific issues); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973) (U.S. new source performance standard for Portland cement plants invalidated after deferential review of substance of scientific issues); RONALD BRICKMAN ET AL., *CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES* 114–15 (1985).

74. *Rio Declaration on Environment and Development*, *supra* note 5, at 879.

75. Organization for Economic Cooperation and Development, *supra* note 8.

76. Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, *supra* note 21, at 9.

77. SPS Agreement, *supra* note 48, at 72.

category of situations. As discussed in section II above, precautionary public policies are additionally intended to address situations of fundamental or irreducible uncertainties in which the state of scientific knowledge is not yet sufficiently advanced to the extent that a risk can be fully characterized. In such a situation, a precautionary approach could counsel maintaining a measure despite scientific uncertainty which cannot be immediately resolved. Article 5.7 consequently addresses only a subset of the situations in which a precautionary methodology could find application and is at most a temporary safe harbor, as elaborated in the Appellate Body's subsequent jurisprudence discussed in the following section.

### C. *The Quarantine Disputes and SPS Article 5.7*

Subsequent to the *EC-Hormones* decision the Appellate Body addressed three disputes challenging agricultural quarantines: Australia's ban on importing fresh chilled or frozen salmon to protect the domestic salmon population from disease;<sup>78</sup> Japan's requirement to test each variety of certain agricultural products to protect against the introduction of codling moths;<sup>79</sup> and Japan's prohibition on importing mature, symptomless apples in an effort to prevent the spread of fire blight, a plant disease.<sup>80</sup>

None of these reports revisited the legal applicability of precaution addressed by the Appellate Body's analysis in *EC-Hormones*. In that dispute, the EC relied on normative standards for precaution as a principle extrinsic to the SPS Agreement, such as the Rio Declaration, and did not litigate the applicability of Article 5.7.<sup>81</sup> Consequently, the Appellate Body's discussion of Article 5.7 in *EC-Hormones* was indirect, triggered by the EC's reference to the precautionary principle, and might plausibly be characterized as *obiter dictum*.<sup>82</sup> In the quarantine cases, by contrast, the Appellate Body addressed the requirements of Article 5.7 explicitly.<sup>83</sup> In

---

78. Panel Report, *Australia—Measures Affecting Importation of Salmon*, WT/DS18/AB/R, ¶¶ 2.11, 2.14 (Jun. 12, 1998) [hereinafter *Australia-Salmon*].

79. Appellate Body Report, *Japan—Measures Affecting Agricultural Products*, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter *Japan-Varietals*].

80. Appellate Body Report, *Japan—Measures Affecting the Importation of Apples*, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter *Japan-Apples*].

81. *EC-Hormones*, *supra* note 56, ¶ 124.

82. *Id.* (reversing Panel's findings under article 5.7, citing "numerous flaws . . . in the Panel's analysis").

83. See generally Rosie Cooney & Andrew T.F. Lang, *Taking Uncertainty Seriously: Adaptive Governance and International Trade*, 18 EUR. J. INT'L L. 523 (2007) (discussing approaches taken by the Appellate Body in determining the requirements of Article 5.7).

*Australia-Salmon*, Australia did not expressly identify Article 5.7 as a justification for the measure, but the Appellate Body commented on that provision as relevant to the dispute.<sup>84</sup> In the two disputes challenging Japanese measures, *Japan-Varietals* and *Japan-Apples*, the applicability of Article 5.7 was litigated more actively. In each dispute, the Appellate Body concluded that Article 5.7 was inapplicable.<sup>85</sup>

The Appellate Body's report in *Australia-Salmon* established that Article 5.7 is the only "exception to the obligation to base sanitary measures on a risk assessment."<sup>86</sup> In *Japan-Varietals* the Appellate Body referred to Article 5.7 as a "qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence," noting that "[a]n overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless."<sup>87</sup> Accordingly, the threshold for a Member to take advantage of the exceptions in Article 5.7 would appear to be high. The Appellate Body appears to view Article 5.7 as a potential escape hatch whose operation would relieve WTO Members of the need to comply with the disciplines in the SPS Agreement, and consequently adopted a presumption against its application. This approach is reminiscent of the GATT-era approach to the Article XX exceptions, which stressed their narrow scope and limited availability.<sup>88</sup> It is important to note, however, that a narrow interpretation of Article 5.7 is not necessarily inconsistent with a greater level of receptivity to precautionary approaches employed within the framework of the other obligations in the SPS Agreement.

Relying on the text of the SPS Agreement, the Appellate Body in *Japan-Varietals* established a four-prong test to determine whether a measure satisfies the requirements of Article 5.7 as a limited "safe harbor." Under the test: (1) the situation must be one "where relevant scientific information is insufficient;" (2) the measure must be based on "available pertinent information;" (3) the Member maintaining the measure must "seek[] to obtain the additional information necessary for a more objective assessment of risk;" and (4) the Member must "review[] the measure . . . within a reasonable period of time."<sup>89</sup> All four requirements must be satisfied for Article 5.7 to apply, and failure to meet any one means that Article 5.7 is unavailable as a justification for the challenged measure.

