Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law

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I. INTRODUCTION

In August 2003, the United States, Canada, and Argentina initiated dispute settlement procedures at the World Trade Organization (WTO) against the European Communities (EC) for delaying approvals of genetically modified (GM) crops within its borders.[1] A dispute settlement panel has convened to settle this matter, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products* (*Biotech Products*), and the parties began submitting written complaints in May 2004. The dispute implicates not only technical concerns about barriers to trade but also political questions about democratic participation in the design and operation of the WTO.[2] Its resolution will have consequences for the global development of agricultural biotechnology, the democratic regulation of risks in world trade, and, not least, the WTO's very legitimacy as an institution of global governance.[3]

As the U.S. submission in this case makes clear, the central legal issues in *Biotech Products* involve the interpretation of important provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement),[4] especially those portions concerning "scientific justification" and "risk assessment."[5] The latter is a crucial term underpinning the entire

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1. The United States, Canada, and Argentina first called for consultations on May 14, 2003, concerning Europe's alleged ad hoc moratorium on GM crops. On August 8 of that year, the three countries each requested that a panel be formed to hear the dispute. Permanent Mission of the United States to the Chairman of the Dispute Settlement Body, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by the United States*, WT/DS291/23 (Aug. 8, 2003); Permanent Mission of Canada to the Chairman of the Dispute Settlement Body, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by Canada*, WT/DS292/17 (Aug. 8, 2003); Permanent Mission of Argentina to the Chairman of the Dispute Settlement Body, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by Argentina*, WT/DS293/17 (Aug. 8, 2003).

2. On the theme of legitimacy and democracy in international trade law, *see, e.g.*, J.H.H. Weiler, *The Rule of Lawyers and the Ethos of the Diplomats: Reflections on the Internal and External Legitimacy of WTO Dispute Settlement*, 35 J. WORLD TRADE 191, 193 (2001) (acknowledging that political legitimacy has become "an essential part" of international trade law); ROBERT HUDEC, *Concepts of Fairness in International Trade Law*, *in* ESSAYS ON THE NATURE OF INTERNATIONAL TRADE LAW 227 (1999); Robert Howse & Kalypso Nicolaïdis, *Legitimacy and Global Governance: Why Constitutionalizing the WTO Is a Step Too Far*, *in* EFFICIENCY, EQUITY, AND LEGITIMACY: THE MULTINATIONAL TRADING SYSTEM AT THE MILLENNIUM 227 (Robert B. Porter et al. eds., 2001).

3. *See, e.g.*, Grant E. Isaac & William A. Kerr, *Genetically Modified Organisms at the World Trade Organization: A Harvest of Trouble*, 37 J. WORLD TRADE 1083 (2003); Christian Joerges & Jürgen Neyer, *Politics, Risk Management, World Trade Organisation Governance and the Limits of Legalisation*, 30 SCI. & PUB. POL'Y 219 (2003).

4. Enacted in April 1994 as part of the agreement establishing the WTO, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) covers and restricts the laws, regulations, and other measures that WTO members impose in efforts to protect against food- and plant-borne threats to animal, plant, and human health. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 27, *available at* http://www.wto.org/english/docs_e/legal_e/15-sps.pdf [hereinafter SPS Agreement].

5. Permanent Mission of the United States, *First Submission of the United States in European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, 292 & 293 (Apr. 21, 2004) [hereinafter *First U.S. Submission*]; SPS Agreement, *supra* note 4, art. 5.7 (allowing member states to impose provisional SPS measures "where relevant scientific evidence is *insufficient*," but requiring that such members "seek to obtain the additional information

free flow of trade in food products under the WTO's science-based disciplines.[6] In *Biotech Products*, the U.S. Trade Representative has challenged the scientific basis of European Union (EU)[7] actions preventing the import of GM crops and food products, alleging that reversals of GM regulatory policy within the EU and its member states illustrate the EU's departure from a fixed body of sound science and constitute "unreasonable" or "undue delay" under the SPS Agreement.[8] The European Commission[9] focuses its argument on the safe harbor provision of SPS Article 5.7—which permits members to impose provisional or precautionary measures under certain circumstances—arguing that at the time of the regulatory decisions in question, the scientific evidence was "insufficient" to perform an "adequate" risk assessment.[10] If the dispute settlement panel decides that the European actions do indeed constitute an "SPS measure,"[11] the decision will turn on the interpretation of *scientific sufficiency* for *adequate* assessment of risks.

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necessary for a more objective assessment of risk and review the [SPS] measure accordingly *within a reasonable period of time*") (emphasis added); *id.* art. 5.1, 5.4 (WTO members shall evaluate their SPS measures "taking into account *risk assessment techniques developed by the relevant international organizations*. . . . With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member *shall avoid arbitrary or unjustifiable distinctions* in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade") (emphasis added).

6. *See* Vern R. Walker, *Keeping the WTO from Becoming the 'World Trans-Science Organization': Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, 31 CORNELL INT'L L.J. 251, 277 (1998) (emphasizing that fact-finding panels under the SPS Agreement "must adequately understand the nature of risk assessment, the pervasiveness of scientific uncertainty, and the role of science policy").

7. Although the European Union (EU) has been a WTO member state since January 1995, it is "known officially as the European Communities in WTO business." World Trade Organization, Member Information: The European Communities and the WTO, http://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm. The *Biotech Products* dispute arises from regulatory actions taken by the EU. Thus, references to official European actions in this Article will be made to the EU. References to official WTO proceedings or actions, however, will be to the EU or the EC, as appropriate.

8. *See First U.S. Submission*, *supra* note 5, at 17, 35, 50; SPS Agreement, *supra* note 4, art. 5; *id.* at Annex C(1)(a) (WTO members must ensure that any SPS measures "are undertaken and completed *without undue delay* and in no less favourable manner for imported products than for like domestic products") (emphasis added).

9. The European Commission, the executive body of the EU's supranational governmental structure, consists of twenty commissioners nominated by the governments of the EU member countries and approved by the European Parliament. For an overview of the emerging governmental structure in Europe, see DAVID M. WOOD & BIROL A. YESILADA, THE EMERGING EUROPEAN UNION 1-10 (3d ed. 2004). Within the WTO, "while the member States coordinate their position in Brussels and Geneva, the European Commission alone speaks for the EU and its members at almost all WTO meetings and in almost all WTO affairs." World Trade Organization, Member Information: The European Communities and the WTO, http://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm.

10. Permanent Delegation of the European Commission, *First Written Submission by the European Communities in European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, 292 & 293 (May 17, 2004); SPS Agreement, *supra* note 4, Annex C(1)(h) (when the specifications of a previously approved product change, member states must limit their control and inspection procedures for the new product to those measures "necessary to determine whether *adequate confidence* exists that the product still meets the regulations concerned") (emphasis added); *id.* art. 5.7 (allowing provisional SPS measures in "cases where relevant scientific evidence is insufficient").

11. The SPS Agreement defines a "sanitary or phytosanitary measure" as "any measure applied (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks

The outcome of *Biotech Products* carries profound implications for the balance between state and global power and the relationship of science to democracy. WTO adjudicators will define the extent to which particular conceptions of sound science can be used to set boundaries on members' precautionary health and environmental measures. How far will the WTO go toward invoking the epistemic authority of sound science to overcome claims based on national political authority? Who will dictate what scientific authority actually stands for in a given case? At stake in the answers to these questions are the very parameters of state self-determination with regard to food biotechnology and risk-based decision-making—not just for the EU, but for all WTO members. Furthermore, the ultimate *Biotech Products* decision will also help construct international norms about the types of evidence that justify a precautionary approach to regulation.

Judicial interpretations of these concepts will help settle ambiguities in the SPS Agreement and existing case law regarding how the global trade regime ought to balance the competing goals of trade liberalization and the regulatory self-determination of WTO members.[12] Previous commentators have been relatively sanguine about the utility of employing the sound science concept to help harmonize national regulations and reduce disguised restrictions on trade without trampling upon the value-based and democratically enacted choices of member states.[13] This position presumes a level of consensus on the meaning of sound science that is contradicted by the *Biotech Products* case. Exactly how WTO judges apply disputed science to their evaluation of a policy judgment or a precautionary environmental measure, and whether or not such judgments interfere with cultural self-determination, remain open questions.

Thus, *Biotech Products* is making explicit the legal and political complexities inherent in the judicial review of risk-assessment science. Much is at stake both for the trajectory of biotechnological development and also for the WTO's legitimacy as an institution, since the issues raised by GM organisms (GMOs) bear upon all matters of scientific justification and risk assessment in international trade law.

This being so, it is vital to offer—and for the WTO to rely upon—a characterization of the risk-assessment process and science-informed policymaking that adequately embraces the results of current social science scholarship and recent regulatory experience. In practice, effective and reliable risk assessment diverges from the simple science-based models promoted by the United States and other complaining members in the *Biotech*

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arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages, or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." SPS Agreement, *supra* note 4, Annex A, para. 1.

12. *See, e.g,* David M. Driesen, *What is Free Trade?: The Real Issue Lurking Behind the Trade and Environment Debate*, 41 VA. J. INT'L L. 279 (2001) (arguing that the failure of WTO officials, members, and scholars to articulate a clear concept or definition of free trade—vacillating between nondiscrimination and laissez-faire liberalism—has left the WTO unable to defend its legitimacy, especially in the face of increasing tension with other legal regimes).

13. *See, e.g.*, Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329, 2330 (2000).

Products case.[14] Social science and regulatory experience instead emphasize that value judgments and public participation play an important role in generating reliable and conclusive risk assessments, especially in new and contested risk situations. Accordingly, WTO judges charged with interpreting the SPS Agreement should use anti-protectionism as their guiding norm, rather than fall back upon a singular conception of scientific sufficiency. This orientation would not only foster coherent science-based policymaking but would also be consistent with the spirit of the SPS Agreement—and the entire postwar history of the trading regime.

This perspective on the proper approach to science-based trade regulation yields recommendations for how WTO adjudicators should approach their task in *Biotech Products* and future such cases. Specifically, judges should adopt a procedural outlook, as described below, that takes into account the proper role of national values and policy judgments in scientific regulation. Especially important will be the further development of jurisprudence under the Article 5.7 safe harbor. Interpreting Article 5.7 with an anti-protectionist orientation that nevertheless recognizes the legitimacy of public engagement in novel risk situations will be crucial if the WTO wishes to preserve its political legitimacy. *Biotech Products*, therefore, affords the trade body an opportunity to preserve a space for legitimate cultural differences in risk assessment and technology policy within the trading system. The European regulatory treatment of GMOs can and should be deemed legitimate under Article 5.7 without damaging the anti-protectionist tools of the SPS Agreement as a whole.

Part II of this Article provides factual background to the transatlantic GMO dispute and an overview of the legal and political developments leading up to the complaint brought against the EU at the WTO. It also lays out the existing scholarship on the SPS Agreement's inherent tensions between a sound science principle and democratic self-determination, suggesting that the *Biotech Products* case will play a significant role in resolving these tensions.

Part III draws upon the substantial scholarship on risk analysis and the recent international regulatory work on assessing risk. It provides an account of science's role in policymaking that differs from earlier understandings, and which can help lay the conceptual foundations for more legitimate risk-based decision-making by WTO dispute settlement tribunals.

Part IV argues that the realities of risk assessment and public participation in science policy militate against using SPS law to enforce a particular conception of scientific sufficiency in risk-based decision-making. An emphasis on anti-protectionism would be more consistent with the history and goals of the trading regime, and could be implemented consistently with the recognition that legitimate public concerns and values can inform risk assessment.

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14. *See, e.g.*, *Executive Summary of Oral Statement of the United States at the First Substantive Meeting with the Panel: European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, 292 & 293, para. 27 (June 17, 2004), *available at* http://www.trade-environment.org/output/theme/tewto/us_oral_statement_June04_summary.pdf (failing to acknowledge that public dialogue and values, along with existing scientific studies, might be legitimate inputs into the original assessment of risks).

Part V gives a general account of how WTO judges should handle risk-based regulation in order to implement an anti-protectionist vision of the SPS Agreement. It argues that a procedural approach—comprising the prudent use of regulatory experts, an awareness of the diversity of risk situations and definitions, and the recognition of valid public participation in regulatory policy—will help judges negotiate the dual SPS Agreement goals of disciplining protectionism and recognizing legitimate value differences. Furthermore, this Part suggests how Article 5.7 and other science-based provisions of the SPS Agreement can and should be interpreted—in light of the text itself, existing WTO case law, and the anti-protectionist orientation of the trade regime—such that genuine value divergence may be defended. Although such an approach risks widening the avenues for national protectionism under the veil of scientific regulation, careful judicial review that permits only transparent and accountable risk-based regulations would maintain the efficiency of global trade law in the short term, while building institutional legitimacy for the WTO in the long term.

Finally, Part VI argues that GMOs fall into the class of risk situations characterized by both low certainty and low consensus. The science surrounding GMO products and technologies and the developing GMO risk-assessment techniques are relatively immature, leading to substantial areas of uncertainty. At the same time, with numerous international institutions working on issues relating to GMOs, and with public input playing an important role in GMO risk assessment to date, there is also a notable lack of consensus on the topic. With certain provisos, this low certainty and low consensus militate for allowing the EU a temporary safe harbor under Article 5.7.

II. BACKGROUND TO *BIOTECH PRODUCTS*

A. *The Dispute*

International trade in agricultural products accounts for nearly ten percent of the total volume of world trade,[15] and in some parts of the world, production of GM crops has been increasing sharply.[16] At the same time, regulatory polarization in the agricultural biotechnology sector threatens to develop into a drawn-out trade conflict.[17]

The current conflict traces back to choices made in the United States and Europe in the mid-1980s about how to regulate emergent agricultural

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15. WORLD TRADE ORGANIZATION, INTERNATIONAL TRADE STATISTICS 103 (2003), *available at* http://www.wto.org/english/res_e/statis_e/its2003_e/its2003_e.pdf.

16. *See* Donald E. Buckingham & Peter W.B. Phillips, *Hot Potato, Hot Potato: Regulating Products of Biotechnology by the International Community*, 35 J. WORLD TRADE 1, 1 (2001). One pro-biotech nonprofit organization estimated a 15% production increase in GM crops in 2003 alone, with the annual figure of 67.7 million hectares (167.3 acres) worldwide. CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, PREVIEW: GLOBAL STATUS OF COMMERCIALIZED TRANSGENIC CROPS: 2003, *available at* http://www.isaaa.org/kc/CBTNews/press_release/briefs30/-es_b30.pdf (last visited Dec. 12, 2004).

