

<http://www.lancs.ac.uk/fss/ieppp/wtoamicus/amicus.brief.wto.pdf>

*AMICUS CURIAE BRIEF*

---

**SUBMITTED TO THE DISPUTE SETTLEMENT PANEL  
OF THE  
WORLD TRADE ORGANIZATION**

---

**IN THE CASE OF**

***EC: MEASURES AFFECTING  
THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS***

**LAWRENCE BUSCH  
ROBIN GROVE-WHITE  
SHEILA JASANOFF  
DAVID WINICKOFF  
BRIAN WYNNE**

### **BIOGRAPHICAL DETAILS ON THE AUTHORS (in alphabetical order)**

**Lawrence Busch** is University Distinguished Professor of Sociology, Director of the Institute for Food and Agricultural Standards, and Director of the Partnerships for Food Industry Development – Fruits and Vegetables project at Michigan State University. He is coauthor or coeditor of a number of books including *Plants, Power, and Profit: Social, Economic, and Ethical Consequences of the New Biotechnologies*, as well as more than 100 other publications. He is past president of the Rural Sociological Society and past president of the Agriculture, Food, and Human Values Society. He recently was named *Chevalier de l'Ordre du Mérite Agricole* by the French government and has been long been a consultant to the International Service for National Agricultural Research and the Food and Agriculture Organization of the United Nations.

**Robin Grove-White** is Professor of Environment and Society at Lancaster University, with the Institute for Environment, Philosophy and Public Policy. He is also a member of the UK Government's Agriculture and Environment Biotechnology Commission, and has been a Board Member of the UK Forestry Commission, adviser to the Rotal Commission on Environmental Pollution on GM crop regulation, and a specialist adviser to several Parliamentary committees.

**Sheila Jasanoff** is Pforzheimer Professor of Science and Technology Studies at Harvard University's John F. Kennedy School of Government. She has held faculty appointments at Yale, Oxford, Kyoto and Cornell, where she founded and chaired the Department of Science and Technology Studies. She has been a Fellow at the Berlin Institute for Advanced Study (*Wissenschaftskolleg*). Her research centers on the use of science in legal and political decisionmaking, with particular emphasis on risk management and science advice. Her books on these topics include *The Fifth Branch, Science at the Bar*, and *Designs on Nature* (forthcoming), a comparative study of biotechnology policy in Europe and the United States. Jasanoff has served on the Board of Directors of the American Association for the Advancement of Science and as President of the Society for Social Studies of Science. She has advised the European Commission, the US Environmental Protection Agency, and the US Congress on issues raised by this brief.

**David Winickoff** is Adjunct Lecturer in Public Policy at Harvard University's John F. Kennedy School of Government, and in July 2004 he will become Assistant Professor of Bioethics and Society at the University of California at Berkeley. His research focuses on the convergence of law, science and ethics, especially in the areas of international trade, biotechnology, public health, and the environment. He holds degrees from Yale University, Cambridge University and Harvard Law School.

**Brian Wynne** Brian Wynne is Professor of Science Studies and a member of the Centre for the Economic and Social Aspects of Genomics at Lancaster University. He has published widely in the international peer-reviewed literature on risk, scientific knowledge and public policy, and public responses to risk and other scientific knowledge. He was Research Leader on Risk at the International Institute for Applied Systems Analysis, and between 1994 and 2000, a member of the Management Board and Scientific Committee of the European Environment Agency. He is currently a member of the London Royal Society's Science in Society committee, and chair of the advisory board of the UK Economic and Social Research Council's 'Science in Society' research program.

## OUTLINE OF ARGUMENT

### I. Introduction

#### A. Summary of Argument

#### B. This *Amicus Curiae* Brief

### II. Factual Background to the Legal Case

### III. Risk-based Decisionmaking: Conceptual Foundations

#### A. Value Judgments in Risk Assessment

1. Risk assessment versus risk management
2. The FAO and Codex Alimentarius Commission on risk assessment

#### B. Contextual Contingency, Framing and Regulatory Styles

1. Dependence of risk analysis on political and cultural context
2. Framing
3. U.S. and EU have different styles of science-based regulation

#### C. Public Participation

1. U.S. National Research Council
2. Defining what is ‘at risk’
3. Scientific and political value of participation

### IV. Language in the Agreements Applied to the GMO Case

#### A. ‘Sufficient scientific evidence’ (2.2) and ‘Scientific justification’ (3.3)

1. Science of GMOs is low certainty, low consensus
2. Risk assessment of GMOs is an evolving technical practice
3. Risk assessment of GMOs should be locally based

#### B. SPS Measures Must Be Based On a Risk Assessment (5.1, 5.2)

1. Regulatory and scientific development in the EU
2. Risk assessment under the SPS permits qualitative factors
3. Risk embedded in the social system
4. The role of public deliberation in risk assessment
5. Retaining democratic elements in regulatory process

#### C. Discrimination Disciplines

1. Introduction
2. SPS Article 5.5 and GATT Article III:4
  - a. ‘Properties, nature and qualities’
  - b. ‘Consumer attitudes and perception’

#### D. Provisionality (5.7) and ‘Undue Delay’ (8, Annex C)

1. ‘Where relevant scientific evidence is insufficient’
2. ‘On the basis of available pertinent information’
3. Members shall ‘seek to obtain the additional information necessary for a more objective assessment of risk’
4. ‘Reasonable period of time’ and ‘undue delay’ require comparison

- a. Ongoing regulatory and scientific development in the EU
  - b. Using U.S. GMO regulation as a comparison
    - i. Starlink case
    - ii. Prodigene case
    - iii. FDA Equivalence rules
    - iv. Post-harvest risk assessment
  - c. Using international GMO regulation as a comparison
    - i. Codex Alimentarius Commission
    - ii. Cartagena Protocol
5. Conclusion on the issues of provisionality and delay

**V. Reviewing Risk-Based Decisionmaking at the WTO**

**A. Risk-based Regulation, Democracy and Judicial Review**

**B. Enforcing Transparent, Accountable, and Reasoned Use of Science**

**C. Selection of Experts**

**D. Use of Experts**

**E. DSU and Case Law Supports this Understanding of Judicial Role**

**VI. Summary and Conclusion**

## I.

### INTRODUCTION

#### A. Summary of Argument

Regulatory polarization in the agricultural biotechnology sector has created tensions in the world trading system and threatens to develop into a full-blown trade conflict.<sup>1</sup> Before that happens, the Dispute Settlement Panel at the World Trade Organization has a chance to render informed judgment on these issues in the present case of *EC – Measures Affecting the Approval and Marketing of Biotech Products* (hereinafter *Biotech Products*). The case results from complaints against the European Community brought by a number of other Member States, including the United States, Canada and Argentina.<sup>2</sup> Contrary to the arguments advanced by the recent U.S. submission in *Biotech Products*, both the risks and benefits of this family of technologies remain the subject of ongoing scientific and political contention around the world.<sup>3</sup>

As the U.S. submission makes clear, the *Biotech Products* dispute will center on the interpretation of key provisions of the Sanitary and Phytosanitary Agreement,<sup>4</sup> especially those concerning ‘scientific justification’ and ‘risk assessment.’ Indeed, ‘risk assessment’ is a key term underpinning the free flow of trade under the WTO’s science-based disciplines.<sup>5</sup> As exemplified by the U.S. submission, risk assessment has been conventionally understood as a factually grounded, objective, and value-free, analytic exercise requiring (1) precise identification of possible harms to human health and the environment, and (2) use of formal, expert-based assessments of the likelihood of such harms. Public values and concerns are thought to be relevant and appropriate only in the phase of risk management, which is perceived to follow risk assessment and remain separate from it.