---

84. *Australia-Salmon*, *supra* note 78, ¶ 8.57.

85. *See Japan-Varietals*, *supra* note 79, ¶ 143(b); *Japan-Apples*, *supra* note 80, ¶ 243(c).

86. *Australia-Salmon*, *supra* note 78, ¶ 8.57.

87. *Japan-Varietals*, *supra* note 79, ¶ 80 (emphasis in original).

88. *See generally* Wirth, *supra* note 40 (discussing the directional change of environmental influence from the U.S. influencing Europe to the current European influence on the U.S.).

89. *Japan-Varietals*, *supra* note 79, ¶ 89 (quoting SPS agreement, art. 5.7, *supra* note 48).

The panel in *Japan-Varietals* examined the challenged measure on the basis of all four factors, but the Appellate Body based its conclusions only on the last two, apparently reasoning that because these conditions were not satisfied there was no need to examine the others.<sup>90</sup> With respect to the requirement to seek additional information, the Appellate Body observed that the Member's investigational inquiry must collect "information . . . germane to conducting such a risk assessment," presumably so as to satisfy the other requirements of the SPS Agreement.<sup>91</sup> The Appellate Body affirmed the panel's conclusion that Japan's subsequent research agenda did not satisfy this requirement because it was not targeted at preparing "a more objective risk assessment."<sup>92</sup>

With respect to the requirement to conduct further studies within a reasonable time, the Appellate Body stated that the availability of the exception "has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review *and* the characteristics of the provisional SPS measure."<sup>93</sup> Although the WTO SPS requirements had been in place only since the beginning of 1995 and the United States, as the complainant, had requested consultations only slightly more than two years after that, the Appellate Body concluded that this requirement was not satisfied because "collecting the necessary additional information would be relatively easy."<sup>94</sup> In *Australia-Salmon*, the Appellate Body observed that a measure adopted twenty years earlier "can . . . hardly be seen as a measure 'provisionally' adopted."<sup>95</sup>

In *Japan-Apples*, the Appellate Body addressed the somewhat more challenging question of the adequacy of the scientific evidence, as directed by the first sentence of Article 5.7.<sup>96</sup> The United States, as complainant, argued that 200 years of studies and practical experience with fire blight

---

90. *Id.* ¶ 91.

91. *Id.* ¶ 92.

92. *Id.*

93. *Id.* ¶ 93 (emphasis in original).

94. *Id.* This result is similar to that in the subsequent proceedings in *EC-Hormones*, in which the EC identified four years as a "reasonable period of time" for implementation of the Appellate Body's report, so as to allow for further investigational studies and the adoption of necessary legislation. In a proceeding under article 21.3(c) of the DSU, an arbitrator rejected these arguments, noting that "[i]t would not be in keeping with the requirement of *prompt* compliance to include in the reasonable period of time, time to conduct studies or to consult experts to demonstrate the *consistency* of a measure already judged to be *inconsistent*." Award of the Arbitrator, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶¶ 38–39, WT/DS26/15, WT/DS48/13 (May 29, 1998) (emphasis in original). Although analytically distinct because this was not a situation governed by Article 5.7, the underlying policy motivation appears similar to that of the Appellate Body's approach in *Japan-Apples*.

95. *Australia-Salmon*, *supra* note 78, ¶ 8.57.

96. *Japan-Apples*, *supra* note 80, ¶¶ 169–88.

already provided sufficient evidence to conclude that Article 5.7 was inapplicable and that the measure was consequently infirm by reference to the remainder of the SPS Agreement.<sup>97</sup> The panel and the Appellate Body agreed, concluding that existing scientific evidence was sufficient to demonstrate the *absence* of the need for regulation, establishing a very narrow scope of accessibility to the provision indeed.<sup>98</sup>

Significantly, Japan argued that the panel's interpretation of Article 5.7 excluded what Japan referred to as "unresolved uncertainty," or uncertainty that cannot be dispelled by scientific evidence.<sup>99</sup> In response, the Appellate Body concluded without explanation that:

The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence . . . . The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of "scientific uncertainty."<sup>100</sup>

Japan also objected to the panel's apparent conclusion that Article 5.7 is inapplicable in cases in which some information is available but the available data do not resolve the question of policy-relevant science presented. "We do not read the Panel's interpretation as excluding cases where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results," responded the Appellate Body.<sup>101</sup> "Article 5.7 would be applicable to a situation where a lot of scientific research has been carried out on a particular issue without yielding reliable evidence."<sup>102</sup>

While the jurisprudence under Article 5.7 is still evolving, some broad areas of divergence with normative statements urging precaution as a public policy are already apparent. First, the presumptions embedded in the two approaches are quite different from one another. The Appellate Body has stated that Article 5.7 should be available only as a narrowly crafted exception to justify a measure that otherwise would be subject to the SPS Agreement's more rigorous requirements. By contrast, a precautionary perspective counsels the early adoption of policy measures to avert threats characterized by scientific uncertainty.