17. *See generally*, THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 44-66, 118-67 (2003); Mark A. Pollack & Gregory C. Shaffer, *Biotechnology: The Next Transatlantic Trade War?*, 23 WASH. Q. 41, 42 (2000).

biotechnologies. Generally speaking, policymakers faced a fundamental choice about the appropriate criteria to use in regulatory decision-making—whether to assess GM risk on the basis of the *products* themselves, or on the basis of the underlying *production processes.* Genetic modification, or genetic engineering, involves "the manipulation of an organism's genetic endowment by introducing or eliminating specific genes through modern molecular biology techniques." [18] Producing a GM crop involves transgenesis, the transfer of genes from one species of plant, animal, or virus into another organism.[19] The "products approach" to regulating GMOs assumes that no untoward risk occurs merely from applying this technology to agricultural production. GMOs are subjected to stricter rules only when the end products are not substantially equivalent to their conventional counterparts. In contrast, the "process approach" rests on the idea that genetic engineering itself may entail novel and unique risks to human health or the environment. Whereas the United States has embraced the products approach to GM agriculture, the European Union and its member states have tended to adopt the more precautionary process approach.[20] In 1990, the European Council adopted the first measure aimed specifically at controlling environmental aspects of GMOs, the process-based Deliberate Release Directive 90/220/EEC.[21]

The inherent tensions between these two divergent regulatory philosophies first produced open conflict in the 1990s, when the "genetic modification of dietary staples such as corn and soybeans . . . caused strong trade frictions" in transatlantic relations.[22] In 1996, farmers in the United States began growing Monsanto's GM soybeans.[23] The new seeds had easily passed regulatory muster in the United States, and the EU authorized their import without segregation or labeling requirements under Directive

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18. BIOTECH LIFE SCIENCE DICTIONARY, *at* http://biotech.icmb.utexas.edu/search/dict-search.phtml?title=engineer; *cf.* European Parliament and Council Directive 2001/18/EC, art. 2.2, 2001 O.J. (L 106) 4 (defining "genetically modified organism" for the purposes of all GMO regulation as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.").

19. FAO GLOSSARY OF BIOTECHNOLOGY FOR FOOD AND AGRICULTURE (2003), *at* http://www.fao.org/biotech/find-formalpha-n.asp.

20. *See, e.g.*, BERNAUER, *supra* note 17, 44-65; Sheila Jasanoff, *Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology*, *in* RESISTANCE TO NEW TECHNOLOGY: NUCLEAR POWER, INFORMATION TECHNOLOGY, AND BIOTECHNOLOGY 311-31 (Martin Bauer ed., 1995); David Vogel, *Ships Passing in the Night: GMOs and the Politics of Risk Regulation in Europe and the United States* (2001), *available at* http://www.insead.fr/events/gmoworkshop/papers/-1_Vogel.pdf.

21. Council Directive 90/220/EEC, art. 8.5, 1990 O.J. (L 117) 15 (on the deliberate release of genetically modified organisms); *see also* BERNAUER, *supra* note 17, at 45.

22. MARSHA A. ECHOLS, FOOD SAFETY AND THE WTO: THE INTERPLAY OF CULTURE, SCIENCE, AND TECHNOLOGY 71 (2001); *see also* J. McNichol & J. Bensedrine, *National Institutional Contexts and Construction of Multilateral Governance Systems: US-EU Struggles Over Labeling Rules for Genetically Modified Food* (2001), *available at* http://www.insead.fr/events/gmoworkshop/papers/-6_Bens_McNichol.pdf. Note, however, that the first GM food marketed in the United States and available for international trade was the Flavr Savr® tomato. This breed was developed by Calgene, a U.S. company, to ripen on the vine until red but not soft by suppressing a key enzyme that breaks down pectin. *See* MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE? THE SCIENCE AND ETHICS OF GENETIC ENGINEERING 132-36 (1996).

23. McNichol & Bensedrine, *supra* note 22, at 7.

90/220/EEC in April 1996.[24] "Almost immediately," however, "the European decision ignited an insurgency against Monsanto's new crops and against GM organisms more generally." [25] Through Eurocommerce (the organization representing European retail, wholesale, and international trade interests) and the European Community of Consumer Cooperatives (Eurocoop), "retailers called very strongly for GMO labeling and segregation of products at the source."[26]

By 1998, public opposition to GM crops and food was growing across Europe, whereas in the United States the issue had caused little such public controversy.[27] European concerns about the risks of genetic modification to human health and to the environment[28] resulted in both increased demand for consumer choice and in an ongoing ethical discourse regarding genetic tampering with nature.[29] In discussions about new imports of GM crops, a number of EU member states expressed concern at the levels of uncertainty surrounding such products and the potential harmful effects of such crops.[30] At a meeting of the EU Council of Environment Ministers in June 1999, France, Denmark, Greece, Italy, and Luxembourg stated that they would block new authorizations of GMOs until Directive 90/220/EEC was revised and legislation had been put in place to cover labeling and traceability. Austria, Belgium, Finland, Germany, The Netherlands, Spain, and Sweden did not go as far, but stated they would take a "thoroughly precautionary approach" in dealing with new GMO authorizations.[31]

As a result of this change in policy, EU member states granted no new approvals of GMOs after 1998, giving rise to the charge of a de facto European moratorium. In the meantime, the EU negotiated new environmental and food-safety rules for GM crops, including: (1) the revised EU Deliberate Release Directive (2001/18/EC) on environmental impacts, which came into force in October 2002; [32] and (2) new EU Regulations 1829/2003 and 1830/2003 concerning the authorization, traceability, and labeling of GMOs and GMO-derived products, which became law in September 2003 and went into force in April 2004.[33] This new regime now requires full traceability, and

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24. Commission Decision 96/281/EC, 1996 O.J. (L 107), *available at* http://www.biosafety.be/GB/Dir.Eur.GB/Market/96-281/96-281.html.

25. McNichol & Bensedrine, *supra* note 22, at 8.

26. *Id*.

27. *See* George Gaskell et al., *Worlds Apart? Public Opinion in Europe and the USA*, *in* BIOTECHNOLOGY: THE MAKING OF A GLOBAL CONTROVERSY 351 (Martin W. Bauer & George Gaskell eds., 2002).

28. *See generally id*.

29. *Id*.

30. GENEWATCH UK, *Briefing no. 25*, THE GM DISPUTE AT THE WTO: FORCING GM FOODS ON EUROPE? (2003), *available at* http://www.genewatch.org/Publications/briefs/brief25.pdf.

31. *Council of Envtl. Ministers, Declarations Regarding the Proposal to Amend Directive 90/220/EEC on Genetically Modified Organisms*, 2194th Council Meeting, June 24-25, 1999, at 24, http://www.eel.nl/council/2194.pdf.

32. European Parliament & Council Directive 2001/18/EC, 2001 O.J. (L 106) 1, *available at* http://www.biosafety.be/PDF/2001_18.pdf (adding the consideration of indirect effects in risk assessment, a requirement for post-market monitoring, and a ten-year time limit on approval).

33. European Parliament & Council Regulation 1829/2003, 2003 O.J. (L 268) 1, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf; European Parliament & Council Regulation 1830/2003, 2003 O.J. (L 268) 24, *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf. For an overview of these regulations and

labels must accompany all GM-derived products, even if the final product lacks foreign DNA or protein.[34]

Under the WTO's dispute resolution process, the United States, Canada, and Argentina first called for consultations concerning Europe's alleged moratorium on GM crop imports on May 14, 2003.[35] According to U.S. trade officials, they believed such a challenge was necessary to discourage other countries, especially those in the developing world, from adopting the European regulatory approach.[36] Talks at the WTO failed almost immediately, and the United States, Canada, and Argentina each formally requested a dispute settlement panel on August 7, 2003.[37]

In their formal requests for a panel, the complaining member states cited three measures that, they argued, adversely affect exports of agricultural and food products in violation of WTO law:[38]

> (1) "a moratorium on the approval of products of agricultural biotechnology" in which "the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system";
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> (2) blockage under existing EC legislation of all "applications for placing [further] biotech products on the market"; and
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> (3) the maintenance by EC member states of "national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC"[39]

Since the revision of the Deliberate Release Directive in late 2002 and the 2004 implementation of the new EU labeling requirements,[40] the European

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an initial assessment of the trade issues they raise, see Joanne Scott, *European Regulation of GMOs and the WTO*, 9 COLUM. J. EUR. L. 213 (2003).

34. GENEWATCH UK, *supra* note 30, at 3.

35. Permanent Mission of the United States, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*; *Request for Consultations by the United States*, WT/DS29/1, G/L/627, G/SPS/GEN/397, G/AG/GEN/60, G/TBT/D/28 (May 20, 2003), *available at* http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#gmos [hereinafter *U.S. Request for Consultations*].

36. *See* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. V. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD 11 (2003), *at* http://pewagbiotech.org/resources/issuebriefs/europe.pdf [hereinafter PEW INITIATIVE, U.S. V. EU].

37. *See supra* note 1.

38. In their initial complaints, the United States, Canada, and Argentina claimed that these measures are inconsistent with particular provisions of several WTO accords: the SPS Agreement; the General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, *reprinted in* 33 I.L.M. 1154 (1994), *available at* http://wto.org/english/docs_e/legal_e/legal_e.htm [hereinafter GATT 1994]; the Agreement on Agriculture, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, *available at* http://wto.org/english/docs_e/legal_e/legal_e.htm; and the Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, *available at* http://wto.org/english/docs_e/legal_e/legal_e.htm. For the provisions of the respective agreements cited in the request for a panel, see PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, U.S. V. EU, *supra* note 36, at 2. In the initial submission to the dispute settlement panel, however, the United States relied exclusively on provisions of the SPS Agreement to make its claims. *First U.S. Submission*, *supra* note 5.

39. *U.S. Request for Consultations*, *supra* note 35.

40. *See supra* notes 32-34 and accompanying text.

Commission has begun to receive new GMO applications. Bt-11 corn gained Commission approval for human consumption (but not planting) in May 2004, the first biotech product to get beyond the Commission since 1998.[41] Yet despite these developments, the complaining members in *Biotech Products* have continued to pursue the case against the alleged moratorium under the SPS Agreement.

B. *The SPS Agreement, Sound Science, and Democracy in Trade Law*

The SPS Agreement has been described as one of the most significant achievements of the Uruguay Round of international trade negotiations that created the WTO.[42] The Agreement explicitly aims for regulatory "harmonization"[43] in the sphere of food safety by requiring that WTO members either adopt international health and safety standards or justify deviant measures with risk-assessment analysis and scientific evidence.[44] At the same time, the text explicitly affirms that members are free to adopt and enforce all measures "necessary to protect human, animal or plant life or health," so long as such measures are not applied in a discriminatory way.[45]

These aspirations are given meaning and teeth in the science-based provisions of the SPS Agreement, which supply judicial mechanisms for distinguishing legitimate safety standards from illegitimate regulatory measures. *Biotech Products* will largely turn on the WTO panel's interpretation of risk assessment, scientific evidence, and the relationship between them under the SPS Agreement. Article 2.2 requires members to ensure that each SPS measure is "based on scientific principles and is not maintained without sufficient scientific evidence."[46] Measures based on existing international standards are deemed to satisfy both this provision and the agreement as a whole.[47] Likewise, Article 3.3 allows members to maintain a higher level of protection than that achieved under existing international standards, but requires "scientific justification" for the extra protection.[48] "Scientific justification" under the SPS Agreement is explained in Article 5, which requires that challenged SPS measures be "based on an assessment . . . of the risks to human, animal, or plant life or health."[49]

The term "risk assessment," in turn, is defined in Annex A as:

> The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and

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41. *European Union Lifts GM Food Ban*, BBC NEWS WORLD EDITION, *available at* http://news.bbc.co.uk/2/hi/europe/3727827.stm (May 19, 2004).

42. Steve Charnovitz, *Improving the Agreement on Sanitary and Phytosanitary Standards*, *in* TRADE, ENVIRONMENT, AND THE MILLENNIUM 171 (Gary P. Sampson & W. Bradnee Chambers eds., 2000).

43. *See* SPS Agreement, *supra* note 4, pmbl. (stating that WTO members desire "to further the use of harmonized sanitary and phytosanitary measures"); *id.* art. 3 (entitled "Harmonization").

44. *Id.* art. 3.3.

45. *Id.* pmbl.

46. *Id*. art. 2.2.

47. *Id*. art. 3.2.

48. *Id*. art. 3.3.

49. *Id*. art. 5.1.

> economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.[50]

This risk assessment also must take into account "available scientific evidence," as well as "relevant processes and production methods, . . . relevant ecological and environmental conditions," and other factors.[51]

Under Article 5.7, member states may legitimately maintain provisional SPS measures without meeting the usual requirements of risk assessment and scientific justification, but only when "relevant scientific evidence is insufficient" and other conditions are met.[52] In the November 2003 *Japanese Apples* decision,[53] the WTO Appellate Body stated that "relevant scientific evidence will be 'insufficient' within the meaning of . . . Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an *adequate* assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement."[54]

Judicial interpretation in the *Biotech Products* case will be critical not only for settling the case at hand, but also for helping to resolve a fundamental tension that lies at the core of the SPS Agreement and is inherent in the above-cited provisions. Using science to enforce harmonization is a more ambitious goal than using it to combat protectionism, but the SPS Agreement text is ambiguous about how the goals of harmonization and nondiscrimination should be balanced. Scholars have debated the proper and legitimate use of science at the WTO since its inception. Applying rigid concepts of sound science to scrutinize member states' regulatory decisions, especially in areas of scientific uncertainty and contested politics, raises problems in terms of cultural autonomy and democratic legitimacy. For this reason, David Wirth has recommended that panels charged with hearing SPS disputes be "highly deferential to the scientific determinations of national authorities," fearing that otherwise panels will demand "excessively high correlation" between the "scientific support and the regulatory measure chosen."[55] In a similar vein, Vern R. Walker has argued that if SPS reviewers were not to exercise deference, the WTO would come to stand for the "World Trans-Science Organization."[56]

Other commentators have even predicted that applying science-based disciplines to international trade law ought to help create a permissive stance toward individual state deviations from international food safety standards.

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50. *Id*. annex A, para. 4.
51. *Id*. art. 5.2.
52. *Id*. art. 5.7.
53. *Japan—Measures Affecting the Importation of Apples*, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter *Japanese Apples, AB*].
54. *Id*. para. 179 (emphasis added).
55. David Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT'L L.J. 817, 857-59 (1994).
56. *See, e.g.*, Walker, *supra* note 6. Alvin Weinberg has defined "trans-science" questions as theoretical questions of fact that can be asked of, but not answered by, science. "Scientists have no monopoly on wisdom where this kind of trans-science is involved; they shall have to accommodate the will of the public and its representatives." Alvin M. Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 222 (1972).