By contrast, over the past few decades, both national and international regulatory frameworks have been developing in ways that systematically call into question this account of risk assessment. Social scientific research has identified and analyzed these developments and their implications for policy practice in various institutional contexts. The issues identified as problematic for conventional accounts of risk

---

<sup>1</sup> See generally, THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 44-66, 118-167 (2003).

<sup>2</sup> The US, Canada and Argentina first called for consultations on 14 May 2003 concerning Europe’s alleged *ad hoc* moratorium on GM crops. The U.S. (WT/DS291/23), Argentina (WT/DS293/17) and Canada (WT/DS292/17) each requested a panel on 8 August 2003.

<sup>3</sup> First Submission of the United States in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, 292, and 293 (Apr. 21, 2004).

<sup>4</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, at <[http://www.wto.org/english/docs\\_e/legal\\_e/final\\_e.htm](http://www.wto.org/english/docs_e/legal_e/final_e.htm)> [hereinafter SPS Agreement].

<sup>5</sup> See Vern R. Walker, *Keeping the WTO from Becoming the ‘World Trans-Science Organization’: Scientific Uncertainty, Science Policy, and Fact-finding in the Growth Hormones Dispute*, 31 CORNELL INT’L L.J. 251, 277 (1998) (emphasizing that factfinding panels under the SPS Agreement “must adequately understand the nature of risk assessment, the pervasiveness of scientific uncertainty, and the role of science policy”).

assessment include:

- The degree of maturity and/or comprehensiveness of the scientific knowledge base in which particular risk assessments may need to be grounded;
- The extent to which scientific risk assessments in particular national contexts are necessarily shaped by contingencies – scientific and cultural – which help determine the selection of particular analytic foci and strategies as relevant or valid; and
- Wider background assumptions and value commitments that are unavoidably embedded within scientific knowledge generated for policy applications.

The complexities inherent in risk assessment are now becoming explicit in the particular circumstances of the GMO case. This being so, it is vital to offer – and for the WTO to rely upon – a characterization of risk assessment that adequately embraces the results of current scholarship, one that was not taken into account in the U.S. submission. In offering such an alternative, this *amicus curiae* brief hopes to assist not only the Panel’s consideration of the present case, but also the development of more scientifically and politically robust procedures for comparable cases in the future.

For this purpose, it is essential to recognize that risk assessment is neither a single methodology, nor a ‘science’. Rather, contrary to the view advanced in the U.S. submission, we must reconceptualize ‘risk’ situations as lying within a matrix defined by two variables: *certainty* and *consensus*. At one extreme are cases characterized by *high certainty* with respect to the knowledge base to be relied upon, and *high consensus* with respect to the parameters of the scientific issues to be addressed, the analytic methods to be applied, and the values to be protected. At the other extreme are *low certainty* and *low consensus* on such matters.

The nature and adequacy of any risk assessment depends on the position of an issue within this matrix, and GM technologies fall in the *low certainty, low consensus* range. Previous cases such as *Salmon*<sup>6</sup> and *Asbestos*<sup>7</sup> (and even, in some respects, *Japanese Apples*<sup>8</sup> and *Hormones*)<sup>9</sup>, were characterized by *high certainty* and *high consensus* with respect to the basic parameters, scientific knowledge, analytic methods, and values relied upon in risk assessment. The GMO issue by contrast is characterized by *low certainty* and *low consensus* with regard to these matters because the case presents:

---

<sup>6</sup> *Australia — Measures Affecting Importation of Salmon* [hereinafter *Salmon*], Report of the Appellate Body, WT/DS18/AB/R (Oct. 20, 1998).

<sup>7</sup> *European Communities — Measures Affecting the Prohibition of Asbestos and Asbestos Products* [hereinafter *Asbestos*], Report of the Appellate Body, WT/DS135/AB/R (Mar. 12, 2001).

<sup>8</sup> *Japan — Measures Affecting the Importation of Apples* [hereinafter *Japanese Apples*], Report of the Appellate Body, WT/DS245/AB/R (Nov. 26, 2003).

<sup>9</sup> *European Communities — Measures Concerning Meat and Meat Products* [hereinafter *Hormones*], Report of the Appellate Body, WT/DS26/AB/R (Jan. 16, 1998).

- An emergent suite of technologies whose biological properties and environmental and social impacts are neither well defined nor certain;
- Differences in public values regarding health and the environment that are relevant not only to the management of hazards, but to the initial definition of hazards, their characterization and assessment.
- A scientific basis for risk assessment that is fluid and changing even within national decision-making contexts, and where international guidelines and understandings are still emerging and not yet universally accepted;
- Technologies whose use and impact will depend on the behavior of users and consumers in widely varied social and environmental contexts, necessitating deeper understanding of the social and behavioral dimensions of risk.

In the light of these characteristics of the present dispute, the following recommendations are specially merited:

1. Full consideration of the range of relevant scholarship, prominently including the social sciences, in interpreting the meanings of key terms such as ‘risk’, ‘risk assessment’, ‘rational’, ‘objective’, and ‘sufficient scientific evidence.’
2. Recognition that risk assessments of GMOs conducted within specific national or institutional settings are necessarily limited and partial, constrained by the decisionmaking cultures within which such assessments are produced.
3. Recognition that risk assessment is not a singular concept but that it has to vary with context; processes of public deliberation and review are essential components of risk assessment, especially for *low certainty*, *low consensus* technologies such as GMOs, and most especially in relation to the transfer of the technological products across national borders.
4. In light of the developing status of risk assessment techniques associated with GMOs, and the important role of public confidence in regulating new food technologies, the alleged European moratorium should not be deemed an “undue delay” under Article 8, annex C; for the same reason, the period of time which the European Commission has committed to collecting additional necessary information for better risk assessment of GMOs (in order to conduct, e.g., farm-scale trials and public consultations) should be deemed ‘reasonable’, especially in light of the developing regulatory approach to GMOs within the United States itself. ‘Undue’ and ‘reasonable’ are legal standards that cannot be interpreted without reference to actual regulatory experience.
5. Recognition that the WTO dispute resolution panel’s appropriate role in reviewing the arguments of the parties should be that of an administrative tribunal reviewing the adequacy of executive decision-making processes – not that of an adjudicatory body reviewing the substantive merits of the parties’ risk assessments.