---

97. *See id.* ¶¶ 61–67 (summarizing U.S. argument).

98. *Id.* ¶ 182.

99. *Id.* ¶ 33.

100. *Id.* ¶ 184.

101. *Id.* ¶ 185.

102. *Id.*



Second, the substantive scope of Article 5.7 is considerably narrower than normal standards for precaution. Although the difference between the two textual formulations may not be readily apparent, the Appellate Body's clear distinction in *Japan-Apples* between sufficiency of scientific evidence as used in the text of Article 5.7 on the one hand, and scientific uncertainty addressed by precautionary methodologies on the other, plainly narrows the range of situations in which Article 5.7 might be available as a surrogate for precaution. In principle, uncertainty can be reduced or eliminated through further scientific inquiry. But a precautionary perspective acknowledges that some uncertainties may be irreducible or fundamental, in the sense that they cannot be removed relying on currently available scientific methodologies within a time frame commensurate with the need for regulatory intervention, and consequently counsels an early, proactive policy response nonetheless.

As the Appellate Body stressed in *Japan-Apples*, Article 5.7 by contrast speaks of an "insufficient" scientific predicate, a narrow subset of the lack of full scientific certainty addressed by a precautionary methodology, and allows a WTO member to maintain a measure relying on this provision only on an interim basis pending development of sufficient information.<sup>103</sup> An alternative approach might have been to begin with the presumption, explicitly articulated in the SPS Agreement, that WTO Members have a right to adopt and apply sanitary and phytosanitary measures, which would translate into a presumption of validity. This interpretive approach in turn might have led to somewhat greater receptivity to the application of Article 5.7 under less rigorous conditions, and for a longer period.

Third, as highlighted in *Japan-Varietals*, for a measure to be justified by Article 5.7 a Member must collect more scientific information until the scientific basis for the action can be determined to be either sufficient—in which case the measure may presumably be maintained indefinitely—or inadequate—in which case it must presumably be removed, in both instances consistent with the requirements of the remainder of the SPS Agreement. Consequently, the provision is at most a temporary "safe harbor" pending further scientific investigation. Article 5.7 says nothing about a third, and very real, possibility involving fundamental or irreducible uncertainties, a situation expressly anticipated by a precautionary methodology. In any event, the Appellate Body has not yet found a measure

---

103. *Id.* ¶ 176.

to be justified by Article 5.7 despite litigation of this question in the two Japanese SPS disputes.<sup>104</sup>

#### D. *The GMO Dispute*

A fifth major dispute in which precaution, or Article 5.7, or both, were litigated under the SPS Agreement was a challenge initiated by the United States, Canada, and Argentina to the EC's *de facto* moratorium, maintained between 1999 and 2003, on the importation of genetically engineered crops and foods.<sup>105</sup> The EC scheme requires prior governmental authorization before a GMO may be "plac[ed] on the market."<sup>106</sup> This structure is common to regulatory schemes in place in many WTO member countries for such substances as drugs, food additives, and pesticides, but the implications for WTO rules of such an approach had not been considered earlier in WTO dispute settlement processes. The EC framework for approving GMOs is typical in requiring a private party applicant, such as a manufacturer, to demonstrate that the substance meets a test of safety or the absence of adverse effects.

##### 1. Community-Level Actions

Before taking up the arguments of the complaining parties, the panel's report<sup>107</sup> considered the relevance of extrinsic authorities, including the UN

---

104. *But see* Appellate Body Report, *United States—Continued Suspension of Obligations in the EC-Hormones Dispute*, ¶¶ 674-735, WT/DS320/AB/R (Oct. 16, 2008). After modifying the measures challenged in *EC-Hormones*, *supra* note 56, by substituting a provisional ban for five of the six hormones at issue in that dispute, the EC initiated a dispute settlement proceeding against the United States and Canada objecting to the continued maintenance of sanctions. *Id.* The Appellate Body, citing "numerous flaws . . . in the Panel's analysis" of the application Article 5.7, reversed the Panel's finding that a "critical mass" of new scientific evidence was necessary to satisfy that provision's requirement of "insufficiency"; concluded that the Panel had misallocated the burden of proof under that article; and found that the Panel had applied an incorrect test in interpreting its requirements. *Id.* ¶ 735. Because of the inadequacy of the Panel's analysis, the Appellate Body concluded that it was unable to determine the applicability of Article 5.7. *Id.*

105. Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, ¶ 4.10, WT/DS291/R, WT/DS292/R, WT/DR293/R (Sept. 29, 2006) [hereinafter EC-GMOs].

106. Council Directive 2001/18 art. 1, 2001 O.J. (L 106/1) 4 (EC) (defining "placing on the market" as "making available to third parties, whether in return for payment or free of charge"); *see also* David A. Wirth, *The Transatlantic GMO Dispute Against the European Communities: Some Preliminary Thoughts*, in *EU AND WTO LAW: HOW TIGHT IS THE LEGAL STRAITJACKET FOR ENVIRONMENTAL PRODUCT REGULATION?* 175, 177-180 (M. Pallemmaerts ed., 2006) (providing a more detailed discussion of the EC scheme at issue in this dispute).