For instance, Jeffery Atik suggested that "the science-based disciplines create new premises for the maintenance of national prerogatives in the face of globalizing regulatory power," reasoning that these disciplines "permit countries to freely make risk assessment, setting standards as high or low as they see fit."[57] He based this conclusion on the fact that contemporary scholars have generally repudiated of the possibility of value-free science. Thus, in his view, science "promises little hope as a source for neutral principles to resolve economic disputes among nations."[58]

Nevertheless, Atik worried that the advent of the SPS Agreement would instigate a "new kind of international discourse" whereby "the validation of certain 'scientific voices' [would] further exacerbate the democracy problem affecting trade pacts generally, and [would] affect internal allocations of power and influence."[59] Indeed, the outcomes of four disputes under the SPS Agreement seem to bear out this prediction. In all four cases—which concerned European restrictions on hormone-treated meats,[60] Australian import restrictions on salmon,[61] a Japanese quarantine on certain agricultural products,[62] and Japanese import restrictions on apples suspected of possible disease contamination[63]—WTO adjudicators have struck down national regulatory measures for failing to meet SPS Agreement requirements.

Scholarly reaction to these decisions has been split. Some have seen judicial review of science-based disciplines as a stable yet flexible institutional solution to science policy disputes. Steve Charnovitz has applauded the WTO's "science-based analysis" under the SPS Agreement, and he laments the lack of similar standards in other WTO agreements.[64] Responding to the notion that the use of science under the SPS Agreement is anti-democratic, Robert Howse has recently claimed that the "SPS [science-based] provisions and their interpretation by the WTO dispute settlement organs . . . can be, and should be, understood not as usurping legitimate democratic choices for stricter regulations, but as enhancing the quality of rational democratic deliberation about risk and its control."[65]

Other scholars argue that sound science standards implement a conception of trade liberalization that moves too far beyond nondiscrimination in trade toward excessive laissez-faire.[66] These critics perceive the use of science in these SPS decisions as "a serious threat to the democratic system of

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57. Jeffery Atik, *Science and International Regulatory Convergence*, 17 NW. J. INT'L L. & BUS. 736, 758 (1996-1997).

58. *Id.* at 758.

59. *Id.* at 758.

60. *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS/48/AB/R (Jan. 16, 1998) [hereinafter *Hormones, AB*].

61. *Australia—Measures Affecting Importation of Salmon*, WT/DS18/AB/R (Oct. 20, 1998) [hereinafter *Salmon, AB*].

62. *Japan—Measures Affecting Agricultural Products*, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter *Japanese Varietals, AB*].

63. *Japanese Apples, AB, supra* note 53.

64. Steve Charnovitz, *Improving the Agreement on Sanitary and Phytosanitary Standards, in* TRADE, ENVIRONMENT, AND THE MILLENNIUM 171, 185 (Gary P. Sampson & W. Bradnee Chambers eds., 1999). Charnovitz points to the absence of any scientific basis for the WTO's requirement that governments issue patents for at least twenty years, or its broad anti-dumping provisions. *Id.* at 185-86.

65. Howse, *Democracy, Science, and Free Trade*, *supra* note 13, at 2330.

66. *See, e.g.*, David M. Driesen, *supra* note 12, at 293-312.

government of the WTO member states in the areas of health and environmental protection."[67] In this view, the WTO has measured different risk-management decisions against a rigid standard of scientific evidence that becomes a sort of procrustean bed: any measures that are unscientifically stringent will be chopped to meet the standard size. (Of course, the analogy is not perfect, as unscientifically *low* risk assessments are favored in a regime of trade liberalization.) Thus, the SPS Agreement's critics see the accord not only as usurping legitimate, culturally specific decision-making, but as evincing an anti-regulation bias in the areas of food and environmental safety.

In *Biotech Products*, the U.S. case against the EU rests to a significant degree on the idea that reversals of regulatory policy regarding GMOs within the EU and its member states illustrate their departure from a fixed body of sound science and constitute "undue delays" under the SPS Agreement.[68] In its submission to the panel, the United States adduced that there were eighteen biotech products with notifications pending under EU Directive 2001/18, all of which had first been submitted under EU Directive 90/220/EEC and had then failed to advance through the approval process.[69] Nine of these products still languished at the European Commission level despite having received favorable initial assessments, the submission points out, and positive opinions from the Scientific Committee for Plants.[70]

The *Biotech Products* case, therefore, represents a crucial moment in trade law and international science policymaking. It may shape not only the trajectory of new agricultural biotechnologies, but also the extent to which the WTO can and should invoke particular conceptions of sound science to legitimate trade products. Specifically, the decision rendered by the dispute settlement panel, and perhaps a subsequent decision by the Appellate Body, will help construct international norms around what sorts of scientific or cultural evidence will justify a precautionary approach to food regulation. More generally, the WTO adjudicatory body will redefine the balance between state and global power in legal, political, and epistemic terms.

III. SOCIAL SCIENCE AND PRACTICAL EXPERIENCE: LESSONS ON SCIENTIFIC RISK ASSESSMENT IN THE GMO CONTEXT

In this Part we explore why it may be wrong to think that science alone can decide questions of adequacy in risk assessment. We present existing social science research on risk assessment in order to demonstrate that it is neither a science nor a single methodology based on sound science. Rather, risk assessment always incorporates policy and value judgments, and it is far from a one-size-fits-all scientific endeavor. Furthermore, public participation has an important role to play in generating reliable and conclusive risk assessments, especially in novel and contested risk situations.

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67. *See, e.g.*, Theofanis Christoforou, *Settlement of Science-Based Trade Disputes in the WTO: A Critical Review of the Developing Case Law in the Face of Scientific Uncertainty*, 8 N.Y.U. ENVTL. L.J. 622, 622-23 (2000) [hereinafter Christoforou, *Settlement of Science-Based Trade Disputes in the WTO*]; *see also supra* note 2.

68. *See First U.S. Submission*, *supra* note 5, at 17, 35, 50.

69. *Id.* at 17.

70. *Id.* at 17.

A. *Risk Assessment Is Contingent on Values and Policy Judgments*

State-of-the-art social science scholarship and recent international regulatory work have emphasized the fact that science and values interact dynamically in the process of risk analysis, even at early stages when risks are first being assessed. As an initial example, it is now widely acknowledged in the policy literature that risk identification (the starting point of all formal risk analysis)[71] is not simply a matter of recognizing a problem, but involves a process of selection and characterization known as "framing."[72] Frames are "principles of selection, emphasis, and presentation composed of little tacit theories about what exists, what happens, and what matters." [73] A policymaker's perceptions and judgments are a function both of empirical observation and of the conceptual lenses used to view the evidence.[74] Framing, it can be seen, is integrally related to the possibility of control. Problems that have been framed with particular causal explanations can also, in principle, be controlled by addressing the perceived causes. At the same time, framing is by its nature also an instrument of exclusion. As some parts of an issue come within a problem frame, other parts are left out as irrelevant, incomprehensible, or uncontrollable.

One way in which framing assumptions and values shape risk assessment is by dictating how different types and sources of scientific uncertainty will be integrated into the risk-identification and risk-evaluation process. A significant amount of scientific uncertainty underlies most risk assessments, and decision-makers must somehow narrow the inevitable knowledge gaps in order to assign risk values to particular objects of study.[75] For example, limiting the probabilistic measure for risk assessment to human mortality tacitly places zero value on protecting non-humans; it also places little value on protecting humans from non-fatal forms of harm. Even the tradeoff between mortality and morbidity (for example, pain associated with illness) involves tacit value judgments. There is no guarantee that such technical practices and relative weighting reflect wider societal values and priorities—or even defensible approximations thereof.

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71. *See, e.g.*, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

72. *See, e.g.*, NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY (1996) [hereinafter NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK]; MARTIN REIN & DONALD A. SCHÖN, FRAME/REFLECTION: TOWARD THE RESOLUTION OF INTRACTABLE POLICY CONTROVERSIES (1994); Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 MINERVA 223, 240-41 (2003) (arguing that frame analysis is a critically important tool of policymaking); Brian Wynne, *Frameworks of Rationality in Risk Management: Towards the Testing of Naïve Sociology*, *in* ENVIRONMENTAL THREATS: PERCEPTION, ANALYSIS, AND MANAGEMENT 33, 33 (Jennifer Brown ed., 1989).

73. TODD GITLIN, THE WHOLE WORLD IS WATCHING: MASS MEDIA IN THE MAKING AND UNMAKING OF THE NEW LEFT 6 (1980).

74. *See generally* GRAHAM T. ALLISON, ESSENCE OF DECISION: EXPLAINING THE CUBAN MISSILE CRISIS 1-9 (1971).

75. *See* Vern R. Walker, *The Myth of Science as a "Neutral Arbiter" for Triggering Precautions*, 26 B.C. INT'L & COMP. L. REV. 197, 205 (2003).

Vern R. Walker has identified different types of scientific uncertainty with which risk assessors must cope.[76] *Conceptual uncertainty* refers to the latitude scientists have in selecting relevant variables, categories, and hypotheses, all of which are shaped by the particular conceptual frame and causal theory employed.[77] Other sources of uncertainty include *sampling decisions*, the *selection of models*, and the *existence of complex causation*.[78] Risk assessors cope with and integrate these sources of uncertainty into their analyses through working assumptions and policy judgments—which are, by definition, non-scientific.[79]

This conception of the dynamic interplay between science and values in risk assessment has recently been taken up in international regulatory discourse. The United Nations Food and Agriculture Organization (FAO), for example, convened an expert panel to examine the proper role of ethics in food risk assessment. In 2002, the panel concluded that risk assessors' choices of data and methods may differ according to the particular values emphasized, leading to divergent estimates of risk.[80] For example:

> (1) Hazard identifications can be based on mortality or morbidity, economic consequence, or other perceived values;[81]
>
> (2) A choice may be made regarding whether hazards are based on "best practice" or "typical use";[82]
>
> (3) Different extrapolation models may be required when moving from animal to human toxicity studies,[83] when shifting from micro-ecosystems to farm-scale agricultural environments, or when extending dose-response curves;[84]
>
> (4) Populations from which exposure estimates are drawn may be selected in different ways;[85] and
>
> (5) The level and type of precaution appropriate to a given situation may vary.[86]

As this FAO report makes clear, choices regarding risk identification, methodological design, sampling, and extrapolation assumptions can involve

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76. Vern R. Walker, *The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers*, 23 CONN. L. REV. 567, 574-624 (1991).

77. *See* Walker, *supra* note 75, at 205 ("For example, the proposition 'inhaling air containing high concentrations of benzene can cause leukaemia in people' asserts a causal relationship between certain inhalation events and the development of leukaemia [sic] . . . . [and] does not refer to other potentially causal factors—for example, genetic, developmental, or environmental factors.").

78. *See id.* at 208-11.

79. *See, e.g.*, CONRAD BRUNK ET AL., VALUE ASSUMPTIONS IN RISK ASSESSMENT (1991); Karsten Klint Jensen & Peter Sandøe, *Food Safety and Ethics: The Interplay Between Science and Values*, 15 J. AGRIC. & ENVTL. ETHICS 245 (2002).

80. Food and Agriculture Organization of the United Nations (FAO), *FAO Expert Consultation on Food Safety: Science and Ethics* (September 2002), ftp://ftp.fao.org/docrep/fao/006/-j0776e00.pdf (last visited Dec. 12, 2004) [hereinafter *FAO Expert Consulation*].

81. *Id.* at 10.

82. *Id.* at 18.

83. *See, e.g.*, L. S. Gold et al., *Extrapolation of Carcinogenicity Between Species: Qualitative and Quantitative Factors*, 12 RISK ANALYSIS 579 (1992).

84. *FAO Expert Consultation*, *supra* note 80, at 18.

85. *Id.* at 18.

86. *Id.* at 18, 21.

substantial policy decisions that must be made prior to, and throughout, the risk-assessment process.

The Codex Alimentarius Commission (Codex),[87] to which the SPS Agreement grants special authority in setting international food safety standards,[88] has itself emphasized the crucial interplay of science and values throughout the risk-analysis process. In July 2003, the Codex adopted principles stating that risk managers must set normative priorities to dictate the thresholds, methodologies, and working assumptions used in conducting risk assessments. By describing risk analysis as "an iterative process" in which "interaction between risk managers and risk assessors is essential for practical application,"[89] the new "working principles for risk analysis" under the Codex recognize the value-laden nature of risk assessment itself. As one commentator has put it, "both science and policy could be better served by recognizing the scientific limits of risk-assessment methods and allowing scientific and policy judgment to interact to resolve unavoidable uncertainties in the decision-making process."[90]

It is important to point out that the WTO has already articulated a sympathetic view toward value-infused scientific policymaking. In *Hormones*, the Appellate Body refused to recognize a legal demarcation between risk assessment (which is based on quantitative analysis of risks) and risk management (which involves judgments of value) in the determination of optimal risk-management strategies.[91] This approach should be supported in the actual practice of risk analysis. It is neither feasible nor appropriate to separate science policymaking into a purely technical phase and a political phase.

B. *Risk Assessment Depends on Political, Social, and Regulatory Contexts*

A significant body of social science comparing the treatment of risk-based decision-making across national political systems demonstrates how differences in issue framing and science policy can lead to systematic transnational variations in the assessment of health, safety, and environmental

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87. According to the Codex website,

> [T]he Commission was created in 1963 by FAO and WHO [the United Nations World Health Organization] to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

http://www.codexalimentarius.net.

88. The Codex's food safety standards and guidelines provide a safe harbor for food regulations challenged under the SPS Agreement, *supra* note 4, pmbl. & arts. 3.1, 3.4. The WTO Appellate Body has interpreted the language "based on" in Article 5.1 of the SPS Agreement ("Members shall ensure that their sanitary or phytosanitary measures are *based on* an assessment, as appropriate to the circumstances, of the risks . . . .") to require the showing of a rational relationship between the Codex standard and the measure adopted by the member state. SPS Agreement, *supra* note 4, art. 5.1.

89. Codex Alimentarius Commission, *Report of the Twenty-Sixth Session* (Rome, June 30-July 7, 2003), at 127, *available at* http://www.codexalimentarius.net/web/session_26.jsp.

90. Ellen K. Silbergeld, *Risk Assessment and Risk Management: An Uneasy Divorce*, *in* ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT 99 (Deborah G. Mayo & Rachelle D. Hollander eds., 1991).