## B. This *Amicus Curiae* Brief

Only the SPS agreement, and no other WTO agreement, imposes on its Members an obligation to base regulations on scientific evidence, regardless of whether there is discrimination. This so-called ‘sound science’ obligation means a higher justificatory burden on all WTO Members wishing to regulate GMOs and permits complaining parties to challenge such regulations on the basis of the underlying scientific evidence and reasoning.<sup>10</sup> The centrality of these concepts is widely recognized. For example, U.S. Under-secretary of State for Economics Business and Agricultural Affairs, Alan Larson has said, “The only way to maintain a free and fair trading system is for products traded in that system to be regulated in a logical, objective and science-based manner... [This] must be based on scientific risk assessment and risk management.”<sup>11</sup>

The authors of this *amicus curiae* brief argue that statements of this misinterpret the meanings of key terms of the WTO agreements. Both recent WTO case law and national regulatory practice in the US and EU have been evolving in ways that indicate the need for a more complex understanding of risk assessment as practiced in real-world conditions. This brief analyzes these developments in law and regulatory policy in the light of current social and policy sciences so as to assist the Dispute Settlement Panel in its consideration of the present case—a case in which tensions between different *versions* of what may constitute adequate risk assessment have emerged as central and salient. These differences cannot be understood simply as the results of better or worse scientific risk assessments. Rather, risk assessment can take a number of forms, and the choice of an appropriate method depends on the scientific and regulatory context.

At stake in the resolution of the dispute are the global development of agricultural biotechnology, the democratic governance of risks in world trade, and, not least, the legitimacy of the WTO as an institution of global governance. The GMO dispute implicates not only technical concerns about barriers to trade but also political concerns about a democratic deficit in the design and operation of the WTO itself.

Given these large stakes, it is important that the Panel receive the best possible information and opinion pertinent to the resolution of the case.<sup>12</sup> The authors of this

---

<sup>10</sup> See 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, 323 (2000).

<sup>11</sup> Alan Larson, *Trade and Development Dimensions of U.S. International Biotechnology Policy*, 8:3 ECONOMIC PERSPECTIVES 1, at 7. Available at <http://usinfo.state.gov/journals/ites/0903/ijee/larson.htm> (last visited on Apr. 28, 2004).

<sup>12</sup> See, e.g., Daniel C. Esty, *Linkages and Governance: NGOs At the World Trade Organization*, 19 U. PA. J. INT’L ECON. L. 709, 727 (1998) (arguing that *amicus brief* submissions in general do not disrupt, and by most accounts actually enhance, judicial decision-making and that “within the WTO, this type of contribution would add to the diversity of views available to the decision-makers and thus to the legitimacy of their decisions.”); Ernesto Hernández-López, *Recent Trends and Perspectives for Non-State Actor Participation in World Trade Organization Disputes*, 35 J. WORLD TRADE L. 469, 497 (concluding that “WTO dispute resolution will greatly benefit from increased use of *amicus curiae* participation”); See also Daniel C. Esty, *Non-Governmental Organizations at the World Trade Organization: Cooperation, Competition, or Exclusion*, 1 J. OF INT’L ECON. L. 123, 145 (1998).



*amicus* brief aim to provide such information with respect to two fundamental dimensions of the dispute: (1) the interpretation of the terms ‘science’, ‘risk assessment’, and ‘risk management’ in the context of evaluating agricultural biotechnologies; and (2) the relationship of risk assessment to the broader role of public deliberation and rational decisionmaking in supporting the free flow of trade.

The authors are a team of international scholars of science, technology and society.<sup>13</sup> Our collective scholarly expertise is in the areas of risk and regulation, with individual competences in environmental law, international trade law, scientific advice, comparative studies of risk assessment and management, public understanding of science and technology, and food and agricultural policy. We have contributed extensively to the literature on risk in general and the regulation of GMOs in particular. Our expertise also includes extensive practical experience as advisers to national governments, international organizations, and national science academies, and as officers of scientific professional societies and NGOs actively engaged with GMO issues.

This submission seeks to promote a more informed resolution of the present dispute. In presenting the brief, we draw upon widely accepted understandings of the role of *amici curiae* in complex judicial disputes.<sup>14</sup> In particular, we aim to provide:

- Discussion and citation of relevant social science information and authorities not likely to be contained in the submissions of the parties;
- Arguments based on pertinent social science research that the parties may be unable or reluctant to make in the context of this dispute;
- Assistance to the panel in entering a novel and complex area of dispute resolution requiring interdisciplinary expertise;
- Expert knowledge of risk and regulation that bears on the broader implications of the decision in the present case, and goes beyond the particular interests of the parties;
- Information from social science research bearing on the public understanding and appreciation of issues related to GMOs.

---

<sup>13</sup> See page 1 *infra* for biographical details about the authors.

<sup>14</sup> *Issues of Amicus Curiae Submissions: Note by the Editors*, J. INT’L ECON. L. 701-706 (2000). See also, Dinah Shelton, *The Participation of Nongovernmental Organizations in International Judicial Proceedings*, 88 AM. J. INT’L L. 611, 611 (1994).

## II.

### FACTUAL BACKGROUND TO THE LEGAL CASE

The international trade dispute on Genetically Modified Organisms (GMOs) has been developing for some time. Through the mid-1980s, officials within the EU, the US, and other countries were divided over whether to promote emergent agricultural biotechnologies, and whether to regulate the technology only through its products or also on the basis of production processes. “Genetic modification” (GM), or “genetic engineering,” involves the manipulation of an organism's genetic endowment by introducing or eliminating specific genes through modern molecular biology techniques.<sup>15</sup> The production process of a genetically modified crop involves transgenesis, or the transfer of genes from one plant, animal, or virus into another organism.<sup>16</sup> The “products approach” to regulation assumes that nothing uniquely risky occurs in applying the technology to agricultural production as a function of the GM process itself. Genetically engineered products 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 may entail novel and unique risks to human health and/or the environment even if the product is ostensibly ‘equivalent’ to a non-GM product. Whereas the US in the 1980s adopted the products approach to GM agricultural products, the European Union and its member states have tended to adopt a more precautionary process approach.<sup>17</sup> In 1990, the European Council adopted the first measure aimed specifically at controlling environmental aspects of GMOs, Directive 90/220, which was based on the process approach.<sup>18</sup>

The first GM food marketed in the United States and available for international trade was the “Flavr Savr®” tomato,<sup>19</sup> but it was the subsequent marketing of GM dietary staples such as corn and soybeans that caused strong trade frictions.<sup>20</sup> In 1996, farmers

---

<sup>15</sup> See entry on “Genetic engineering,” University of Texas, *Life Science Dictionary (Online)*, at <http://biotech.icmb.utexas.edu/search/dict-search.phtml?title=engineer>; cf. Art.2(2) of Directive 2001/18/EC of the European Parliament and of the Council, which defines “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.”

<sup>16</sup> See FAO Glossary of Biotechnology for Food and Agriculture, entry for “transgenesis,” at <http://www.fao.org/biotech/find-formalpha-n.asp>.

<sup>17</sup> See, e.g., BERNAUER, *supra* note 1, 44-65; Sheila Jasanoff, *Product, Process, or Program: Three Cultures and the Regulation of Biotechnology*, in RESISTANCE TO NEW TECHNOLOGY: NUCLEAR POWER, INFORMATION TECHNOLOGY, AND BIOTECHNOLOGY 311-331 (Martin Bauer ed., 1995); David Vogel, *Ships Passing in the Night: GMOs and the Politics of Risk Regulation in Europe and the United States*, Paper presented at the workshop on European and American Perspectives on Regulating Genetically Engineered Food, INSEAD (June 2000) at [http://www.insead.fr/events/gmoworkshop/papers/1\\_Vogel.pdf](http://www.insead.fr/events/gmoworkshop/papers/1_Vogel.pdf).