107. EC-GMOs, *supra* note 105, ¶ 7.73. In November 2006, the Commission decided not to appeal the panel's report to the WTO Appellate Body because the moratorium was terminated by 2004

Biodiversity Convention, the Biosafety Protocol to that instrument, and the precautionary principle. The panel found that, because the United States had signed but not ratified the Biodiversity Convention and consequently is not a party to it, that agreement is not “applicable” to relations among those WTO members.<sup>108</sup> Argentina and Canada signed the Biosafety Protocol but have not yet ratified, and the United States has not signed the agreement. Consequently, none are parties to the Protocol and it, too, is inapplicable to the dispute.<sup>109</sup>

The EC vigorously asserted the application of the precautionary principle and the complainants forcefully denied that precaution has any legal content or relevance. The panel first recalled the Appellate Body’s treatment of precaution in the *EC-Hormones* dispute.<sup>110</sup> The panel then addressed the status of precaution in international law, concluding that, as the Appellate Body had found in 1998, there is no standard formulation for the principle and that the question of its legal force “remains unsettled.”<sup>111</sup> In light of this, the panel stated that there was no need to address the matter in greater detail because the precautionary principle did not apply to the dispute as a general matter and it was irrelevant to the task of adjudicating the rights and obligations of the disputing parties.<sup>112</sup>

Although the precautionary principle as such may not have been applicable to the legal claims before the panel, a prior approval scheme by its very structure contains elements of precaution. Requirements for prior governmental approval serve a gatekeeping function by shifting the burden onto the proponent of a product, substance, or process to justify the approval sought, usually by reference to a predetermined test or criterion. Before or pending approval, the action for which the approval must be

---

and the regulatory provisions at issue in the dispute are not affected by the panel’s report. As of this writing there is some potential, as yet unclear, for the EC’s traceability and labeling requirements to give rise to a second dispute over biotech foods and crops. The Codex Alimentarius has made efforts to harmonize GM food labeling. See generally Jack A. Bobo, *Two Decades of GE Food Labeling Debate Draw to an End—Will Anybody Notice?*, 48 IDAHO L. REV. 251 (2012) (examining the compilation of labeling guidance created by a commission outside the WTO and the SPS agreement).

108. EC-GMOs, *supra* note 105, ¶ 7.74. The panel’s conclusion concerning the Biodiversity Convention, to which Argentina, Canada and the EC are parties, appears to be an application of WTO law and not purely a question of treaty interpretation. See Vienna Convention, *supra* note 67, art. 30 (declaring that application of successive treaties on the same subject matter to be presumed unless the agreements are “incompatible” with each other).

109. EC-GMOs, *supra* note 105, ¶ 7.75.

110. *Id.* ¶¶ 7.78–7.88.

111. *Id.* ¶ 7.89. The panel found that the status of the precautionary principle had not changed in the time between the Appellate Body’s report in *EC-Hormones* and the panel’s report in *EC-GMOs*. *Id.* ¶ 7.88.

112. *Id.* ¶ 7.3211 (discussing that there is no need to examine precautionary principle as such in review of national-level safeguard measures under Article 5.7).

granted is ordinarily prohibited. For that reason, requirements for prior governmental approval are regulatory tools which by their very structure express a public policy preference for erring on the side of caution, and are consequently inherently precautionary.<sup>113</sup> Because the default option in such a scheme is to prohibit market entry in the absence of affirmative governmental action, of necessity there will be no exposure to risks from a product, substance, or process for which approval is required until the approval is granted. The purpose of the application process is to clarify the nature of the risks, if any, often through a process of give-and-take between the applicant and governmental authorities as in, for instance, requests for more studies or further information. Not surprisingly, one of the EC directives at issue in the dispute expressly invokes the precautionary principle.<sup>114</sup>

The principal discipline in Annex C of the SPS Agreement relevant to prior approval schemes, such as the EC's for GMOs, is a prohibition on "undue delay."<sup>115</sup> The interaction between this discipline and domestic regulatory requirements quite obviously has the potential to alter the dynamics between governmental officials and private sector applicants in the implementation of a prior approval scheme. It is not infrequent in the context of prior approval schemes for governmental authorities to request more information from the applicant. If that causes delay in the final approval, as it may well, then the question becomes whether the delay is "undue"—that is, related to a legitimate public policy goal on the one hand or a pretext for abuse on the other. Presumably, inordinate foot-dragging in processing an application could also amount to "undue" delay. The appropriateness of a precautionary perspective in drawing this line consequently could be expected to be an element in the interpretation of the extent to which delay is "undue." At least under some circumstances, determining whether an approval process has resulted in "delay"—a term which by its plain meaning invites a conclusion of abuse—that is "undue"

---

113. See, e.g., Helle Tegner Anker & Margaret Rosso Grossman, *Authorization of Genetically Modified Organisms: Precaution in US and EC Law*, 3 EUR. FOOD & FEED L.R. 3 (2009).