91. *Hormones, AB*, *supra* note 60, para. 181. *See also* Howse, *supra* note 13, at 2343.

risks.[92] This literature establishes that risks are defined, and hence can be meaningfully interpreted and evaluated, only within particular political and cultural contexts. These contexts influence both the initial identification of hazard and subsequent attempts to assess the magnitude, seriousness, and distribution of potential harms. Judgments about the same hazard, based on the same scientific knowledge and evidence, do not always lead to the same estimates of possible harm in different national regulatory systems. As regulatory experience with nuclear power demonstrates, informed citizens in one democratic society may discern unacceptable risks in a technology assessed to be safe by their equally informed counterparts in another democratic society.[93] Nor do regulatory authorities in different national contexts necessarily agree on answers to the threshold question of whether a hazard even exists in a given case.[94] In short, regulatory systems are characterized by particular "cultures of rationality."[95]

Furthermore, different social systems might themselves tolerate different structures and sources of risk. Risks are always created and distributed in social systems, including by the organizations and institutions that are supposed to control the risky activity.[96] As a consequence, the magnitude of the physical risk is, inter alia, a direct function of the qualities and characteristics of the social relations and processes within those systems.

This canonical finding from the social sciences has been borne out in recent cases. For instance, the official report on the *Columbia* space shuttle accident recognized the important role that NASA's history and organizational culture played in its management of the expedition. Indeed, the sources of risk *within the organizational structure* of the space program were emphasized as the investigation proceeded.[97] The Chernobyl disaster likewise demonstrated that the risks associated with nuclear power could no longer be evaluated outside the political and organizational structures in which they operated: even though the machinery of the nuclear reactor operated exactly as expected, unexpected human behavior led to a meltdown of the system.[98]

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92. *See, e.g.*, DAVID VOGEL, NATIONAL STYLES OF REGULATION: ENVIRONMENTAL POLICY IN GREAT BRITAIN AND THE UNITED STATES (1986); Sheila Jasanoff, *Technological Risk and Cultures of Rationality*, *in* NAT'L RESEARCH COUNCIL, INCORPORATING SCIENCE, ECONOMICS, AND SOCIOLOGY IN DEVELOPING SANITARY AND PHYTOSANITARY STANDARDS IN INTERNATIONAL TRADE 65 (2000); Michael Power & Lynn S. McCarty, *A Comparative Analysis of Environmental Risk Assessment/Risk Management Frameworks*, 32 ENVTL. SCI. & TECH. 224A, 231A (1998).

93. *See generally* ANGELA LIBERATORE, THE MANAGEMENT OF UNCERTAINTY: LEARNING FROM CHERNOBYL (1999); DOROTHY NELKIN & MICHAEL POLLACK, THE ATOM BESIEGED: EXTRAPARLIAMENTARY DISSENT IN FRANCE AND GERMANY 107-18 (1981).

94. *See, e.g.*, R. BRICKMAN ET AL., CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES (1985).

95. Jasanoff, *supra* note 92.

96. *See, e.g.*, U. BECK, RISK SOCIETY: TOWARDS A NEW MODERNITY (1992); C. PERROW, NORMAL ACCIDENTS (1984); SOCIAL THEORIES OF RISK (Sheldon Krimsky & Dominic Golding eds., 1992).

97. Columbia Accident Investigation Board, *Final Report Vol. 1*, at 9 (2003), *available at* http://caib.us/news/report/volume1/default.htm ("[T]he Board broadened its mandate at the outset to include an investigation of a wide range of historical and organizational issues [and its] conviction regarding the importance of these factors strengthened as the investigation progressed, with the result that this report, in its findings, conclusions, and recommendations, places as much weight on these causal factors as on the more easily understood and corrected physical cause of the accident.").

98. LIBERATORE, *supra* note 93, at 225-47.

Finally, the European beef scare involving Bovine Spongiform Encephalopathy (BSE) further illustrates how physical risk should not be viewed in isolation. In the BSE case, those giving scientific advice to the British government about the BSE risks in British beef from 1989 to 1995 were assuming that all the relevant regulations would be, and were being, fully enforced. Because the official narratives were so reassuring, however, compliance and enforcement were often incomplete. When the committee advising the government eventually learned of the scale of the enforcement deficit, it revised its assessment of the risks.[99]

The WTO Appellate Body seems to recognize that risk is contingent on particular social contexts. In *Hormones*, it stated that decision-makers should be concerned about "not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also *risk in human societies as they actually exist*, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[100] This ruling effectively encourages WTO member states to consider how risk arises within patterns of human behavior and social practice.

For the purposes of understanding the regulatory conflict at the heart of *Biotech Products*, it is particularly important to consider other areas in which the United States and Europe have diverged in their regulatory cultures. Throughout recent regulatory history, U.S. and European risk regulation has diverged at the initial stage of hazard identification, with different hazards commanding different levels of public concern and attention across national borders. Cancer, for example, has been more of a concern in the United States than in Europe, while risks to forests and countryside have attracted more attention in some European countries.[101] Approaches to assessing similar hazards have also diverged. U.S. agencies on the whole have made greater use than their European counterparts of formal and quantitative methodologies in assessing risks, costs, and benefits for purposes of regulation. Even in instances where U.S. and EU scientists have agreed on the nature of the hazard, they have not always agreed on how the hazard should be managed. In food regulation, for example, many EU nations permit the sale of fresh cheeses made from unpasteurized milk, which are banned from the United States.[102] Finally, a major, long-entrenched trade dispute between the United States and the EU over hormone-treated beef continues to this day. Simple

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99. *See* Lord Phillips of Worth Matravers et al., *The BSE Inquiry: The Report, Findings & Conclusions* (2000), *available at* http://www.bseinquiry.gov.uk/report/volume1/execsum5.htm [hereinafter *BSE Inquiry Report*]. This inquiry was announced in the British Parliament on December 22, 1997, and set up on January 12, 1998, to establish and review the history of the emergence and identification of BSE and the new variant Creutzfeldt-Jakob Disease (CJD) in the United Kingdom, and the action taken in response to them up to March 20, 1996.

100. *Hormones, AB*, *supra* note 60, para. 187 (emphasis added).

101. *See, e.g.*, BRICKMAN, *supra* note 94. A four-country comparison of U.S. and European chemical regulation in the mid-1980s showed that European nations neither worried about carcinogens to the same extent as the United States nor developed comparable programs of testing and risk assessment. *Id.* at 37-48, 203. Note also that despite overall similarities, significant differences exist between the United States and Canada even on seemingly uncontroversial issues such as the proper daily intake of Vitamin C. *See* JOSEPH. H. HULSE, SCIENCE, AGRICULTURE, AND FOOD SECURITY 62 (1995).

102. *See, e.g.*, Lawrence Busch, *Témerité Américaine et Prudence Européenne?*, 339 LA RECHERCHE 19 (2001).

protectionist explanations for such divergences ignore the "long-standing and broader differences in regulatory cultures and food safety laws on either side of the Atlantic."[103]

These systematic variations demonstrate that risk assessment includes not only an objective, science-based analysis of technical evidence but also political understandings about appropriate forms and means of governance, that are conventionally seen as falling within the domain of risk management. Indeed, the very decision to develop or elaborate risk-assessment methods depends on a prior political judgment that a risk worth assessing exists. Thus, chemical risk-assessment procedures developed earlier and went further in the United States than in Europe in the 1970s and 1980s.[104] By contrast, with respect to GM crops and foods, EU member states have arguably taken the lead in evaluating the ecological impacts of commercial GM crop production.

C. *Public Participation Helps Generate Reliable Risk Assessment*

Most experts in science policy have recognized the importance of bringing public deliberation into the process of risk assessment. They acknowledge that such public participation is often crucial for achieving both scientifically and politically reliable results. Scientific risk assessment necessarily involves the prior selection of the objects of analytic attention, reflecting what is collectively valued and thus worthy of possible protection. There is no guarantee that such technical practices of relative weighting reflect wider societal values and priorities, or even defensible approximations of those values, without adequate public consultation.

Indeed, an inclusive procedural approach to risk assessment—as distinguished from the hitherto conventional, objective evaluation of risk probabilities by technical experts—has been proposed and in some cases implemented in regulatory settings within the United States and elsewhere. The U.S. National Research Council (NRC) has been called on to consider how to improve risk analysis for national public health, safety, and environmental regulation.[105] In response, the NRC's *Understanding Risk: Informing Decision in a Democratic Society* concluded that the success of the risk-assessment process depends on:

> deliberations that formulate the decision problem, guide analysis to improve decision participants' understanding, seek the meaning of analytic findings and uncertainties, and improve the ability of interested and affected parties to participate effectively in the risk decision process; and . . . an appropriately diverse participation or representation of the spectrum of interested and affected parties, of decision makers, and of specialists in risk analysis, at each step.[106]

In making the important role of public deliberation and consultation explicit, this report built upon other canonical works by the NRC, one of which concluded that "the first and probably most important step in effective risk

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103. Pollack & Shaffer, *supra* note 17, at 42. *See generally* Jasanoff, *supra* note 20.
104. *See* BRICKMAN, *supra* note 89.
105. *See* NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK, *supra* note 72, at ix.
106. *Id*. at 3.

assessment and risk management is to establish public participation that involves all the stakeholders."[107]

1. *Public Contributions to GMO Risk Assessment in Europe*

Regulatory experience with GMOs has established sound scientific reasons for including the public in the assessment of the risk of novel technologies: public deliberation can help establish priorities, define exactly what is at stake, and suggest crucial avenues of further scientific learning.[108] As the recently released *GM Science Review* in the United Kingdom has concluded, "the provision of robust scientific advice to policy making, depends not only on the involvement of a wide range of specialist disciplines, but also on in-depth critical engagement with public values and concerns."[109]

The years of the GMO "moratorium" in the EU created the opportunity for informational triangulation involving publics, experts, and regulators across EU member states. It ultimately provided important feedback about the sources of risk in the GM context.

For example, the public's perceived need for larger and locally based field trials on the ecological effects of GMOs led to the so-called Farm Scale Evaluations (FSEs) in the United Kingdom. Begun in 1998 and only recently completed, the FSEs have made a very important contribution to knowledge about the ecological impacts of growing GM crops outside the greenhouse.[110] The FSEs involved four years of field trials carried out in 273 fields across Britain, at a cost of £5.9 million and involving more than 100 scientists.[111] The trials' primary purpose was to investigate the ecological impacts of the distinctive herbicide regimes associated with four herbicide-resistant GM

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107. NAT'L RESEARCH COUNCIL, BUILDING CONSENSUS THROUGH RISK ASSESSMENT AND MANAGEMENT OF THE DEPARTMENT OF ENERGY'S ENVIRONMENTAL REMEDIATION PROGRAM 26 (1994). Along these lines, this report also states that "risk assessments concerning possible future outcomes at DOE [the U.S. Department of Energy] weapons-complex sites . . . must involve the public (in its many guises) in the whole process, including the planning of the process and the definition of the scope of risk assessment." *Id.* at 3. *See also* NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 267 (1994) (stating that in assessing the risk of hazardous air pollutants, the Environmental Protection Agency "should provide a process for public review and comment with a requirement that it respond, so that outside parties can be assured that the methods used in risk assessments are scientifically justifiable").

108. *See, e.g.*, NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002); GM Science Review Panel, *GM Science Review, Second Edition: An Open Review of the Science Relevant to GM Crops and Food Based on Interests and Concerns of the Public* § 1 (2004), http://www.gmsciencedebate.org.uk/report/default.htm#second (last visited Dec. 12, 2004); Life-Sciences and biotechnology—A Strategy for Europe, Commission Communication to the Council, the European Parliament, the Economic and Social Committee, and the Committee of the Regions, COM(02)27 final at 4, *available at* http://europa.eu.int/eurlex/en/com/cnc/-2002/com2002_0027en01.pdf.

109. GM Science Review Panel, *supra* note 108, at 12.

110. *See, e.g.*, L.G. Firbank et al., *An Introduction to the Farm-Scale Evaluations of Genetically Modified Herbicide-Tolerant Crops*, 40 J. APPLIED ECOLOGY 2-16 (2003); *see also* Bayer CropScience, *Farm Scale Evaluations of GM Crops: Answers to Some Frequently Asked Questions*, *at* http://www.bcsbioscience.co.uk/pdfs/FAQs%20on%20the%20FSEs%20-%20October%2003.pdf (last visited Dec. 12, 2004).

111. U.K. DEP'T FOR ENV'T, FOOD AND RURAL AFFAIRS, GM CROPS: EFFECTS ON FARMLAND WILDLIFE (2003), http://www.defra.gov.uk/environment/gm/fse.

crops—beet, maize, and spring and winter oil-seed rape. On receiving the results, U.K. Environment Secretary Margaret Beckett stated:

> The Government commissioned this research—the biggest GM crop trials anywhere in the world—to address a specific gap in our knowledge. The trials demonstrate the precautionary approach which the Government has taken on GM crops from the start. The results will be considered as part of the comprehensive risk assessment undertaken for every GM crop.[112]

Findings from these recent FSE studies extend the GM-related science base significantly.[113] For spring rape and beet, a substantial decrease in weed and insect biodiversity was found (compared with equivalent conventional crop-management regimes) with run-on indirect food chain implications for insects including butterflies and bees, birds, and other creatures.[114] One follow-up study established the inevitability of major cross-pollination between GM and wild rape in the English countryside, in the event of no steps being taken to block hybridization genetically.[115]

Beyond providing feedback about particular crops, the FSE trials ultimately led to the creation of the Agriculture and Environment Biotechnology Commission (AEBC) in 2000,[116] with responsibility for advising the British government on strategic issues at the intersection of public values and scientific knowledge. The trials also helped spur a formal three-pronged process of public dialogue in 2003. This process involved a national public debate, a systematic review of the state of GM science,[117] and

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112. U.K. DEP'T FOR ENV'T, FOOD AND RURAL AFFAIRS, FARM SCALE EVALUATION RESULTS—IMPORTANT NEW EVIDENCE ON GM CROPS (2003), http://www.defra.gov.uk/news/-2003/031016a.htm.

113. For the full results of the farm-scale evaluations, see 358 PHIL. TRANSACTIONS ROYAL SOC'Y: BIOLOGICAL SCI. (2003), *available at* http://www.pubs.royalsoc.ac.uk/phil_bio/news/-fse_toc.html.

114. *See* D.R. Brooks et al., *Invertebrate Responses to the Management of Genetically Modified Herbicide-Tolerant and Conventional Spring Crops. I. Soil-Surface-Active Invertebrates*, 358 PHIL. TRANSACTIONS ROYAL SOC'Y: BIOLOGICAL SCI. 1847 (2003); A.J. Haughton et al., *Invertebrate Responses to the Management of Genetically Modified Herbicide Tolerant and Conventional Spring Crops. II. Within-Field Epigeal and Aerial Arthropods*, 358 PHIL. TRANSACTIONS ROYAL SOC'Y: BIOLOGICAL SCI. 1863 (2003); D.B. Roy et al., *Invertebrates and Vegetation of Field Margins Adjacent to Crops Subject to Contrasting Herbicide Regimes in the Farm Scale Evaluations of Genetically Modified Herbicide-Tolerant Crops*, 358 PHIL. TRANSACTIONS ROYAL SOC'Y: BIOLOGICAL SCI. 1879 (2003).