<sup>18</sup> This regulation was Directive 90/220/EEC “on the deliberate release of genetically engineered organisms into the environment.” BERNAUER, *supra* note 1, at 45.

<sup>19</sup> A breed developed by Calgene, Inc., 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 OF GENETIC ENGINEERING 132-136 (1996).

<sup>20</sup> See, e.g., MARSHA A. ECHOLS, FOOD SAFETY AND THE WTO: THE INTERPLAY OF CULTURE, SCIENCE, AND TECHNOLOGY 70-75 (2001); J. McNichol & J. Bensedrine, *National Institutional Contexts and*

in the United States began growing Monsanto Corporation’s GM soybeans.<sup>21</sup> The new seeds had easily passed regulatory muster in the United States, and imports into the EU were also authorized without segregation or labeling under Directive 90/220 in an EC decision dated 3 April 1996.<sup>22</sup> “Almost immediately,” however, “the European decision ignited an insurgency against Monsanto’s new crops and against genetically modified organisms more generally.”<sup>23</sup> Through Eurocommerce – the organization representing European retail, wholesale and international trade – and Eurocoop, Europe-wide “retailers called very strongly for GMO labeling and segregation of products at the source.”<sup>24</sup>

By 1998, there was growing public opposition to GM crops and food across Europe. Whereas in the United States there was little public outcry,<sup>25</sup> in the EU there was increasing debate about the risks of genetic engineering. In discussions about new imports of GM crops, a number of EU Member States expressed concern at the levels of uncertainty and the potential for harmful effects.<sup>26</sup> 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 the Deliberate Release Directive (90/220/EEC) was revised and there was legislation 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 authorizations.<sup>27</sup>

As a result of this policy, no new approvals of GMOs were granted by EU Member States after 1998, giving rise to the charge (denied by the EU) of a *de facto* moratorium. In the meantime, new environmental and food safety rules for GM crops were negotiated, including: (1) the revised EU Deliberate Release Directive (2001/18/EC) on environmental impacts, which came into force in October 2002;<sup>28</sup> and (2) new EU Regulations (Nos 1829/2003 and 1830/2003) concerning the authorization, traceability and labeling of GMOs and GMO derived products, which became law in September 2003 and will come into force in April 2004.<sup>29</sup> This new

---

*Construction of Multilateral Governance Systems: US-EU Struggles Over Labelling Rules for Genetically Modified Food*, Paper presented at the workshop on European and American Perspectives on Regulating Genetically Engineered Food, INSEAD, June 2001, available at <[http://www.insead.fr/events/gmoworkshop/papers/6\\_Bens\\_McNichol.pdf](http://www.insead.fr/events/gmoworkshop/papers/6_Bens_McNichol.pdf)>.

<sup>21</sup> *Id.* (McNichol and Bensedrine) at 7.

<sup>22</sup> Commission Decision 96/281/EC, Official Journal L107 of Apr. 30, 1996, 10, available at <[http://biosafety.ihe.be/GB/Dir.Eur.GB/Market/96\\_281/96\\_281.html](http://biosafety.ihe.be/GB/Dir.Eur.GB/Market/96_281/96_281.html)>.

<sup>23</sup> McNichol and Bensedrine, *supra* note 20, at 7

<sup>24</sup> *Id.*; *See also*, *Agence Europe*, July 2, 1997.

<sup>25</sup> *See* George Gaskell et al., *Worlds Apart? Public Opinion in Europe and the USA*, in *BIOTECHNOLOGY: THE MAKING OF A GLOBAL CONTROVERSY* 351-378 (Martin W. Bauer & George Gaskell eds., 2002).

<sup>26</sup> *The GM Dispute At the WTO: Forcing GM Foods on Europe?* 15 *GENEWATCH-UK* 2 (December 2003).

<sup>27</sup> *Declarations Regarding the Proposal to Amend Directive 90/220/EEC on Genetically Modified Organisms*, 2194<sup>th</sup> Council Meeting (Environment), Luxembourg, June 24-25, 1999, at 23.

<sup>28</sup> At <[http://biosafety.ihe.be/PDF/2001\\_18.pdf](http://biosafety.ihe.be/PDF/2001_18.pdf)> (adding the consideration of indirect effects in risk assessment, a requirement for post-market monitoring, and a 10-year time limit on approval).

<sup>29</sup> At <[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00010023.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf)> and <[http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l\\_268/l\\_26820031018en00240028.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00240028.pdf)>, respectively.

regime requires full traceability, and labeling will now include all GM derived products even if these lack foreign DNA or protein in the final product.<sup>30</sup> Since the revision of the Deliberate Release Directive, GMO applications have been resubmitted. According to some sources, over twenty are currently being assessed.<sup>31</sup> Most recently, a new bill in Germany would allow the cultivation and sale of GM crops so long as clear labeling and traceability are maintained.<sup>32</sup>

Under the WTO's dispute settlement process, the US, Canada and Argentina first called for consultations on 14 May 2003 concerning Europe's so-called 'moratorium' on GM crops.<sup>33</sup> These talks failed almost immediately and the U.S., Canada and Argentina formally requested a panel on 8 August 2003.<sup>34</sup>

In its formal request for a Panel in the case, the complaining Member states cited three measures that they argue have adversely affected exports of agricultural and food products and amount to violations of WTO law: (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"; (2) blockage under EC existing legislation of all "applications for placing [further] biotech products on the market;" and (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."<sup>35</sup> The U.S., Canada, and Argentina claim that these "measures" are inconsistent with particular provisions of the SPS Agreement, GATT 1994, the Agreement on Agriculture, and the TBT Agreement.<sup>36</sup>

---

For an overview of these regulations and 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).

<sup>30</sup> GENEWATCH-UK, *supra* note 26, at 3.

<sup>31</sup> *Id.*

<sup>32</sup> Kristina Merkner, "Germany to allow import of GMOs," F.A.Z. WEEKLY, 16 January 2004, 4. Available at <<http://www.iht.com/pdfs/faz/04-FAZ-Weekly-KW03.pdf>>.

<sup>33</sup> *European Communities - Measures Affecting the Approval and Marketing of Biotech Products* [Hereinafter cited as *Biotech Products*], Request for Consultations by the United States, 5/20/03, available through WTO website, at <[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_subjects\\_index\\_e.htm#gm0s](http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#gm0s)>

<sup>34</sup> *See supra* note 2.

<sup>35</sup> *Biotech Products*, Request for the Establishment of a Panel by the United States, WT/DS291/23 (Aug. 8, 2003).

<sup>36</sup> Agreement on Technical Barriers to Trade, Apr. 15, 1994, WTO Agreement, Annex 1A, at <[http://www.wto.org/english/docs\\_e/legal\\_e/final\\_e.htm](http://www.wto.org/english/docs_e/legal_e/final_e.htm)> [hereinafter TBT Agreement].