114. Council Directive 2001/18, *supra* note 106, arts. 1 & 4(1).

115. SPS Agreement, *supra* note 48, at 82 ¶ 1(a) ("Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products[.]"). A strict reading of the introductory language, which limits this requirement to "any procedure to check and ensure . . . the fulfilment of sanitary or phytosanitary measures," might very well lead to the conclusion that this discipline is inapplicable by its terms. A prior approval scheme, strictly speaking, is not designed to "check and ensure . . . the fulfilment of" a normative standard in an enforcement mode; rather a prior approval scheme is itself a normative process in which a governmental authority is requested to determine the appropriateness of entry into commerce.

could raise delicate questions concerning review of the scientific rationale for the length of time required by governmental authorities to reach a conclusion.

In response to a political agreement in the EC to amend the 1990 directive governing GMO approval procedures, five EC Member States—Denmark, Greece, France, Italy, and Luxembourg—in 1999 issued a joint statement expressing concern about the adequacy of the new legislation and announcing that “in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended.”<sup>116</sup> Another group of seven Member States—Austria, Belgium, Finland, Germany, the Netherlands, Spain, and Sweden—stated its intention “to take a thoroughly precautionary approach in dealing with applications and authorizations.”<sup>117</sup> The Group of Five’s statement resulted in an across-the-board moratorium, whereas the Group of Seven announced an objective of rigorously reviewing applications on a case-by-case basis by reference to precautionary approaches.

The complaining parties objected to the blanket moratorium as well as to the EC’s treatment of individual applications.<sup>118</sup> The panel rejected the argument that the general moratorium was a “measure” for the purposes of the SPS Agreement, because the pending applications had not been the result of a final official action such as approval or disapproval.<sup>119</sup> The panel then went on to examine the consistency of the moratorium with the other requirements of the SPS Agreement, most notably the provision prohibiting “undue delay.”<sup>120</sup> As part of that analysis, the panel took up the question of whether precautionary perspectives, as identified by both groups of countries but with different operative effects, might justify the general *de facto* moratorium.<sup>121</sup>

In addressing this question, the panel first noted that the SPS discipline proscribing undue delay “does not preclude the application of a prudent and precautionary approach.”<sup>122</sup> The panel stated that the appropriateness of a particular action, such as a request for additional information, would be determined on a case-by-case basis, “in the light of all relevant facts and circumstances.”<sup>123</sup> As a general matter, however, the panel opined that:

---

116. EC-GMOs, *supra* note 105, ¶ 7.474.

117. *Id.* ¶ 7.484.

118. *Id.* ¶ 7.98.

119. *Id.* ¶ 7.1613.

120. *Id.* ¶¶ 7.1466, 7.1503.

121. *Id.* ¶ 7.3220.

122. *Id.* ¶ 7.1522.

123. *Id.*

It is quite possible that . . . where science evolves and there is limited available scientific evidence, a deferral of substantive decisions might allow for better decisions at a later point in time, provided that appropriate analyses and research are undertaken. However, we do not consider that [the SPS discipline prohibiting undue delay] can or should be interpreted to allow Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data.<sup>124</sup>

Consequently, “evolving science, scientific complexity and uncertainty, and limited available scientific information or data are not, in and of themselves, grounds for delaying substantive approval decisions.”<sup>125</sup> In such a situation, observed the panel, Article 5.7 might be available to support a measure implemented on a provisional basis.<sup>126</sup>

In the end the panel concluded that twenty-four of the twenty-seven challenged applications at the EC level had resulted in “undue delay.”<sup>127</sup> This required the panel to examine the facts and circumstances of each application individually, explicitly reviewing the scientific rationale for the alleged delay in each instance,<sup>128</sup> and impliedly engaging with principles of precautionary decision-making in undertaking that analysis. Because the EC-level applications were not “measures,” Article 5.7 was not explicitly part of that analysis.

## 2. National Safeguard Measures

The complaining parties also challenged nine national-level measures maintained by the EC Member States of Austria, France, Germany, Greece, Italy, and Luxembourg as so-called “safeguard measures” under the relevant directives. These provisions in the directives permit an EC Member State to restrict or prohibit use or sale in its territory, even after authorization is given at the EC level, if a Member State nonetheless believes that the GMO in question may pose a risk to health or the environment. As with the approval process at the Community level, the EC invoked Article 5.7 as a justification for these national measures.

---

124. *Id.* ¶ 7.1527.

125. *Id.* ¶ 7.1526.

126. *Id.* ¶ 7.1527.

127. *Id.* ¶ 8.7.

128. *Cf.* Antonia Eliason, *Science Versus Law in WTO Jurisprudence: The (Mis)Interpretation of the Scientific Process and the (In)Sufficiency of Scientific Evidence in EC-Biotech*, 41 N.Y.U. J. INT'L L. & POL. 341, 344 (2009) (discussing Appellate Body review as focused on issues of law, with limited capacity to review facts or scientific determinations made by panels).