115. M.J. Wilkinson et. al, *Hybridization Between* Brassica Napus *and* Brassica Rapa *on a National Scale in the United Kingdom*, 302 SCIENCE 401, 401-03 (Oct. 17, 2003).

116. *See Agriculture and Environment Biotechnology Commission*, http://www.aebc.gov.uk.

117. *GM Science Review* underscores the importance of public review in securing robust and legitimate assessment of uncertainties. Over time, expert identification of areas of scientific uncertainty and concern converged with expressed public concern over such matters as unknown environmental and health consequences. *See GM Science Review*, *supra* note 108; *see also* Ambuj Sagar et al., *The Tragedy of the Commoners: Biotechnology and Its Publics*, 18 NATURE BIOTECH. 2, 4 (2000) (arguing that governing institutions and regulators "stand to gain greater acceptance only by soliciting public input, implementing policies in a transparent and democratically representative fashion, and demonstrating their responsiveness to concerns raised by scientific experts, other organizations, and citizens and consumers around the world"). Processes such as these have enriched understanding of both the scientific and the societal dimensions of GM crop developments. *See* Agriculture and Environment Biotechnology Commission (AEBC), *GM Crops?: Coexistence and Liability* (2003), http://www.aebc.gov.uk/aebc/reports/coexistence_liability.shtml. They have also informed AEBC's recommendations for new statutory guidelines aimed at guaranteeing acceptable levels of coexistence of GM and non-GM crops and appropriate liability regimes. *See id.*

an assessment of the potential national economic implications of possible GM commercialization.

The FSE trials are one important example of the frequent mismatch between official risk assessment and public attitudes with respect to the framing of risk issues to be addressed. These trials also illustrate how public participation can inform scientific risk assessment and provide procedural improvements to general risk-assessment systems.

2. *Lack of Public Participation in U.S. GMO Risk Assessment*

In contrast to Europe, where time has been allocated for public inputs that have helped frame GMO risk assessment in ways that respond to public concerns and values, the United States has implemented a regulatory approach without engaging with the public regarding the likely risks associated with GM technologies. Instead, the Unites States has relied almost exclusively on post-market oversight.[118] Indeed, even though the United States has been doing field trials for some fifteen years, it has neither engaged in any post-harvest testing of GM crops nor conducted any systematic testing of the ingestion of foods produced through genetic modification.[119]

A more inclusive and rigorous risk-assessment process from the outset may have spared the United States two of its own regulatory reversals, concerning StarLink and Prodigene, which occurred during the very years of the alleged EU moratorium. Both reversals resulted from human behaviors that the initial risk assessments had failed to anticipate. As one legal commentator has noted, industry failures and changes in the regulatory approach to GMOs in the United States during this period produced a credibility problem among U.S. consumers.[120]

The first case involved the maize hybrid called StarLink. StarLink contained the Cry9c protein from *Bacillus thuringiensis* that was licensed to the Aventis CropScience Corporation. Under U.S. law, StarLink was at once a crop, a food, and a pesticide, requiring risk assessments by three separate agencies: the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).[121]

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118. Michael R. Taylor & Jody S. Tick, *Post-Market Oversight of Biotech Foods: Is the System Prepared?* (2003), *at* http://pewagbiotech.org/research/postmarket/ (raising questions about how the U.S. regulatory system works and whether it is prepared for the challenges it will face in the future). *See also* Pew Initiative on Food and Biotechnology, About the Pew Initiative on Food and Biotechnology, at http://pewagbiotech.org/about:

> The Pew Initiative on Food and Biotechnology was established in 2001 to be an independent and objective source of credible information on agricultural biotechnology for the public, media and policymakers. Funded through a grant from The Pew Charitable Trusts to the University of Richmond, the Initiative advocates neither for, nor against, agricultural biotechnology. Instead, the Initiative is committed to providing information and encouraging debate and dialogue so that consumers and policymakers can make their own informed decisions.

119. There is no available evidence as to why this is the case.

120. Rebecca M. Bratspies, *Bridging the Genetic Divide: Confidence-Building Measures for Genetically-Modified Crops*, 44 JURIMETRICS J. 63, 74 (2003) (proposing measures aimed at building the trust of consumers with regard to environmental concerns raised by GMOs).

121. Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,176 (Nov. 14, 1985) (acknowledging that "new scientific issues arising frequently could be of concern to several [federal

As a result of concerns raised about StarLink's potential allergenicity in humans, a 1998 ad hoc committee with representatives from all three agencies determined that a "split registration" would be granted: the maize was to be used in animal feed but not in human food.[122]

In September 2000, StarLink DNA was discovered in a number of processed food products.[123] Aventis, the USDA, the EPA, grain elevator operators, food processors, and grocers became involved in a massive and costly recall. In light of these events, the EPA called two Scientific Advisory Panel (SAP) meetings in November 2000 and July 2001 to discuss the evidence concerning the impact of StarLink on human health. The panels concluded that there was a medium probability that the Cry9c protein was an allergen, and a low probability that it would cause an allergic reaction. Nevertheless, the July SAP asserted that, while reducing the probability, the evidence presented to the SAPs did not "eliminate StarLink Cry9c protein as a potential cause of allergenic reactions."[124] The EPA ultimately rejected Aventis' request for a tolerance exemption. As a result of this incident, the U.S. government decided to no longer permit split registrations. This represented a marked change in risk assessment of products that fall into two or more categories, such as food and feed.

The Prodigene case that emerged in October 2002 marked the second time that U.S. risk-assessment procedures were reviewed and revised after further experience. In this instance, the Prodigene Corporation received permission to engage in a field test of a GM maize plant containing an insulin precursor, Trypsin.[125] The maize was planted in an unmarked field in rural Iowa and was to be used to produce pharmaceutical products. Part of the agreement with the USDA, which approved the field trials, was that the field would be quarantined the following year so as to remove any "volunteer" plants.[126]

In fact, the fields were not adequately isolated and an undetermined quantity of GM maize was harvested along with about 500,000 bushels of

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regulatory] agencies," and authorizing the new Biotechnology Science Coordinating Committee to "receive information regarding the scientific aspects of biotechnology applications submitted to federal research and regulatory agencies for approval," in order to "conduct analyses of broad scientific issues that extend beyond those of any one agency and develop generic scientific recommendations that can be applied to similar, recurring applications."); *see also* Envtl. Prot. Agency, Introduction to Biotechnology for Pesticides, http://www.epa.gov/oppbppd1/biopesticides/regtools/biotech-reg-prod.htm#I ("As part of a coordinated federal framework for biotechnology, biotech crops undergo a food safety and environmental approval process by the EPA, . . . FDA and the . . . USDA.").

122. *See* Alejandro E. Segarra & Jean M. Rawson, *StarLink Corn Controversy: Background*, Cong. Res. Serv. Rep. RS20732 (Jan. 10, 2001), *available at* http://www.ncseonline.org/nle/crsreports/-agriculture/ag-101.cfm.

123. William Lin et al., *StarLink: Where No Cry9C Corn Should Have Gone Before*, CHOICES, Winter 2001-2002, at 31.

124. FIFRA SCI. ADVISORY PANEL, EPA, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: ASSESSMENT OF ADDITIONAL SCIENTIFIC INFORMATION CONCERNING STARLINK™ CORN 10 (2000), *available at* http://www.epa.gov/scipoly/sap/-2000/november/one.pdf.

125. Bill Hord, *The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination*, OMAHA WORLD HERALD, Jan. 19, 2003, at 1(d).

126. When plants (usually from the previous season) that do not belong in the field emerge, e.g., a corn stalk in a soybean field, they are called "volunteers."

soybeans the following season. The USDA learned of the problem and had the soybeans destroyed, thereby removing all potential for harm—but at a considerable cost. In addition, the U.S. Grocery Manufacturers Association and the National Food Processors Association raised their concerns that future such incidents be avoided.[127] In light of this mishap, the USDA decided to review its risk-assessment process, requiring that future trials be conducted under far more controlled conditions. This case drives home the point that in conducting assessment of the risks posed by new technologies, one cannot ignore the organizational structure in which these technologies are managed and overseen.

Finally, a case emerged in September 2004 that highlights how U.S. regulators have begun to solicit public input in the consideration of particular biotech products, and how this change has in turn generated both new scientific studies and new regulatory approaches to risk assessment. After hearing public comments in March 2004 concerning the release of a strain of bentgrass that had been genetically modified to resist Roundup herbicide, EPA scientists conducted a study of the gene flow from the grass pollen to wild strains in surrounding areas.[128] The resulting study found that GM bentgrass pollinated test plants of the same species growing at least as far as thirteen miles downwind.[129] These findings exacerbated previously stated concerns of the federal Forest Service and the Bureau of Land Management that the grass could spread to areas where it is not wanted, or transfer its herbicidal resistance to other plant species, creating superweeds immune to weed killers.[130] This result has led to demands by the mainstream U.S. press to conduct "a careful reassessment of how such plants are regulated" because of the need to "ensure that the genes from genetically engineered plants do not escape into the wild and wreak havoc in natural ecosystems."[131] As a result of the public comments and this latest study, the USDA decided to produce a full environmental impact assessment, which is estimated to take a year or more.[132]

D. *Risk Situations Lie on a Certainty-Consensus Continuum*

Risk situations themselves vary greatly. In order to capture this diversity, we propose that risk situations should be reconceptualized as lying on a continuum from *low certainty* and *low consensus* to *high certainty* and *high consensus*. At one extreme, cases are characterized by *high certainty* with respect to the knowledge base to be relied upon and the analytic methods to be applied, as well as *high consensus* with respect to the framing of the scientific issues to be addressed and the values to be protected through public policy. Such a characterization is not unprecedented; it accords well with

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127. Stephanie Simon, *Fearing a Field of Genes*, L.A. TIMES, Dec. 23, 2002, at 1.

128. Andrew Pollack, *Genes From Engineered Grass Spread for Miles, Study Finds*, N.Y. TIMES, Sept. 21, 2004, at A1.

129. Envtl. Prot. Agency, EPA Provides Methods for Studying Genetically Modified Pollen, http://www.epa.gov/ord/htm/bentgrass.htm.

130. Pollack, *supra* note 128.

131. Editorial, *The Travels of a Bioengineered Gene*, N.Y. TIMES, Sept. 30, 2004, at A28.

132. Pollack, *supra* note 128.

previous suggested approaches to evaluating scientific uncertainty in science policy decision-making. Environmental scholarship, for instance, has discussed how uncertainty "may be thought of as a continuum ranging from zero for certain information to intermediate levels for information with statistical uncertainty and known probabilities (risk) to high levels for information with true uncertainty or indeterminacy."[133] Our continuum builds on this work, but it acknowledges consensus on values and methods as a crucial component in any taxonomy of risk situations.

A good example of such a high certainty–high consensus area might be the risks known to be associated with smoking cigarettes. In such situations, the ratio of reliable and accepted science to science policy and value judgment in any risk assessment will be fairly high. With regard to cigarettes, many international epidemiological and toxicological studies have come to similar conclusions about the potential of smoking to cause cancer and heart disease. There are accepted ways of studying health effects in living people. As a result, the body of scientific evidence itself may provide a more reliable basis on which to judge the legitimacy of regulatory interventions.

Other risk situations, by contrast will be characterized by *low certainty* and *low consensus* on such matters. In these situations, little epidemiological evidence might be available, or there may be a limited number of animal toxicological studies, necessitating choices concerning the proper extrapolation values. There may be underlying disagreement about what the potential harm consists of, or how the harm should be framed, and a more limited array of scientific studies investigating different dimensions of the problem.

Two important corollaries emerge from this framework. First, risk-based knowledge tends to move through the certainty-consensus continuum over time. For example, although the risks of smoking for the smoker have clearly been in the high-certainty, high-consensus range for some time, health risks due to second-hand smoke have only recently begun to be studied and established. Likewise, over the course of twenty years, international scientific consensus began to emerge concerning the anthropogenic effects on global climate change and the associated risks of loading the atmosphere with carbon.[134] Risk situations that are novel, such as those involved in the introduction of new technologies, can therefore be expected to begin as low-certainty, low-consensus risk situations but potentially migrate into higher levels of agreement over time.

Second, in conditions of low certainty and low consensus about the values and methodologies underlying risk assessment, public input assumes even greater social and scientific importance. From the perspective of democratic legitimacy, public input will be more important in these situations

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133. Robert Constanza & Laura Cornwell, *The 4P Approach to Dealing with Scientific Uncertainty*, ENV'T, Nov. 1992, at 13-14; *cf.* Silvio Funtowicz & Jerome R. Ravetz, *Three Types of Risk Assessment and the Emergence of Post-Normal Science*, *in* SOCIAL THEORIES OF RISK, *supra* note 96, at 251 (setting out a matrix of three types of "problem solving strategies" along axes of "Decision Stakes" and "Systems Uncertainty").

134. CLIMATE CHANGE 2001: THE SCIENTIFIC BASIS 10-12 (J. T. Houghton et al. eds., 2001) [hereinafter CLIMATE CHANGE 2001].

because greater political discretion is exerted. From the perspective of utilitarian benefit, public input will help frame risk in ways that make regulation more relevant and effective. From the perspective of science, public input can help present the relevant questions that need to be answered before risks are assumed.

IV. RE-ORIENTING THE SPS AGREEMENT: EMBEDDED LIBERALISM AND RISK ASSESSMENT

The insights described above suggest that the science used in risk assessment is not a body of knowledge fixed at a particular moment in time through a universally valid expert calculus. Nor is it a body of knowledge arising in isolation from political and cultural values and perfectly transferable across regulatory systems. Rather, sound science in the regulatory sphere needs to be understood as being shaped by the normative priorities, institutional cultures, and collective experiences that influence the framing of risk itself. The temptation will be to invoke a singular conception of sound science in order to achieve harmonization. But, as we have illustrated in the preceding discussion, risk analyses and the standards they support "incorporate not only 'objective' assessments of technical evidence but also collective, often tacit, cultural judgments about the appropriateness of particular social roles, power relationships," public attitudes, and regulatory styles.[135] Risk assessments and their integration into regulatory policies are value-laden processes, though the values involved often remain implicit.

These reminders of the practical applications of science in risk analysis highlight the problems faced by WTO dispute settlement panels when determining the adequacy of risk assessment and sufficiency of the evidence presented to justify a given scientific regulation. How can a panel usefully evaluate whether the available science supports a given state's policy judgment or precautionary environmental measure without interfering with cultural self-determination, when experience shows that scientific uptake is an important domain of culture and values? How can the goals of international regulatory harmonization and reducing disguised restrictions on trade be accomplished without trampling upon the value-laden choices of democratically accountable WTO member states?