### III.

#### RISK-BASED DECISIONMAKING: CONCEPTUAL FOUNDATIONS

The conventional understanding of risk is the statistical probability of a harmful event, with the corollary that *risk assessment* is concerned with the identification and evaluation of the potential for such events in particular contexts.<sup>37</sup> Research on the actual regulation of risk, however, suggests that such a probabilistic understanding is misleading and incomplete, particularly in relation to fields such as GMO regulation that are characterized by high technical uncertainties and low consensus on methods and values. An alternative, and more nuanced, view of risk and of risk assessment has developed in the social science literature on risk and regulation. This alternative comprises several salient components.

##### A. Value Judgments in Risk Assessment

Within international regulatory circles, risk assessment has often been represented as an objective, science-based, value-free analytic exercise requiring precise identification of possible harms to human health, agricultural production, and the environment.<sup>38</sup> It has been seen as requiring formal, expert-based assessments of the likelihood of the identified harms. A distinction has been drawn between processes of *risk assessment*, which is considered to be a technical operation independent of political choices, and the *management* of those risks (e.g., setting an “appropriate level of protection,” making judgments that balance risks against anticipated benefits, and choosing an appropriate SPS measure).<sup>39</sup> Public values and concerns are thought to be relevant and appropriate only in the phase of risk management, which follows and is procedurally separated from risk assessment.

These propositions are inconsistent with state-of-the-art scholarship on risk and regulation in both the sciences and social sciences.<sup>40</sup>

##### 1. Risk assessment versus risk management

According to a growing body of social scientific research and expert panel reports, judgment enters into both risk assessment and risk management. In the *Hormones* case, the Appellate Body rejected the strict separation between risk assessment and risk management — the former based on quantitative analysis of risks and the latter involving judgments of value — in the determination of the best strategy to manage risk.<sup>41</sup> This approach should be supported because it is neither feasible nor appropriate to separate risk analysis into a purely technical phase (assessment) and a subsequent

---

<sup>37</sup> See, e.g., World Health Organization, *Application of Risk Analysis to Food Standards Issues* (Report of the Joint FAO/WHO Expert Consultation, Geneva) (March 1995), at 6.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> See, e.g., Karsten K. Jensen, Peter Sandøe, *Food Safety and Ethics: The Interplay between Science and Values*, 15 J. AGRICULTURAL & ENV'TL ETHICS 245-253 (2002); C. BRUNK ET AL., VALUE ASSUMPTIONS IN RISK ASSESSMENT (1991).

<sup>41</sup> *Hormones*, Report of the Appellate Body, para. 181. See also Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L.R. 2329, 2343 (2000).

political phase (management). A strict division between the technical and the political impedes public deliberation on important dimensions of expert judgment and interferes with the recognition and resolution of both scientific and regulatory issues. Indeed, 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 judgments to interact to resolve unavoidable uncertainties in the decision-making process.”<sup>42</sup>

## 2. The FAO and Codex Alimentarius Commission on risk assessment

As a mechanism for encouraging the harmonization of food safety standards across the regulatory regimes of its Members, the SPS Agreement text gives special authority to the Codex Alimentarius Commission (Codex).<sup>43</sup> The Codex’s food safety standards and guidelines provide a safe harbor against SPS or GATT 94 challenge, so long as Members’ regulations are ‘based on’ those standards.<sup>44</sup> The use of the Codex standards as a baseline means that the SPS Agreement recognizes their scientific and regulatory reliability.

In 2002, however, an expert panel of the Food and Agricultural Organization (FAO) – one of the Codex Alimentarius Commission’s founding bodies – convened an expert panel specifically charged to examine the relationship between ethics and food safety.<sup>45</sup> The panel concluded that risk assessment cannot be separated from ethics: risk assessment is and must be based on shared values. In its report, the FAO Expert Panel highlighted that value judgments enter into each risk analysis. Further, the panel specified several values that are implicit in all risk-based decisions about food safety:

1. *Trust*. In the real world citizens have neither the time nor the skills to collect and analyze the information required to make decisions about which foods are safe to eat. Decisions are delegated to specialized government agencies, and it is essential that citizens have trust in the actions and decisions made by such agencies. Such trust is built up over time according to different criteria in different regulatory contexts, both nationally and internationally.

---

<sup>42</sup> Ellen K. Silbergeld, *Risk Assessment and Risk Management: An Uneasy Divorce*, in ACCEPTABLE EVIDENCE: SCIENCE AND VALUES IN RISK MANAGEMENT 99-114 (Deborah G. Mayo & Rachele D. Hollander eds., 1991), at 99.

<sup>43</sup> The Codex was created in 1963 by the Food and Agricultural Organization (FAO) and the World Health Organization (WHO) 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 the Codex 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.” See The Codex Alimentarius Commission website home page, at <<http://www.codexalimentarius.net/>>.

<sup>44</sup> SPS Agreement, *supra* note 4, at Preamble and Art. 3(1-3). It should be mentioned that the words ‘based on’ in this context have not been interpreted by WTO judges. However, the Appellate Body has interpreted the language ‘based on’ in the context of Art.5(1) (which states ‘Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks . . .’), requiring that there be a ‘rational relationship’ between the Codex standard and the measure adopted by the Member state. This interpretation of the ‘based on’ language carries its own ambiguities and problems. See § IV.B *infra*.

<sup>45</sup> Food and Agriculture Organization of the United Nations (FAO), *Report of the FAO Expert Consultation on Food Safety: Science and Ethics* (September 2002).

2. *Optimization versus informed consent.* Optimization of risks and benefits usually involves a series of tradeoffs in which policies are only justified if they produce the optimal ratio of risks and benefits. In contrast, an ethic of informed consent requires that people bear given risks (however great or trivial) voluntarily and knowingly. From this perspective, optimization is inappropriate since it disregards what are seen as basic rights of citizens. The SPS agreement implicitly recognizes this conflict between optimization and informed consent in its insistence that risk decisions be science-based, even as it recognizes that appropriate levels of protection must be established in each nation, according to national political judgments.

3. *Equity.* Equity refers to the distribution of risks and benefits associated with a particular food safety decision.<sup>46</sup> Food safety decisions may favor the interests of one nation, region, class, age group, or ethnic group at the expense of another. For example, a food safety decision in favor of the unrestricted use of GM crops may preclude organic production in the same region. Indeed, even scientific data may favor those nations that have greater means to collect the data necessary to engage in formal risk assessment.

This report also concluded that, depending on which values are emphasized, different data and methods may be used in risk assessment, leading to different estimates of risk. For example:

1. Hazard identifications can be based on mortality or morbidity, economic consequence, or other perceived values;
2. A choice may be made regarding whether hazards are based on ‘best practice’ or ‘typical use’;
3. Different extrapolation models may be required when moving from animal to human toxicity studies,<sup>47</sup> when shifting from micro-ecosystems to farm-scale agricultural environments, or when extending dose-response curves from high to low doses;
4. Populations from which exposure estimates are drawn may be selected in different ways;
5. The level and type of precaution appropriate to a given situation may vary.