By contrast with the EC-level applications, the Member State safeguard prohibitions as a matter of form qualified as “measures” as that term is used in the SPS Agreement, because they had resulted in final actions in the form of prohibitions on use. In view of the EC’s characterization of the safeguard measures as “provisional,” the first question addressed by the panel consequently was the test for the threshold applicability of Article 5.7.<sup>129</sup> The procedural posture of the Member State-level safeguard measures consequently led the panel to articulate in greater detail the requirements of Article 5.7 than was called for by the panel’s characterization of the applications considered at the EC level.

Relying on language from the two Japanese quarantine cases, the panel concluded that the trigger for applicability of Article 5.7 was not the characterization of the measure as provisional by the WTO Member State, but, rather, insufficiency of the scientific evidence.<sup>130</sup> In other words, the availability of Article 5.7 depends not on how the WTO Member State describes the measure, but on the state of scientific evidence as determined by the panel itself.

The panel then went on to examine the relationship between Article 5.7 on the one hand and Articles 2.2 and 5.1 on the other, which specify that SPS measures must be “based on scientific principles[,] . . . not maintained without sufficient scientific evidence” and be “based on” a risk assessment, respectively.<sup>131</sup> After a lengthy exegesis, the panel concluded that Article 5.7 is a “qualified right” for a WTO Member temporarily to maintain a measure that does not satisfy Article 5.1’s requirement of a risk assessment.<sup>132</sup> Once Article 5.7 is invoked, stated the panel, the burden is on the complaining party to establish that any one of the four requirements for application of Article 5.7 is not satisfied.<sup>133</sup> After that, the burden shifts back to the responding party, which must demonstrate that all the demands of Article 5.7 have been met.<sup>134</sup> In situations where the requirements of Article 5.7 are not satisfied, the remainder of the SPS Agreement, including Articles 2.2 and 5.1, applies to the measure.<sup>135</sup> The analysis commences with an examination of the measure’s consistency with Article 5.1, and it is

---

129. EC-GMOs, *supra* note 105, ¶¶ 4.373–4.374.

130. *Id.* ¶¶ 7.2939–2.994.

131. *Id.* ¶¶ 7.3027, 7.3031 n. 1867.

132. *Id.* ¶ 7.3004.

133. *Id.* ¶ 7.3006. *Cf.* text *supra* note 89 (discussing test for application of Article 5.7 set out in *Japan-Varietals*).

134. *Id.* ¶ 7.3218–19.

135. *See id.* ¶ 4.631 (analyzing article 5.7 as an exception to articles 2.2 and 5.1).

only after a conclusion that Article 5.1 is not satisfied that consideration of Article 5.7 is necessary.<sup>136</sup>

The panel then applied this analytical framework to the nine challenged safeguard measures maintained by the six EC Member States. First, the panel decided that in determining the extent to which available science is “insufficient” as a condition precedent to the application of Article 5.7, a WTO Member’s choice of appropriate level of protection (ALOP) is irrelevant.<sup>137</sup> Second, the appropriate temporal juncture for assessing the sufficiency of the scientific evidence for the purposes of Article 5.7 is at the time the measure is adopted.<sup>138</sup> After resolving these generic questions, the panel concluded that none of the challenged measures were justified by reference to Article 5.7 because the scientific evidence in each case was sufficient to determine that the measure was not warranted.<sup>139</sup>

#### IV. CONCLUSION: RECONCILING PRECAUTION AND INTERNATIONAL TRADE

The central conundrum of the SPS agreement is the intrusiveness of panel review of domestic, presumably expert, judgments with respect to policy-relevant science. If review by a WTO dispute settlement panel is too cursory, the Agreement will not perform its intended purpose: to provide for international scrutiny of an allegedly protectionist trade barrier. On the other hand, excessive zeal by panels in revisiting the scientific predicate for a national regulatory measure can begin to look like international intrusion into a state’s intrinsic sovereign prerogatives to protect health, safety, and the environment. In the development of SPS jurisprudence, these considerations have played out in a variety of related guises. These include questions familiar in post-hoc, third-party review of scientific and technical data, questions, and judgments, including burden of proof,<sup>140</sup> standard of

---

136. *Id.* ¶ 7.3215.

137. *Id.* ¶ 7.3246.

138. *Id.* ¶ 7.3255.

139. *Id.* ¶ 8.9.