In an age of anxiety about democratic accountability in international lawmaking, this question emerges with special force. Real problems of political legitimacy will result if WTO panels impose a particular science policy on members under the guise of merely demanding sound science. As

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135. Sheila Jasanoff, *Harmonization—The Politics of Reasoning Together*, *in* THE POLITICS OF CHEMICAL RISK 173, 173 (Roland Bal & Willem Halffman eds., 1998). Hazardous-waste risk analysis and management is an important illustrative case here. Even within the EC in the 1980s, problems in international standardization arose. The EC's institutional approach to scientific and technical risk knowledge assumed that a purely technical negotiation of common scientific criteria could harmonize member states' varying technical risk standards for the classification and treatment of hazardous wastes. In fact, however, incommensurable technical criteria reflected particular institutional and cultural realities, implying the need for more complex forms of negotiation and convergence among the waste-trading EC member states. *See* Duncan Laurence & Brian Wynne, *Transporting Waste in the European Community: A Free Market?*, ENV'T, July-Aug. 1989, at 12.

numerous trade commentators have pointed out, the WTO already suffers from a democratic deficit.[136] This deficit is perhaps most widely discussed in connection with the exclusion of ordinary citizens from the ministerial negotiating process, but it also pertains to the judicial use of interpretive discretion in ways that order and enforce the normative priorities of the trading regime in non-trade domains such as health and the environment.[137] The danger of such broad judicial reach is especially acute in low-certainty, low-consensus situations, where public input and values are needed to frame problems and thereby trigger the very scientific questions necessary to produce adequate and credible risk assessments.

Thus, it is naïve to try to use the SPS Agreement to move beyond disciplining protectionism toward disciplining those national regulations that might be deemed unnecessary by the lights of a singular and supposedly universal "sound science." This move would be not only unrealistic with respect to the realities of regulatory science, but also inconsistent with the original goals of the international trading regime. It is important to remember that the structure of the world trading system embodies the idea that free trade cannot be pursued at the expense of other important social goals, and that individual state approaches to social problems should be tolerated within a system of "embedded liberalism."[138] From the beginning, the GATT's goal of trade liberalization was embedded within a political commitment to the interventionist welfare state shared by the major trading nations of that era. The major players had a progressive political and social vision for the trading system that included mutual respect for the diverse avenues through which nations chose to implement that shared vision.[139] The same sort of embedded approach is required when the new trading regime approaches risk-based decision-making and the use of science. Furthermore, it is consistent with the SPS Agreement's stated goals that harmonization be promoted "without requiring Members to change their appropriate level of protection of human, animal, or plant life or health."[140]

V. RETHINKING JUDICIAL REVIEW OF SCIENCE UNDER THE SPS AGREEMENT

The theoretical models of risk and risk assessment that we have just outlined carry two significant implications for guiding judicial review of risk-based decision-making at the WTO. First, when interpreting the SPS Agreement, judges should steer away from adopting any member state's conclusions as scientific truths; they should instead act more as an administrative tribunal searching for transparency and procedural adequacy. Although court-appointed scientific experts may aid the process, the scope of analysis should include expert opinion about the interaction of values and

136. *See supra* note 2.

137. *Id.*

138. *See* John G. Ruggie, *Embedded Liberalism and the Postwar Economic Regimes*, *in* CONSTRUCTING THE WORLD POLITY: ESSAYS ON INTERNATIONAL INSTITUTIONALIZATION 62 (1998).

139. *See, e.g.*, Robert Howse, *From Politics to Technocracy—And Back Again: The Fate of the Multilateral Trading Regime*, 96 AM. J. INT'L L. 94, 94-101 (2002).

140. *See* SPS Agreement, *supra* note 4, pmbl., para. 6.

science in the regulatory process. Such an administrative role for WTO adjudicators would help preserve space for public participation at the member-state level. Second, public participation should be considered as a valid and crucial part of the risk-assessment process under the SPS Agreement, particularly in situations of low-certainty, low-consensus technologies. Recognizing public participation as a legitimate input to risk assessment would help to foster a more robust understanding of the scientific and non-scientific risks actually faced by member states and would help to build the political legitimacy of the WTO itself.

From the perspective of promoting democratic self-determination with regard to risk-based regulation, the advantages of implementing these two ideas are clear enough. Yet how may these ideas be plausibly introduced into the SPS Agreement, and in such a way that does not undermine its anti-protectionist tools? We will answer these questions by focusing on standards of review, the use of experts, and Article 5.7 of the SPS Agreement.

A. *Standard of Review*

As noted above, the WTO faces the dual goals of ferreting out protectionism while protecting legitimate cultural differences that may impact scientific decision-making. These two objectives can be reduced to one basic principle of nondiscrimination: so long as member states are not treating foreign products in a discriminatory manner, WTO judges can have some assurance that the cultural differences are legitimate. Therefore, the review conducted by WTO judges as they assess the facts and the law under the SPS Agreement should be aimed at enforcing the transparent, accountable, and reasoned use of science and risk assessment. Focusing on proper and legitimate procedures for the integration of science and policy will allow the WTO to assess whether discriminatory practices are, in fact, at play. Dispute settlement panels should not function as adjudicatory bodies reviewing the substantive scientific details underlying the parties' risk assessments. Rather, a panel's appropriate role in evaluating the arguments of the parties is akin to that of an administrative tribunal reviewing the adequacy of executive decision-making processes. If adopted, this understanding of the proper judicial role would facilitate an urgently needed international discourse on rational decision-making in the regulatory sphere.[141]

The judicial standard of review established by the WTO's Dispute Settlement Understanding (DSU) and interpreted by previous Appellate Body opinions supports this interpretation of the panel's review function. The "objective assessment of the facts" set out by the DSU falls between total deference and a de novo standard of review.[142] The Appellate Body in

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141. A related conception of the panel's proper role has been argued by others. *See* Howse, *supra* note 13, at 2330 ("SPS provisions and their interpretation by the WTO dispute settlement organs . . . can be, and should be, understood not as usurping legitimate democratic choices for stricter regulations, but as enhancing the quality of rational democratic deliberation about risk and its control").

142. DSU Article 11, "Function of Panels," states:

> The function of panels is to assist the DSB [Dispute Settlement Body] in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective

Hormones made clear that panels should be concerned about their own institutional competence in matters of science policy, stating that "[m]any panels have in the past refused to undertake *de novo* review, wisely, since under current practice and systems, they are in any case poorly suited to engage in such a review."[143] However, the opinion also stated that "total deference to the findings of the national authorities . . . could not ensure an objective assessment as foreseen by Article 11 of the DSU."[144]

The "objective assessment of the facts" standard ought to be applied to the question of whether member states followed a legitimate process of risk analysis, including whether their use of scientific evidence was plausible and whether the member state actively sought or is seeking public input in the areas where the scientific evidence is contested or insufficient. The crucial question is how, exactly, WTO judges are to ascertain whether the facts have been objectively assessed in the context of science-based decision-making. In particular, how are legitimate expressions of political values differentiated from illegitimate protectionism?

Here it is crucial that SPS legitimacy be effectuated by transparency. Enforced transparency with respect to the regulatory uses of science will make protectionist measures much harder to justify, but will do so without interfering with national sovereignty. To this end, WTO panels should make objective findings regarding member states' use of appropriate inputs into policymaking. Were the required elements of risk assessment taken into account? Was the available scientific evidence considered? Were public deliberations conducted, and were the results factored in? Were decisions clearly reasoned? Judges should also investigate whether members made a record of considerations they viewed as germane in their risk assessments, including their identification of the relevant technical issues and values at stake. These questions should be familiar to administrative lawyers and jurists alike, and will help in distinguishing protectionism from sanctionable science policies with trade-distorting effects. This line of review would have the further benefit of promoting public discourse about risk assessment at the member state level, which, as noted above, is important to scientific and political reliability.

It is important to be clear that we are not proposing that WTO panels simply defer in their fact-finding to any member that cries the defense of

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> assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements. Panels should consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution.

Understanding on Rules and Procedures Governing the Settlement of Disputes, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 11, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 33(1), *reprinted in* 33 I.L.M. 112, 120 (1994), *available at* http://www.wto.org/english/tratop_e/dsu_e.htm. In *Hormones*, the Appellate Body explicitly rejected de novo review of the scientific knowledge underpinning a decision, stating that "activities [of the Panel] are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither *de novo* review as such, nor total deference, but rather the objective assessment of the facts." *Hormones, AB, supra* note 60, para. 117.

143. *Id.*

144. *Id*. (citing *United States—Restrictions on Imports of Cotton and Man-Made Fibre Underwear*, WT/DS24/R (Nov. 8, 1996), para. 7.10).

science. Such complete deference would render the SPS Agreement ineffective as a trade instrument, and might even "perversely encourage global fragmentation in science by encouraging trade protectionist interests to co-opt the academy." [145] The judicial posture proposed here preserves the adjudicator's ability to ferret out protectionism without enforcing a procrustean global science policy. In scrutinizing members' regulatory decisions in light of the criteria suggested above, judges should be able to distinguish legitimate forms of local regulatory sensibility from protectionism by requiring reasoned decision-making that takes the presence, absence, and substance of scientific evidence and expressed cultural values into account.

Our suggestion is that judges should adopt a role akin to the famous "hard look" approach to science-based decision-making favored by Judge Harold Leventhal on the D.C. Circuit Court of Appeals in the 1970s. At that time, "[U.S. federal c]ourts demonstrated a willingness to probe the scientific underpinnings of administrative actions and to demand reasoned explanations for agency interpretations of controversial data."[146] Just how "hard" a look should be given to agency decision-making in technical areas remained an active topic of debate.[147] The U.S. Supreme Court adopted the hard look approach in *Citizens to Preserve Overton Park v. Volpe*,[148] in which the Court was asked to review a U.S. Department of Transportation decision to release funds for the construction of a highway through a city park in Memphis, Tennessee. The Court developed an approach to review that fell short of de novo review, and yet still subjected agency decision-making to a "substantial inquiry."[149] Such an inquiry, the Court said, demanded "a thorough, probing, in-depth review" of agency decision-making, but one capable of ensuring that "the decision was based on a consideration of the relevant factors and whether there [had been] a clear error of judgment."[150] Finally, the Court made clear that "although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency."[151] A key point for the analysis here is that U.S. courts inquire into not only the scientific evidence used by an agency, but also into the public hearings and comments that were a relevant factor in the agency's decision. If implemented in the WTO context, such a hard look approach could generate a more vigorous ethos of accountability that would minimize member states' strategic uses of scientific uncertainty for protectionist gains. It would also recognize the important role of public participation in establishing the platform of facts upon which agency decisions must rest.

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145. Walker, *supra* note 6, at 280.

146. SHEILA JASANOFF, SCIENCE AT THE BAR 70 (1995).

147. Judges Bazelon and Leventhal on the D.C. Circuit, for example, became the spokesmen for two different approaches to the problem of judicial review. *Compare* David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817 (1977), *with* Harold Leventhal, *Environmental Decision-making and the Role of the Courts*, 122 U. PA. L. REV. 509 (1974).

148. 401 U.S. 402, 415-17 (1971).

149. *Id.* at 415.

150. *Id.*

151. *Id.*

In sum, we support an understanding of the judicial role in the SPS context that is procedural in orientation and tends to be sensitive to localized science policy decision-making. This posture is especially important in regulatory areas that address risk situations characterized by low certainty and low consensus. A number of trade scholars share this general conception of a dispute settlement panel's proper role,[152] which stays within the DSU language and its existing interpretations, and preserves the power to strike down protectionist regulations.

B. *The Role of Experts*

The key to implementing any review model under the SPS Agreement will be the appropriate selection and use of experts. The role of scientific experts in advising courts and regulators use scientific experts was a major issue in the technical decisions made during the 1970s in the United States,[153] and it remains a lively jurisprudential and policy debate today.[154] In prior cases under the SPS Agreement, the panels sought advice from experts in relevant sciences and risk-assessment fields to help guide their decisions.[155] The language of the text leaves to the discretion of the panel many procedural and substantive questions about the choice of experts, the number of experts, whether they will be consulted individually or as a group, and what their precise role will be.[156]

The selection and use of salient expert knowledge for the review of risk-based regulation are more than routine matters. As discussed above, established bodies of scientific expertise may assume particular selective framings of the salient questions that may be incompatible with those of other, equally qualified and relevant disciplinary subcultures. Disciplinary framings

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152. *See, e.g.*, Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. OF TRANSNAT'L L. 323 (2002); Howse, *supra* note 13, at 2357 (arguing that the science-based disciplines of the SPS Agreement "can be, and should be, understood not as usurping legitimate democratic choices for stricter regulations, but as enhancing the quality of rational democratic deliberation about risk and its control"); Walker, *supra* note 6, at 277-96; Wirth, *supra* note 55, at 857-59.

153. *See, e.g.*, JASANOFF, *supra* note 146, at 42-92.

154. *See, e.g.*, Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 YALE L. J. 1535, 1681 (1998) (arguing that "intellectual due process" demands that "whether it is a scientifically trained judge or juror or agency administrator, the same person who has legal authority must also have epistemic competence in relevant scientific disciplines"); UNION OF CONCERNED SCIENTISTS, SCIENTIFIC INTEGRITY IN POLICYMAKING: AN INVESTIGATION INTO THE BUSH ADMINISTRATION'S MISUSE OF SCIENCE (Feb. 2004), *available at* http://www.ucsusa.org/documents/RSI_final_fullreport.pdf; H.R. COMM. ON GOV'T REFORM, MINORITY STAFF SPECIAL INVESTIGATIONS DIV., POLITICS AND SCIENCE IN THE BUSH ADMINISTRATION (2003), *available at* http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.-pdf.

155. *Japanese Apples*, *supra* note 53; *Japanese Varietals*, *supra* note 62; *Hormones, AB*, *supra* note 60; *Salmon, AB*, *supra* note 61.

156. Article 11.2, which contains the only procedural information specific to the SPS Agreement, states:

> In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

SPS Agreement, *supra* note 4, art. 11.2.

of relevance may also inappropriately exclude dimensions of relevant public knowledge, as discussed above. As a result, the WTO should not limit its experts to the natural sciences. Specialist, practice-based bodies of knowledge such as, say, farming expertise, may be salient to risk assessment in ways that are not covered by the expert knowledge of scientific disciplines.[157] Furthermore, the social sciences may offer insights to risk assessment, especially concerning important social-behavioral variables. Robert Howse has argued, for instance, that panels need "the expertise of those whose research centers on the role of science within the process of regulation and who move between the disciplines of science and regulatory theory."[158] Scientists called upon in previous SPS cases were placed in a virtually impossible position when they were asked to make purely scientific judgments about the adequacy of risk assessment as a regulatory tool.[159]

It is logical, therefore, that prior to the selection of experts there should be a systematic review of the kinds of questions that are relevant to the case, leading to the deliberate identification of bodies of specialist (or public) knowledge and input necessary for a sound resolution of the issue. The selection of experts might to some degree offset perceived deficiencies in the national decision-making processes of the parties in the case. As discussed in more detail below, part of expert analysis should focus on whether the risk situation at hand is in an area of low, medium, or high certainty and consensus.[160] Although we advocate that the scope of expert inquiries should be broadened, this should not be taken to mean that the overall power of expert analysis should be increased: WTO judges should be careful not to attempt (through experts or otherwise) to become the high arbiters of scientific truth in the world trading system. Such a view would directly conflict with the Appellate Body's stated appreciation of legitimate scientific differences and of its own zone of competence.