In July 2003, the Codex Alimentarius Commission built on this report when it codified a notion of proper risk analysis that emphasizes the importance of interaction

---

<sup>46</sup> See also, Tsunehiro Otsuki et al., *A Race to the Top? A Case Study of Food Safety Standards and African Exports*, World Bank Research Paper No 2563 (2001), at [http://econ.worldbank.org/files/1424\\_wps2563.pdf](http://econ.worldbank.org/files/1424_wps2563.pdf) (arguing that the reduction in aflatoxin levels recently required by EU regulations trivially reduces risks for Europeans even while it increases them significantly for Africans).

<sup>47</sup> See, e.g., L. S. Gold et al., *Extrapolation of Carcinogenicity Between Species: Qualitative and Quantitative Factors*, 12 RISK ANALYSIS 579-588 (1992).

between ‘risk assessors’ and ‘risk managers.’ In adopting “Working principles for risk analysis for application in the framework of the Codex Alimentarius,” the Codex incorporated the core idea that risk analysis “is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.”<sup>48</sup> Moreover, such interaction is essential in shaping a “systematic, complete, unbiased, and transparent” risk assessment.<sup>49</sup> As a practical matter, risk managers are charged with setting certain normative priorities in constructing useful risk assessment. For instance, in the view of the Codex, risk managers need to prioritize the value of consumer health as they carry out their role, a role that includes defining “risk assessment policy.”<sup>50</sup>

## **B. Contextual Contingency, Framing and Regulatory Styles**

A significant body of social science has compared the treatment of risk-based decisionmaking across different national political systems.<sup>51</sup> Several findings of this work are relevant in the present case. All point to the variability of the concept of risk assessment and its dependence on a variety of contextual factors.

### **1. Dependence of risk analysis on political and cultural context**

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 (the starting point of all formal risk analysis<sup>52</sup>) and subsequent attempts to assess the magnitude, seriousness, and distribution of harms. Accordingly, risk assessment frequently varies across national regulatory systems. Judgments about the same hazard, based on the same scientific knowledge and evidence, do not always lead to the same estimates of possible harm. As regulatory experience with nuclear power demonstrates, informed citizens in one democratic society may discern insupportable risks in a technology assessed as safe by their equally informed counterparts in another democratic society<sup>53</sup>; nor do regulatory authorities in different national contexts agree on the threshold question of whether a hazard exists in a given case.<sup>54</sup>

---

<sup>48</sup> Codex Alimentarius Commission, *Report of the Twenty-sixth Session* (Rome, 30 June – 7 July 2003), 125-129, at Art. 14.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at Art. 13-16, 27.

<sup>51</sup> See, e.g., Michael Power & Lynn S. McCarty, *A Comparative Analysis of Environmental Risk Assessment/Risk Management Frameworks*, 32 ENV'T L. SCI. & TECH. 224, A-231 (1998); Sheila Jasanoff, *Technological Risk and Cultures of Rationality*, in NATIONAL RESEARCH COUNCIL, INCORPORATING SCIENCE, ECONOMICS, AND SOCIOLOGY IN DEVELOPING SANITARY AND PHYTOSANITARY STANDARDS IN INTERNATIONAL TRADE 65-86 (2000); DAVID VOGEL, NATIONAL STYLES OF REGULATION: ENVIRONMENTAL POLICY IN GREAT BRITAIN AND THE UNITED STATES (1986).

<sup>52</sup> US NATIONAL RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* (1983).

<sup>53</sup> DOROTHY NELKIN & MICHAEL POLLACK, *THE ATOM BESEIGED: EXTRA PARLIAMENTARY DISSENT IN FRANCE AND GERMANY* (1981), especially 107-118; ANGELA LIBERATORE, *THE MANAGEMENT OF UNCERTAINTY: LEARNING FROM CHERNOBYL* (1999).

<sup>54</sup> See, e.g., R. BRICKMAN ET AL., *CONTROLLING CHEMICALS: THE POLITICS OF REGULATION IN EUROPE AND THE UNITED STATES* (1985).



## 2. Framing

It is widely acknowledged in the policy literature that hazard identification is not simply a matter of seeing a problem that exists in the real world, but that it involves a process of selection and characterization known as *framing*.<sup>55</sup> Frames are “principles of selection, emphasis, and presentation composed of little tacit theories about what exists, what happens, and what matters.”<sup>56</sup> What each analyst perceives and judges to be important is a function not only of what happened but also of the ‘conceptual lenses’ used to view the evidence.<sup>57</sup> Framing a problem, in other words, sorts experiences of the world into clearly demarcated patterns of causes and effects, producing coherent problem definitions from what might otherwise be seen as disconnected phenomena or events.

Framing is integrally related to the possibility of control. Problems that have been framed, with particular causal explanations, can also in principle be managed or solved by addressing the causes so identified. At the same time, framing, by its nature, is also an instrument of exclusion. To bring some parts of an issue within a problem frame—to render the issue comprehensible and interpretable—other parts are invariably left out as irrelevant, incomprehensible or uncontrollable.

This dual role of framing, as a device for making sense of reality and of excluding what does not count or make sense, has led to systematic cross-national variation in the assessment of health, safety and environmental risks. In the case of biotechnology, governments of democratic societies have not framed the problems posed by technological developments in the same ways. Such variations have been specifically observed and documented in relation to the risks of GMOs.<sup>58</sup> We note that such divergent framings are not intrinsically right or wrong. Rather, they reflect the institutional capabilities and cultural logics operating in different societies.<sup>59</sup>

## 3. U.S. and Europe have different styles of science-based regulation

Risk assessment reflects basic differences in national styles of regulation.<sup>60</sup> In particular, US and European concerns have diverged at the stage of hazard identification, with different hazards commanding different levels of public concern and attention across countries. Thus, in the context of environmental protection, cancer has been more a concern in the US than in Europe and risks to forests and

---

<sup>55</sup> See, e.g., DONALD A. SCHON & MARTIN REIN, *FRAME/REFLECTION: TOWARD THE RESOLUTION OF INTRACTABLE POLICY CONTROVERSIES* (1994); Brian Wynne, *Frameworks of Rationality in Risk Assessment*, in *ENVIRONMENTAL THREATS: ANALYSIS, PERCEPTION, MANAGEMENT* 85-101 (J. Brown ed., 1989); NATIONAL RESEARCH COUNCIL, *UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY* (1996); Sheila Jasanoff, *Technologies of Humility: Citizen Participation in Governing Science*, 41 *MINERVA* 233, 240-241 (2003) (arguing that frame analysis is a critically important tool of policy-making).

<sup>56</sup> T. GITLIN, *THE WHOLE WORLD IS WATCHING: MASS MEDIA IN THE MAKING AND UNMAKING OF THE NEW LEFT* 6 (1980).

<sup>57</sup> GRAHAM ALLISON, *ESSENCE OF DECISION: EXPLAINING THE CUBAN MISSILE CRISIS* (1971), *especially* introduction.

<sup>58</sup> See, e.g., Jasanoff, *supra* note 17.

<sup>59</sup> LIBERATORE, *supra* note 53, at 225-247.