140. *See* EC-Hormones, *supra* note 56, ¶¶ 97–109 (discussing the burden on the challenging party to establish a prima facie case of violation, after which the burden shifts to responding party to defend by reference to science-based disciplines).



review,<sup>141</sup> and deference to the judgment of national decision-making authorities.<sup>142</sup>

If those questions are not daunting enough, the SPS Agreement also raises a host of other epistemological issues associated with the adjudication of scientific questions in an adversarial setting:<sup>143</sup> To what extent, if any, is it possible to appeal to science as a value-neutral arbiter of public policy disputes, such as the EU hormone and GMO bans?<sup>144</sup> To what extent is it possible to identify a particular methodology as “scientific” or not? To what extent is it possible to adjudicate questions of scientific “fact” in an adversarial setting?<sup>145</sup> What is the appropriate treatment of minority scientific views in an adjudicatory, adversarial setting? Are tests designed to prevent abuses of agricultural quarantines intended to protect commercially important plant and animal species also appropriate for measures to protect human health from contaminants in food (e.g., *EU-Hormones*), and vice versa? What is the optimal procedure for lay adjudicators to collect policy-relevant scientific information from technical experts?<sup>146</sup>

To phrase the issue in the manner in which it demonstrates the greatest concern for the integrity of the trade regime, among those challenges is how to identify abuses of precautionary decision-making. The GMO dispute raises this question, already inherent in the very structure of free trade agreements,<sup>147</sup> in the starkest possible terms.<sup>148</sup> A prior approval scheme,

---

141. *Id.* ¶¶ 110–19 (stating that panels should engage in “objective assessment of the facts”—i.e., science). By contrast, the standard of review to be applied by the Appellate Body in reviewing a panel’s determination is to ascertain whether the panel engaged in “wilful distortion or misrepresentation” of the facts or science, or “an egregious error that calls into question the good faith of a panel.” *Id.* ¶ 133.

142. *Id.* ¶¶ 110–19.

143. See generally Markus Wagner, *Law Talk v. Science Talk: The Languages of Law and Science in WTO Proceedings*, 35 *FORDHAM INT’L L.J.* 154 (2011) (describing the role of science in the SPS Agreement).

144. See, e.g., Vern R. Walker, *The Myth of Science as a “Neutral Arbiter” for Triggering Precautions*, 26 *B.C. COMP. & INT’L L. REV.* 197, 197 (2003) (arguing “science cannot be a ‘neutral arbiter’ for triggering precautionary measures”).

145. See, e.g., CAROLINE FOSTER, *SCIENCE AND THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL COURTS AND TRIBUNALS* (2011) (explaining that committees usually assess scientific matters, precluding the need for judicial review).

146. See Eric Gillman, *Making WTO SPS Dispute Settlement Work: Challenges and Practical Solutions*, 31 *N.W.J. INT’L L. & BUS.* 439, 463–71 (2011) (discussing the role of experts in SPS disputes); Joost Pauwelyn, *The Use of Experts in WTO Dispute Settlement*, 51 *INT’L & COMP. L.Q.* 325 (2002) (discussing the importance of experts in WTO dispute settlement).

147. See Section III, *supra*.

148. See generally David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 *YALE J. INT’L L.* 81 (2005) (discussing objections to European Union actions preventing the importation of genetically modified crops and food products).

such as the EC's for GMOs, is by its very nature skewed toward precautionary outcomes because it places the burden on the proponent of a product to demonstrate safety, the absence of harm, or whatever other test the governmental decision-maker is instructed to employ. It is difficult to question as a matter of principle the inherent legitimacy of prior approval schemes, given their extensive use by a variety of states. But it is important to note that in the absence of an actual, affirmative authorization, a prior approval scheme inherently generates the result "not yet" as opposed to "no." Assuming that the regulatory structure is operating in good faith, the proponent of a product is always free to generate more data to support approval. As is almost painfully evident from the report of the panel in *EU-GMOs*, the SPS agreement and its discipline of "undue delay" inevitably involves intrusive review of sensitive, presumably expert, scientific judgments not as to whether a product should be approved, but whether more information about it is appropriate before a decision is made – exactly the realm of precaution.

Precaution, then, continues to present complex and unique challenges to the law of international trade. As the coverage of trade agreements expands to reach nondiscriminatory public policy measures designed to further other social welfare goals, tensions between those purposes and the aim of trade liberalization tend to become apparent. Norms of precaution, whether binding or not, exhorting states to act or refrain from acting in the face of uncertainty, present particular difficulties because in a trade agreement dispute settlement proceeding they appear to be pretexts for protectionism. The natural tendency then is to approach the question as a zero-sum clash between precaution and the trade disciplines, with an overemphasis on one necessarily attenuating the vigor of the other. An adjudicatory, adversarial setting in which the validity of a measure is resolved at a particular moment—attributes that do not necessarily create a productive interface with protocols of scientific inquiry—further exacerbates the potential for conflict.

The panel in *EC-GMOs* elucidated this perspective, emphasizing the costs associated with tradeoffs between the trade disciplines and other social welfare policies with exquisite clarity. "[I]t is clear," stated the panel, "that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by" the SPS Agreement.<sup>149</sup> The need for closure in adjudicating the rights and obligations of WTO Members trumps precaution in reviewing the irreversible process of releasing GMOs to the environment

---

149. *EC-GMOs*, *supra* note 105, ¶ 7.1523.

because it is not permissible for “Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data.”<sup>150</sup> This interpretation of the SPS Agreement, and particularly Article 5.7, facilitates a crisp and final adjudication of WTO Members’ rights, but it is far from apparent that this approach is responsive to the real-world regulatory milieu that frequently presents challenging and muddy questions of public policy.