C. *Article 5.7 and Public Participation*

As discussed in Part III.D above, in conditions of low scientific certainty and low consensus as to the values and methodologies underlying risk assessment, public input assumes even greater social and scientific importance. In these situations, decision-making should be all the more accountable to and better informed by the public.

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157. *See, e.g.*, Robert Howse & Petros C. Mavroidis, *Europe's Evolving Regulatory Strategy for GMOs—The Issue of Consistency with WTO Law: Of Kine and Brine*, 24 FORDHAM INT'L L.J. 317, 348 (2000) ("[F]ollowing on the remarks of the Appellate Body in the *Hormones* case about the real world in which people live and die, expertise concerning the effectiveness and consequences—social and economic, or even cultural—of particular forms of risk management and regulatory intervention may be appropriate.").

158. Howse, *supra* note 13, at 2346-47.

159. *Id.* This underscores the ambiguity of distinctions between science and values in framing risk analyses. Scientists who are expert in particular technical domains do not necessarily have the expertise needed to determine if a particular form of regulatory tool is adequate.

160. Existing SPS case law supports the use of experts as one input when considering the sufficiency of both a prima facie challenge to an SPS measure and a defence of scientific justification. For instance, the recent *Japanese Apples* report states correctly that panels are "entitled to take into account the views of the experts." *Japanese Apples, AB*, *supra* note 53, para. 166.

Article 5.7 of the SPS Agreement provides a format for addressing concerns about the need for public input. It offers a temporary safe harbor in situations when the body of available scientific evidence does not allow, in quantitative or qualitative terms, for the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement,[161] so long as provisional measures are based on "available pertinent information" and so long as the member seeking the temporary safe harbor undertakes and completes its review of the technology "within a reasonable period of time."[162]

We suggest that classification of the risk situation on the continuum of certainty and consensus should help dispute settlement panels establish the availability and validity of this temporary safe harbor in situations where members claim the need for more time for public participation in the risk-assessment process.

1. *"Insufficient" Scientific Evidence to Perform an "Adequate" Risk Assessment*

In *Japanese Apples*, the Appellate Body confirmed that insufficiency should not exclude "cases where the available evidence is more than minimal in quantity, *but has not led to reliable or conclusive results.*"[163] Reliability and conclusiveness are the key concepts here, and it becomes necessary to recall our previous discussion on the use of science in risk assessment. If one lesson emerges from the body of social science on risk, it is that reliability and conclusiveness of the science involved in risk assessment are functions not only of the scientific facts, but also of the value commitments of regulators and the public. Therefore, science for risk assessment will only be reliable and conclusive if it addresses their risk framings. To use an example relevant to the GMO case, it is possible that the body of scientific evidence needed to support a reliable and conclusive assessment of health risks would differ from that needed to support a reliable and conclusive assessment of environmental risks. Furthermore, sorting out the environmental risks to animal health, plant health, and even insect health might each require different evidence and assessments. In other words, reliability and conclusiveness are characteristics not of the scientific evidence in isolation, but of the scientific evidence in relation to the values of a particular community in a particular regulatory context. Indeed, we have shown how evidence deemed reliable enough to generate a sufficient risk assessment in one regulatory context may fail in other contexts because of the different concerns, risk frames, and particular circumstance.

Accordingly, it makes little sense to claim that existing scientific evidence is sufficient for an adequate assessment of the risks if it fails to address risks that a particular community actually cares about. Values shape the very scientific questions that drive risk assessment. Therefore, we propose that WTO members may take advantage of the temporary SPS Agreement

161. *Id.* para. 179.
162. SPS Agreement, *supra* note 4, art. 5.7.
163. *Japanese Apples, AB*, *supra* note 53, para. 185 (emphasis added).

safe harbor in situations of low and medium certainty and consensus, assuming that the members meet the other requirements of Article 5.7, because the evidence in such situations would be by definition not reliable and conclusive. In high-certainty, high-consensus risk situations, however, assessments would be expected to converge and the safe harbor would be presumptively unavailable.

2. *Available "Pertinent Information"*

Article 5.7 also requires that provisional measures be based on "pertinent information." The term "pertinent information," like all treaty language in the WTO agreements, should be interpreted in accordance with its "ordinary meaning."[164] The *Oxford English Dictionary* defines "pertinent" as "pertaining or relating to the matter in hand; relevant; to the point; apposite."[165] Contextual language is also important for treaty interpretation.[166] The first sentence of Article 5.7 clearly differentiates "pertinent information" from "relevant scientific information," implying that the former is a broader category than the latter. The term should be interpreted to include substantive inputs from officially recognized public deliberations, experiential data not available from the published scientific literature, and other information concerning public values such as consumer data on public attitudes.

3. *"Within a Reasonable Time" and Without "Undue Delay"*

Finally, the SPS Agreement includes a number of provisions concerning the time period for the implementation of SPS measures and their subsequent reassessment. Under Article 5.7, in addition to the requirements already mentioned, members must "review the . . . measure accordingly within a reasonable period of time."[167] Furthermore, Annex C to Article 8 provides that members must "ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that . . . such procedures are undertaken and completed without undue delay."[168]

The terms "reasonable" and "undue" are legal standards left to be defined on a case-by-case basis, and WTO adjudicators would be ill-advised to attempt to set an arbitrary time standard that would apply to all risk assessments. Instead, we argue that questions about what constitutes a reasonable time period for the completion of public participation or further scientific study should be addressed at the national level, as member states take into account the location of a risk issue on the certainty-consensus

164. Vienna Convention on the Law of Treaties, May 23, 1969, art. 31(1), U.N. Doc. A/Conf.39/27, 1155 U.N.T.S. 321, 340 (1980) [hereinafter Vienna Convention] ("A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.").

165. OXFORD ENGLISH DICTIONARY (2d ed. 1989).

166. Vienna Convention, *supra* note 164.

167. SPS Agreement, *supra* note 4, art. 5.7.

168. *Id.* art. 8, Annex C. We analyze this requirement along with the "reasonable time" requirement of Article 5.7 because they both require the assessment of whether the amount of time at issue is justified. In litigation, these provisions would be analyzed separately, but would require similar consideration.

continuum. A member that seeks an Article 5.7 safe harbor would be required to put forth a concrete plan including the studies to be conducted and the expected times for completion; any member opposing the safe harbor could introduce evidence purporting to show that the timetable was unreasonable. A dispute settlement panel would then enlist its own science and social science experts to help in its determination of whether the claim of appropriateness is justified.

4. *Determining the Levels of Certainty and Consensus*

Our proposal of tying the availability of the Article 5.7 safe harbor to the risk situation's position on the continuum of certainty and consensus raises the important issue of how judges should locate the risk at hand along that continuum. Although the characterizations of certainty and consensus must be carried out on a case-by-case basis and may require input from experts appointed by the panel, general principles surface upon review of the social science literature and experiences discussed above.

First, the amount of time that the technology and its underlying science has had to mature and to interact in real-world settings will have significant implications for where the technology falls on the certainty-consensus spectrum. In the case of a relatively new technological use or risk assessment in an uncertain environment, risk-assessment methodologies themselves may not be standardized,[169] and there may not have been sufficient time for public participation to flesh out the real-world enactments and impacts of the technology and the consequential value judgments at stake.

A second important consideration in the certainty-consensus analysis is whether or not the international standard-setting bodies mentioned in the SPS Agreement have enacted standards or risk-assessment methods for the particular risk situation. The SPS Agreement recognizes the Codex as an authoritative source of food safety standards for the world trading system.[170] This means that the international body is a crucial indicator of the degree to which the international food regulatory community has reached consensus on both the risks of GMOs and the risk-assessment methodologies directed toward them.

Panels should also consider the extent to which the record indicates unresolved problems in the quantification of harms because of measurement inadequacies, methodological issues, or unknowns in the conceptualization of products and product effects.[171] Relevant sources of evidence might include articles from the scientific and social scientific press, reports emerging from regulatory agencies within different member states, and also the outcome of dialogues with segments of the public engaged in practices involving the risk at issue. Such evidence could be used by either party to rebut the

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169. Climate change, for example, began in this category of risk situations, and over time the risk assessments in this area have become characterized by greater certainty and greater scientific consensus. *See* CLIMATE CHANGE 2001, *supra* note 134, at 9-16, 471-524 (containing the contribution of Working Group I to the Third Assessment Report of the Intergovernmental Panel on Climate Change, which builds upon the previous five years of work to provide more detailed data and rigorous analysis).

170. SPS Agreement, *supra* note 4, pmbl., art. 3.2.

171. *See generally* Walker, *supra* note 76.

presumptions established in the first test. Where evidence seems to be split, testimony could be taken from experts in relevant fields to determine the structure and weight of scientific and social opinion.

Finally, dispute settlement panels should consider evidence of whether there is consensus and certainty as to the nature, sources, and extent of risk involved in the particular situation. For instance, is there broad agreement as to whether a risk should be framed as an environmental issue, a human health issue, or both? What is deemed to be at risk in environmental and health terms? Here, as above, relevant sources of evidence might include articles from the scientific and social scientific press, reports emerging from regulatory agencies, and also the outcome of public dialogues. Documentation of public inputs into regulatory decision-making, results of national polls and referenda, and consumer attitude and behavior data could also bear on this issue.

D. *During and After the Article 5.7 Safe Harbor*

In situations where the WTO grants a temporary safe harbor under Article 5.7, it should maintain jurisdiction over the case pending the termination of the temporary safe harbor in order to limit its opportunistic abuse. Periodically, the dispute settlement panel or appointed experts would assess whether indeed the member was "seek[ing] to obtain the additional information necessary for a more objective assessment of risk"[172] as the Article requires. In these cases, not only further scientific studies but also public hearings and comment periods would help satisfy this requirement. In such cases, this mechanism would provide a forum to the opposing member to bring concerns directly back to the panel without the need for requesting the formation of a new panel.

When the time allocated for the safe harbor is complete, the case would return for review under the main provisions of the SPS Agreement, and the new information obtained from public participation or other relevant processes would be a part of the risk assessment that the panel would review under the standards articulated in Part V.A. Specifically, the information obtained during the safe harbor period should be considered part of the member's risk assessment under Article 5.1, so long as its influence on the decision has been adequately documented in the record.[173]

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172. SPS Agreement, *supra* note 4, art. 5.7.

173. Article 5.1 of the SPS Agreement requires that members ensure that SPS measures "are based on an assessment, as *appropriate to the circumstances*, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." SPS Agreement, *supra* note 4, art. 5.1. (emphasis added). The term "appropriate to the circumstances" emphasizes that the relationship between a risk assessment and the SPS measure must be analyzed with close attention to the facts of the particular case. The Appellate Body has emphasized that the presence or absence of that relationship can only be determined on a case-by-case basis. *See Hormones, AB, supra* note 60, para. 194. Judicial determination of the certainty and consensus levels in a specific risk situation should also inform a measure's compliance with Article 5.1. Why is this important? In risk situations characterized by low certainty and low consensus, public input and deliberation should be recognized as legitimate and even desirable components of the risk-assessment process under the SPS Agreement. Indeed, WTO case law makes it clear that SPS risk assessment can involve qualitative factors that incorporate the values identified and the frames employed in the public deliberations within member states. It may be the case that an adequate risk assessment in these

When a case leaves the temporary safe harbor of Article 5.7, or when a given SPS measure comes under first-time review, the levels of certainty and consensus should also be relevant under Articles 2.2 and 3.3. How will the certainty-consensus determination help the given panel in evaluating the "rational relationship" standard that these Articles require?[174] In determining whether such a rational relationship exists, WTO judges have emphasized the importance of considering the "quality and quantity of scientific evidence."[175] The Appellate Body has held elsewhere that the SPS Agreement "does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community," and that "[i]n some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty."[176]

When dispute settlement panels seek to decide whether a measure is rationally related to science, it is crucial that they consider where the risk situation falls on the certainty-consensus continuum. When faced with low-certainty, low-consensus issues, dispute panels should take a more deferential

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circumstances actually requires extensive, regular dialogue with the public. This approach is permitted under existing interpretations of the treaty language. Although the SPS Agreement establishes a number of required technical factors in a risk assessment, the Appellate Body in *Hormones* has made it clear that this is not an exhaustive list. *Id.* para. 187. Rather, risk assessment can include "factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences." *Id.* para. 253(j). Nor does risk assessment, as defined by the SPS Agreement, require the scientific establishment of some sort of a minimum threshold of quantifiable risk: "Neither Articles 5.1 and 5.2 nor Annex A(4) of the SPS Agreement require a risk assessment to establish a minimum quantifiable magnitude of risk." *Id.* Likewise, the requirements of harm identification and likelihood evaluation required by Article 5.1 as discussed in *Salmon* do nothing to require rigid processes of quantification. In *Salmon*, the Appellate Body stated that risk assessment within the meaning of Article 5.1 must:

> (1) identify the diseases whose entry, establishment or spread a member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
> (2) evaluate the likelihood of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and
> (3) evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.

Salmon, AB, supra note 61, para. 121. Accordingly, the SPS Agreement, as it has been interpreted, creates a space for public input as a possible component in formal risk assessment. Factoring in public values would seem to be not only appropriate, but also necessary in risk situations of low certainty and low consensus.

174. The SPS Agreement states: "Members shall ensure that any sanitary or phytosanitary measure as applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." SPS Agreement, *supra* note 4, art. 2.2. The Appellate Body has interpreted this language to require that "there be a rational and objective relationship between the SPS measure and the scientific evidence" and that "[t]he context of the word 'sufficient' or, more generally, the phrase 'maintained without sufficient scientific evidence' in Article 2.2, includes Article 5.1 as well as Articles 3.3 and 5.7 of the *SPS Agreement*." *Japanese Varietals, AB*, *supra* note 62, paras. 74 & 84. The Appellate Body has also said that "scientific justification" in Article 3.3 requires that there be a "rational relationship between the SPS measure at issue and the available scientific information." *Id.* para. 79.