<sup>60</sup> See VOGEL, *NATIONAL STYLES*, *supra* note 51.

countryside have attracted more attention in some European countries.<sup>61</sup>

Approaches to assessing similar hazards have also diverged. US agencies on the whole have made greater use than European agencies of formal and quantitative methodologies in assessing risks, costs and benefits for purposes of regulation. Even in instances where US and EU scientists have agreed on the nature of the hazard, they have not always agreed on how the hazard should be managed. In the case of food, for example, many EU nations permit the sale of fresh cheeses made from unpasteurized milk, while they are banned from the US.<sup>62</sup>

These systematic variations demonstrate that risk assessment includes not only an objective, science-based analysis of technical evidence; it also encompasses political understandings about appropriate forms and means of governance that influence technical analysis even though they are conventionally seen as falling within the domain of risk management.

### **C. Public Participation**

A broad consensus of science-policy experts recognizes the importance of bringing public deliberation into the process of risk assessment. Indeed, as discussed below, an inclusive procedural approach to risk assessment, as distinct from the hitherto conventional model of an objective evaluation of risk probabilities by technical experts, has been proposed, and in some cases implemented, in regulatory settings within the United States and abroad.

#### **1. U.S. National Research Council**

In the United States, the National Research Council (NRC) has often been called on to consider how to improve risk analysis for national public health, safety and environmental regulation. The NRC's *Understanding Risk: Informing Decision in a Democratic Society*<sup>63</sup> 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.<sup>64</sup>

---

<sup>61</sup> A four-country comparison of US and European chemical regulation in the mid-1980s showed that European nations neither gave the same priority to carcinogens as did the US nor developed comparable programs of testing and risk assessment. See BRICKMAN, *supra* note 54. Note also that despite overall similarities, significant differences even exist between the US and Canada on seemingly uncontroversial issues such as the proper daily intake of Vitamin C. See J. H. HULSE, SCIENCE, AGRICULTURE, AND FOOD SECURITY 62 (1995).

<sup>62</sup> See, e.g., L. Busch, *Témerité Américaine et Prudence Européenne?*, 339 LA RECHERCHE 19-23 (2001).

<sup>63</sup> See NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY ix (1996).

<sup>64</sup> *Id.* at 3.

In making the important role of deliberation and public consultation explicit, this report built upon other canonical works on risk by the NRC, one of which concludes that “the first and probably most important step in effective risk assessment and risk management is to establish public participation that involves all the stakeholders.”<sup>65</sup>

## 2. Defining what is ‘at risk’

Defining what exactly is ‘at risk’ is properly a matter of democratic value-commitment and of whatever process is appropriate to meet these needs. Scientific risk assessment necessarily involves the prior selection of the objects of analytic attention, reflecting what is collectively valued, and thus worth possible protection. For example, limiting the probabilistic measure for risk assessment to human mortality tacitly places low or zero value on protection of non-humans, as well as on protection of humans from non-fatal forms of harm. Even if morbidity (for example, pain associated with illness) is considered as well, the tradeoff between mortality and morbidity involves tacit value judgments. There is no guarantee that such technical practices reflect wider societal values and priorities, or defensible approximations to these, without adequate public consultation.

## 3. Scientific and political value of participation

The importance of public attitudes and perceptions is only heightened in the GMO case, where scientific knowledge is neither uniform nor complete, and because food has a special cultural status in human society.<sup>66</sup> It has been increasingly recognized by international bodies, and even regulatory bodies in the US, that science and the criteria defining rational uses of science in regulation and policy have to take account of such public concerns for reasons of scientific robustness and democratic legitimacy.<sup>67</sup> 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

---

<sup>65</sup> NATIONAL 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 on page 3 that “. . . risk assessments concerning possible future outcomes at DOE [i.e., the US 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.” See also NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 267 (1994) (stating that for the United States Environmental Protection Agency’s risk assessment of hazardous air pollutants, “the EPA 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”).

<sup>66</sup> ECHOLS, *supra* note 20, at 148-155.

<sup>67</sup> See Codex Alimentarius Commission on “risk communication” in the GMO context, *Report of the Twenty-sixth Session* (Rome, 30 June – 7 July 2003), 125-129, at para. 37 (recognizing the need to involve all interested parties and exchange information in relation to their concerns about food risks). See also, NATIONAL ACADEMY OF SCIENCES, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION (2002); GM Science Review Panel, *GM Science Review An open review of the science relevant to GM crops and food based on interests and concerns of the public* (Second Report, January 2004), at <http://www.gmsciencedebate.org.uk/report/default.htm#second>, especially § 1, “The Significance of the Public Debate For the Science Review”; EC Communication, *Life-Sciences and Biotechnology – a Strategy for Europe*, (2002/C 55/03, 2 March 2003), at [http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002\\_0027en01.pdf](http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf) (especially § 4).

engagement with public values and concerns.”<sup>68</sup> Supposedly singular versions of ‘sound science’ have changed over time in Europe, revealing unsuspected connections between science and values, due in part to public pressure and controversy.

---

<sup>68</sup> *Id.* (GM Science Review), at 12.

#### IV.

##### LANGUAGE IN THE AGREEMENTS APPLIED THE GMO CASE

Two points should be clear from the preceding discussion: (1) the integration of risk assessment into the regulatory architecture of states is a value-laden, political, and culturally influenced process; accordingly, (2) the science of risk assessment is influenced by the deliberative processes of regulation itself.

‘Sound science’ in the regulatory sphere, therefore, should not be conceived of as a body of knowledge fixed at a particular moment in time through a universally valid expert analytical process. Likewise, it should not be conceived as a body of knowledge or a set of methods 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 normative priorities, culture, and collective experience. Its development necessitates public consultation and deliberation, especially in the case of new technologies, such as GM, marked by low scientific certainty and low consensus on values. The validity of risk assessment is measured, ultimately, only by the confidence and trust it inspires—not only among experts but also in the wider public.

It follows that legal interpretations of the ‘science-based’ disciplines of WTO law should keep these realities of regulatory science in constant view. They should inform the understanding of key legal terms such as ‘risk’, ‘based on a risk assessment’, and ‘scientific justification’, just as they should guide the application of standards employing these terms. If the realities of regulatory science are kept in mind, the cross-nationally divergent development of GMO regulation in this case should not be held to violate the science-based and risk-based provisions of WTO law.

We now consider how such an enriched understanding of risk and risk assessment might operate in the present *Biotech Products* case, when applied in the context of the Sanitary and Phytosanitary Agreement – the key instrument guiding the WTO’s jurisdiction in this sphere.

##### A. ‘Sufficient scientific evidence’ (2.2) and ‘Scientific justification’ (3.3)

The quality and quantity of scientific evidence on the health and environmental health risks of GMOs, because it is low certainty / low consensus and because risk assessment methodologies are undergoing active development, establishes that a “rational relationship” does exist between the regulatory activity at issue and the state of scientific knowledge. Where risk methodology is itself uncertain, it makes little sense to require basing science policy on an overly formal and pre-determined conception of risk assessment. Because ‘rational basis’ is the test developed by previous Panels and Appellate Bodies, these ‘science-based’ disciplines should be deemed satisfied.