The WTO dispute settlement mechanism has declined to grapple with these weighty issues, instead eliminating precaution as a legitimate basis for governmental decision-making from consideration altogether, further reinforcing that result with an extraordinarily ungenerous interpretation of Article 5.7 of the Agreement. The difficult question of precaution in international trade law might benefit instead from a different entry point to the problem. The WTO has become a forum for an international discussion of appropriate approaches to regulation. This is particularly apparent in the context of the SPS Agreement, but Appellate Body disputes involving the basic GATT disciplines of non-discrimination<sup>151</sup> demonstrate that the question can arise elsewhere in the WTO suite of agreements as well. The question then is the appropriateness of precaution as a component of a governmental regulatory process. While the precise outlines of a precautionary approach may be less well-established than protocols for risk assessment, precaution is well nigh universally accepted as a public policy approach, including in the states that have been challenging parties in the SPS cases. While the Appellate Body and the GMO panel speak as if precaution were a separate body of law existing in an alternate universe, the 100 heads of state or government that adopted the Rio Declaration are representatives of the same states that are Members of the WTO. It is no coincidence that it is only in the context of international trade, and in particular the potential for restricting market access, that precaution is routinely assailed as a potentially counterproductive policy.

Trade disputes over regulatory measures, such as the beef hormone ban or genetically engineered foods and crops, are often byproducts or artifacts of more fundamental differences in regulatory approaches and philosophy among states. The EC’s continued refusal to abandon the hormone ban despite WTO-authorized sanctions,<sup>152</sup> one of the longest ongoing disputes

---

150. *Id.* ¶ 7.1527.

151. *E.g.*, Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 151, WT/DS332/AB/R (Dec. 3, 2007).

152. The United States and the EC agreed on a settlement of the dispute only in 2009, more than a decade after the Appellate Body’s report. *See* Joint Communication from the European Communities & United States, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/28 (Sept. 30, 2009).

in WTO history, is concrete evidence of the intensity of public sentiment on sensitive public policy issues like food safety. The WTO disciplines, and most notably the SPS Agreement, are an attempt to cabin and constrain public policy decisions by discouraging states from proceeding with and maintaining the most absurd, outlier public policies. Precautionary approaches are now sufficiently well accepted internationally that they fall well within the range of the minimally acceptable.

If precaution is widely accepted as a legitimate approach to crafting public policy, the WTO can ill afford to ignore that perspective in its jurisprudence. Otherwise, the very disciplines that are intended to establish minimum standards for sound approaches to regulation risk diverging from good practice standards established outside the trade context. By virtue of the SPS Agreement, the WTO has become arguably the single most important international forum for addressing philosophies of regulation. By treating precaution as if it exists in another dimension, distinct from the trade-based disciplines, the WTO dispute settlement process risks distorting regulatory decision-making even in areas that have no adverse implications for international trade.

While there may be disagreements about their underlying utility, the public policy measures at issue in trade disputes with scientific overtones have invariably been adopted by public authorities after considerable deliberation. In at least some national settings, that would counsel hesitancy on the part of reviewing authorities like courts to disrupt or reconsider decisions of public authorities on technical scientific questions. A measure of deference on such questions as national determinations as to the sufficiency of scientific information would be an analytical mechanism for dispute settlement panels and the Appellate Body to reconcile apparently competing policy visions. The Appellate Body's expansive and inclusive definition of a risk assessment in *EC-Hormones*,<sup>153</sup> presumably so as to encompass a variety of national-level approaches, is an example of such a deferential interpretation. A presumption of good faith on the part of governmental authorities could similarly create an appropriately circumspect perspective in the international review of science-based measures based in part on precautionary methodologies.

These considerations suggest the utility of an attempt by the Appellate Body to harmonize what may at first appear to be competing public policies such as the SPS disciplines and precaution. To that extent, statements such as the Appellate Body's holding in *Japan-Apples* that scientific uncertainty

---

153. *EC-Hormones*, *supra* note 56, ¶¶ 187 & 198 (stating risk assessment need not be quantitative or "come to a monolithic conclusion").

and sufficiency of scientific evidence are different concepts for the purposes of SPS Article 5.7 are missed opportunities at best. The larger trajectory of Appellate Body jurisprudence is instructive in suggesting greater receptivity to environment, natural resources, and public health concerns by relaxing the strictures of the trade-based disciplines.<sup>154</sup> As the Appellate Body's own jurisprudence has demonstrated, it is not just possible but desirable to reconcile potentially competing public policies with the goals of trade liberalization through the vehicle of the trade agreement dispute settlement process.

---

154. *E.g.*, U.S.-Shrimps, *supra* note 70; *see also* Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 114, 192 WT/DS135/AB/R (Mar. 12, 2001) (concluding that asbestos and alternatives to it are not “like products” for purposes of national treatment discipline by virtue of differences in toxicity).