175. *Japanese Varietals, AB*, *supra* note 62, para. 84 ("Whether there is a rational relationship between an SPS measure and the scientific evidence is to be determined on a case-by-case basis and will depend upon the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence."); *see also Japanese Apples, AB*, *supra* note 53, para. 162.

176. *Hormones, AB*, *supra* note 60, para 194.

approach to the science-based decision-making of members, and should consider public participation as having been a legitimate input during the risk-assessment and risk-management process in question. Where certainty and consensus are at low or even medium levels, regulators must be allowed to take public value choices into consideration when setting appropriate regulatory standards. Indeed, this power falls within the scope of their treaty-given discretion to set appropriate levels as defined in footnote 2 of Article 3.3.[177] In short, judges must make a determination of the plausibility of members' use of science in light of scientific and social facts, both of which have a bearing on the issues of consensus and certainty. When such conditions of low or even medium certainty and consensus obtain, a wider array of science policy decisions and regulatory interventions may be seen as plausibly based on the scientific evidence available. When consensus and certainty are high, the range of rational measures to address the risk situation should be more limited.

VI. CONCLUSIONS FOR *BIOTECH PRODUCTS*

Finally, we turn our attention to the particular facts and circumstances of the *Biotech Products* case at the WTO. We examine information relevant to the question of where GMOs should be located on the certainty-consensus continuum, and argue that they create a low certainty–low consensus risk situation: risk-assessment techniques associated with GMOs remain scientifically and politically contested both within and across different national regulatory systems. Consequently, we argue that the EU's challenged measures satisfy the temporary safe harbor test under Article 5.7. The EU should therefore be allowed to conduct further risk assessment before being forced to litigate its ultimate position on GMOs before the dispute settlement panel.[178]

A. *GMO Risk Assessment Is Marked by Low Certainty and Low Consensus*

GMOs constitute a clear example of a low-certainty, low-consensus situation. The persistence of an international stalemate in establishing risk-

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177. The SPS Agreement defines the requirement of scientific justification the following way:

> [T]here is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a *Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.*

SPS Agreement, *supra* note 4, art. 3.3 n.2 (emphasis added).

178. As a practical matter, ever since the alleged moratorium began, the European Commission and EU member states have continued to engage in fact-finding, scientific review, and public dialogue, which resulted in the passage of the new labeling regime for GM foods that was enacted earlier this year. *See* European Parliament & Council Directive 2001/18/EC, *supra* note 32, at 33. As approvals for biotech products have begun once again, it seems that at least for some, this labeling regime will constitute the ultimate (as opposed to provisional) regulatory treatment of GMOs in the EU. It remains an open question whether the United States and the other complaining WTO members in *Biotech Products* will choose to challenge this new labeling regime under the SPS or other WTO agreements, and whether such a labeling regime would even qualify as a measure under the SPS Agreement, let alone pass muster under the science-based provisions.

assessment guidelines for GMOs, the emergence of an international precautionary norm, and the existence of ongoing regulatory learning within the United States itself all strongly support this characterization.

First, the long-lasting stalemate at the Codex over the risk-assessment methodology for GMOs is a strong indication of a low-certainty, low-consensus situation. Since 1996, the Codex has recognized that the risk assessment of whole-food products containing GMOs, or products involving recombinant DNA in the production process, requires a unique risk-assessment framework.[179] However, for years this initiative remained locked in a political and scientific stalemate. After seven years of intensive and politically contested work, the Codex finally adopted its Principles for the Risk Analysis of Foods Derived from Modern Biotechnology in July 2003.[180] The new recommended framework includes, inter alia, a "Description of the Donor Organism[s]," a detailed "Characterization of the Genetic Modification," an "Evaluation of Metabolites," and an assessment of "Nutritional Modification."[181]

The fact that the Codex labored intensively for seven years before being able to agree on risk-analysis guidelines for biotech foods indicates the extent to which the risk analysis of GMOs has been a contested scientific and political endeavor. Large differences in public values regarding health and the environment are operating in the GMO domain, differences that are relevant not only to the management of hazards, but also to their initial definition, characterization, and assessment. As a result, governments have not framed the scientific issues posed by technological developments in the same ways, as the divergences between product-based and process-based approaches and between health-focused and environment-focused approaches illustrate.[182] Compounding this issue is the fact that GMOs represent an emergent suite of technologies whose biological properties and environmental and social impacts are neither well-defined nor certain. Indeed, there may not be agreement even on an unambiguous characterization of the technological risk-agent itself.[183] Different framings reflect the beliefs and preferences operating in different societies.[184]

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179. *See* Anne A. MacKenzie, *The Process of Developing Labeling Standards for GM Foods in the Codex Alimentarius*, 3 AGBIOFORUM 203 (2000). The twenty-third session of the Codex, held in the summer of 1999 in Rome, established the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to develop standards, guidelines, or recommendations for foods derived from biotechnology or traits introduced into foods by biotechnology. *See* Food & Agric. Org. of the UN, *Task Force analyses* [sic] *the Risks of Foods Derived from Biotechnology*, Mar. 14, 2000, *at* http://www.fao.org/NEWS/2000/000304-e.htm.

180. CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY, CODEX PRINCIPLES AND GUIDELINES ON FOODS DERIVED FROM BIOTECHNOLOGY (2003), *available at* http://www.bgvv.de/cm/208/codex_principles_and_guidelines_on_foods_derived-_from_biotechnology.pdf.

181. *Id.* at 9-14.

182. *See supra* Part II; *see also* SHEILA JASANOFF, DESIGNS ON NATURE (forthcoming 2005).

183. For example, with GM plants, the precise insertion of the foreign gene is recognized not to be rigorously controlled in practice, leading to uncertainties about the precise biological agent which has been created and released in commercial planting. Further development of the scientific understanding of these processes would presumably reduce uncertainty of this kind, increasing the reliability of risk assessment. *Cf.* Hae-Woon Choi et al., *High Frequency Cytogenetic Aberration in Transgenic Oat* (Avena Sativa L.) *Plants*, 160 PLANT SCI. 763 (2001).

184. *See* LIBERATORE, *supra* note 93, at 225-47.

Second, in addition to the efforts of the Codex mentioned above, public debate and input have been instrumental in the creation of a new international regulatory regime for GMOs, one that embraces a precautionary approach to managing risk because of the insufficiency of existing knowledge. During the period of the alleged EU moratorium, popular political pressure mounted in countries throughout the world for an international agreement on regulating transgenic organisms. On January 29, 2000, the representatives of 129 countries met in Montreal and adopted the Cartegena Protocol on Biosafety, an act capping over five years of negotiations regarding the international transport of GMOs.[185] Negotiated under the auspices of the 1992 Convention on Biological Diversity of the United Nations Environmental Programme, the Protocol regulates the transnational movement of the living products of biotechnology in order to protect biodiversity.[186] There was intense public debate and discussion about the scope and importance of the precautionary principle in relation to GM technologies during the Protocol's negotiation.[187] The discussions served as a forum for international informational exchange regarding GM technologies, and the robustness of GMO risk-assessment methodologies. It is notable that the negotiating states reached consensus on the issue of precaution, and the final language of the Protocol states:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.[188]

Although the United States is not a signatory to the Cartagena Protocol, the emergence of broad support for the agreement throughout the rest of the world highlights the fact that simple risk assessment is inadequate for the GMO case. More time is necessary for the development and implementation of regulatory solutions. Indeed, the rigid specification of a particular mode of risk assessment would tend to freeze the ongoing development of risk-assessment science and policy in the GMO area (as visible in the United States as it is in Europe). An overly rigid conception of proper regulation in this area could lead to inadequate risk assessments in the future, threaten human populations or environments, and undermine the legitimacy of the SPS Agreement.

Finally, the United States itself has reversed its regulatory policy for GMOs over the period of the alleged moratorium, as the StarLink, Prodigene, and GM Bentgrass incidents discussed above illustrate.

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185. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, U.N. Doc. UNEP/CBD/ExCOP/1/3, *reprinted in* 39 I.L.M. 1027, *available at* http://www.biodiv.org/biosafety/protocol.asp. The Protocol referred to living biotechnology products as "living modified organisms."

186. *See* Terence P. Stewart & David S. Johanson, *A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization*, 14 COLO. J. INT'L ENVTL. L. & POL'Y 2 (2003).

187. *Id.* at 16-22.

188. *Supra* note 133, art. 10.6.

Together, these factors amply demonstrate that the case of GM products lies squarely within the zone we define as low-certainty, low-consensus.

B. *The EU Should Be Able to Take Advantage of Article 5.7's Temporary Safe Harbor*

It should be concluded that EU authorities can legitimately invoke the provisionality clause and can satisfy the "undue delay" standard of Annex C. The terms "undue" and "reasonable" are legal standards that are meaningless without a comparison of what happened in the particular instance with what is believed to be the general tendency in like situations.[189] The proper inquiry for WTO judges, therefore, is one that is comparative in nature. Far from being a period of delay, the years from 1998 to the present have been characterized by intense social and scientific learning about GM products and their implications both within the EU and elsewhere. Although six years may be deemed an unreasonable amount of time for provisional measures in other risk situations, it seems reasonable in the GMO case in light of the relevant evidence. As we have already discussed above, a succession of authoritative studies on both GM crops and science and environmental regulation have tended to add further substance to the concerns that have been under review.[190] Furthermore, it was the dynamic interaction among agencies, scientists, and the public—facilitated by the provisional measures—that led to methodological and scientific development in the effective risk assessment of GMOs.

VII. CONCLUSION

As we have suggested throughout the discussion, the judicial approach outlined above admittedly entails a number of possible disadvantages, especially from the perspective of trade liberalization. WTO validation of multiple approaches to the assessment of particular products could, at best, cause delay for the larger project of regulatory standardization; at worst, it could open new avenues for protectionism masquerading as risk-based technology policy. A subtler version of this critique is that increasing the evidentiary burden necessary to establish a violation of the science-based provisions, or widening the scope of affirmative defenses, might decrease the sharpness of the SPS Agreement's anti-protectionist tools.

In our view, careful implementation of our approach to reviewing science policy decision-making would not jeopardize the efficacy of world trade law in the short term and could build political legitimacy in the long

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189. *See, e.g.*, HENRY M. HART, JR. & ALBERT M. SACKS, THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW 157 (1958).

190. *See, e.g.*, NAT'L RESEARCH COUNCIL, BIOLOGICAL CONFINEMENT OF GENETICALLY ENGINEERED ORGANISMS (2004); NAT'L RESEARCH COUNCIL, ECOLOGICAL MONITORING OF GENETICALLY MODIFIED CROPS: A WORKSHOP SUMMARY (2001); NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002); NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (2000); ROYAL SOCIETY OF CANADA, ELEMENTS OF PRECAUTION: RECOMMENDATIONS FOR THE REGULATION OF FOOD BIOTECHNOLOGY IN CANADA: AN EXPERT PANEL REPORT ON THE FUTURE OF FOOD BIOTECHNOLOGY (2001), *available at* http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf.

term. As a threshold matter, it is important to remember that the structure of the world trading regime embodies the approach of embedded liberalism, and the SPS Agreement itself explicitly rejects the proposition that what is deemed to be necessary environmental and health regulation should be dictated to WTO members. To a large extent, regulatory diversity across environmental and health domains results from real cultural differences about the extent and character of risks. Furthermore, as in national federations like the United States, diversity itself might be beneficial from the perspective of creating a laboratory for testing the efficacy of regulatory approaches.

The proper direction for judicial doctrine, then, will be to enhance the sensitivity of judicial tools for detecting protectionism masquerading as health and environmental values, while preserving cultural autonomy in important societal domains. Reading public participation into the SPS Agreement would increase the WTO's sensitivity both to the socially embedded nature of the science used in risk assessment and to non-protectionist cultural differences. Consistent with the goals of embedded liberalism, our approach encourages judicial deference toward expressions of objectively documented public will in member states, especially in novel risk situations characterized by low certainty and low consensus. Furthermore, administrative review, including implementation of standards of transparency, would enable judges to distinguish legitimate forms of local regulatory sensibility from protectionism by requiring reasoned decision-making that takes the presence, absence, and substance of scientific evidence and expressed cultural values into account.

Implementing this judicial approach under the SPS Agreement would help avoid the pitfall of using the authority of science, rather than the principle of nondiscrimination, to decide whether regulations stricter than international standards are legitimate. As other trade law commentators have pointed out, such a rigid science-based view would have the perverse effect of removing the ultimate power of decision from the democratic communities that the SPS measures purport to protect.[191]

Our approach could help mitigate this danger of a widening democracy deficit at the WTO in a number of ways. First, as we have argued above, our approach would help incorporate the legitimacy of public participation in risk-based decision-making within the trading system. If discrepant risk framing and public values are viewed as justified and necessary inputs not only to risk management, but also to risk assessment, and if public acceptance is taken as an important measure of the reliability and conclusiveness of the risk assessment, then the dangers of using science to trample upon peoples' real concerns about health and the environment will be minimized. Furthermore, the application of the certainty-consensus framework will help prevent the appropriation of the regulatory functions of sovereign nation states in domains of contested values and risk analysis. Finally, by enforcing a proceduralist approach to the review of science-based decision-making, the WTO can serve a useful role in recognizing and reinforcing a robust conception of deliberative democracy within member states, one that would enhance accountability

191. Howse, *supra* note 13, at 2357; Walker, s*upra* note 6, at 277-96; Wirth, *supra* note 55, at 825.

between national regulatory agencies and the public. Most importantly, our approach would not foreclose the attempt to pool collective knowledge as a resource for the harmonization of standards: in situations of high consensus and high certainty, a heavier burden will be placed on members to establish that their measures stem from non-protectionist values.

To the extent that our proposal enhances democratic control of novel technologies, the trading regime will be strengthened. Free trade need not mean running roughshod over deeply held political and cultural values. In an age of globalization in which anxieties about cultural homogenization and non-accountability of global governance are endemic, the political advantages of such an approach are obvious. The scientific advantages of creating a space for public participation in national science policymaking may be less obvious, but they are no less significant. Indeed, as we have seen in the case of GMOs, public input can have the effect of identifying relevant and crucial scientific questions, problems, and hypotheses. As a result, science aimed at risk assessment will be more vigorous, both intellectually and socially. Recognizing the substance of public dialogue and the actions of civil society as important components within the risk-based decision-making process will help expand frontiers of useful knowledge in these areas, as well as prevent the selective uptake and imposition of a single member's science policies on others in culturally sensitive matters of contested values. Such an approach would not only avoid well-documented problems of scientific competency at the WTO,[192] but would also, if properly carried out, help ensure that legitimate and democratically enacted science policies do not fall prey to a procrustean pursuit of regulatory harmonization.

192. *See, e.g.*, Christoforou, *Settlement of Science-Based Trade Disputes in the WTO*, *supra* note 67, at 622-23.