Article 2.2 of the SPS Agreement states: “Members shall ensure that any sanitary or phytosanitary measure . . . is not maintained without sufficient scientific evidence,

except as provided for in paragraph 7 of Article 5.” In *Varietals*, the AB interpreted this language to require “that there be a rational and objective relationship between the SPS measure and the scientific evidence”<sup>69</sup> and that “the 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.”<sup>70</sup> Finally, the Appellate Body has 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.”<sup>71</sup>

In determining whether such a rational relationship exists, WTO judges have emphasized the importance of considering the “quality and quantity of scientific evidence.”<sup>72</sup> The AB 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 “in some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty.”<sup>73</sup> The ‘rational relationship’ test must be understood within the object and purpose of the treaty, which in its preamble reinforces the right of Members to set appropriate levels of protection so long as they avoid arbitrary discrimination. Where scientific certainty and public consensus are low, regulators must be allowed to take public value choices into strong consideration when setting “appropriate levels” and establishing measures. Indeed, this power falls within the scope of their treaty-given discretion to set “appropriate levels” as defined in Article 3.3, footnote 2.<sup>74</sup>

Finally, the rational relationship test should also be understood within the context of what the Codex Alimentarius Commission has said about the role of science versus other legitimate factors in setting food safety standards.<sup>75</sup> In its “Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account,” the Codex stated that standards are “to be based on sound scientific principles,” but that “other legitimate factors” (OLFs) may be added where appropriate for protecting consumers and promotion of fair practices.<sup>76</sup> The Codex explicitly includes in its list of legitimate

---

<sup>69</sup> *Japan: Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter *Japanese Varietals*], para. 84.

<sup>70</sup> *Id.* at para. 74.

<sup>71</sup> *Id.* at para. 79.

<sup>72</sup> *Id.* at 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*, *supra* note 8, Report of the Appellate Body, at para. 162.

<sup>73</sup> *Hormones*, *supra* note 9, Report of the Appellate Body, at para 194.

<sup>74</sup> The SPS Agreement, at fn.2, defines the requirement of ‘scientific justification’: “there 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*” (emphasis added).

<sup>75</sup> See the explanation of the special relationship between the Codex and the SPS requirements, § II.A.2 *supra*.

<sup>76</sup> See CODEX ALIMENTARIUS COMMISSION, PROCEDURAL MANUAL 165 (12<sup>th</sup> ed.).

OLFs: (1) what is economically practicable, (2) what is technically feasible, and (3) legitimate concerns of governments that do not have worldwide implications.<sup>77</sup>

The ‘quality and quantity of the scientific evidence’ involved in GMO case should encourage the consideration of the above sorts of ‘Other Legitimate Factors’ by regulatory decision-makers, and renders regulatory divergence more justifiable. Three qualities of GMO knowledge in particular suggest that the European response to GMOs should be deemed ‘rationally related to the science’:

### **1. Science of GMOs is low certainty, low consensus**

When panels seek to decide whether a measure is rationally related to science, it is crucial that they consider the extent to which there is scientific certainty and consensus on the issue at hand. The more uncertainty and the less consensus in the knowledge, the broader the range of ‘appropriate levels’ of food safety protection and regulations that should be deemed rational.<sup>78</sup>

In contrast to earlier cases such as *Asbestos* or *Salmon*, the GMO dispute involves scientific knowledge that is characterized by *low certainty* about facts and *low consensus* on methods. In this context, the scientific basis for regulation, and risk analysis, is fluid and changing even within national decision-making contexts.<sup>79</sup> International guidelines for the risk analysis of biotech foods are still emerging and not yet universally accepted.<sup>80</sup>

We further note that in such an area of low certainty and low consensus, public deliberation and input will and should play an essential role in influencing levels of protection deemed appropriate by Members; such a public role is within the Codex Commission’s own conception of sound science policy.

### **2. Risk assessment of GMOs is an evolving technical practice**

Risk assessment of GMOs is an evolving technical practice. The underlying disciplinary scientific knowledges involved in assessing the risks of GMOs – some combination of genetics, agricultural sciences, rural sociology, etc. – have not reached maturity. The agrifood biotechnologies available to scientists today cover a far wider range of techniques and permit more kinds of modification to food organisms than ever before.<sup>81</sup> No single form of risk assessment can incorporate all the known or potential risks that these products and processes pose as uses, functions, volumes, and

---

<sup>77</sup> *Id.*

<sup>78</sup> See, e.g., Walker, *supra* note 5, at 280-282 (arguing at 282 that “it would be prudent to restrict factfinding to a zone of reasonableness when risk assessment determinations involve scientific uncertainty”).

<sup>79</sup> See discussion of regulatory development within the US, *infra* at § IV.D.4(b).

<sup>80</sup> See at § IV.D.4.(c) *infra*.

<sup>81</sup> Plants may be modified using gene guns, Agrobacterium, protoplast fusion, microinjection and other techniques. The types of products now produced and in the pipeline varies from older technologies such as herbicide (glyphosate) tolerance and insect resistance (Bt insertion) to modifications designed to improve nutrition, enhance flavor, remove toxic substances and allergens, improve virus resistance, create new pharmaceutical compounds, and create industrial compounds with greater efficiency. See, e.g., FRUIT AND VEGETABLE BIOTECHNOLOGY (V. Valpuesta ed., 2002); M. CHRISPEELS & D. SADAVA, PLANTS, GENES, AND CROP BIOTECHNOLOGY (2003).

post-harvest handling and processing vary widely among plants and growing environments.

### **3. Risk assessment of GMOs should be locally based**

Risk assessment of GMOs needs to be locally based. Unlike food safety risk assessments, assessments of the environmental risks of GM crops must always be locally specific. For instance, the impact on consumer health of using Sodium Nitrite as an anti-bacterial agent, or Saccharin as an artificial sweetener, will almost certainly vary within a national population, but it may well be similar across different countries. The impact of GM crops on biodiversity, however, could vary within and between different jurisdictions, as a function of the ecosystems into which they might be introduced. It would therefore be unrealistic to envisage a global risk assessment that could assess the environmental risks posed by particular GM varieties in all, or even many, environments. It is consistent with existing environmental scientific principles to require testing of GM crops in local environments before approval.

## **B. SPS Measures Must Be Based On A Risk Assessment (Articles 5.1, 5.2)**

Article 5.1 of the SPS Agreement states that “Members shall ensure that their sanitary or phytosanitary 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.” In *Hormones*, the Appellate Body has stated that: “The requirement that an SPS measure be ‘based on’ a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment.”<sup>82</sup> The term in Article 5.1 “*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 AB itself highlighted that “determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects.”<sup>83</sup>

### **1. Regulatory and scientific developments in the EU**

The circumstances surrounding the alleged EU and EU member-state moratoria suggest that these ‘measures’ – if they are deemed to be measures – were appropriately based on the risk assessment procedures being implemented during this period of fluid scientific and regulatory development.<sup>84</sup> The sequence of interactions among the public, expert, and official spheres during the alleged EU “moratorium” has contributed not only to a greater understanding of GM risk parameters, but also the clarification of important gaps in knowledge.<sup>85</sup> Therefore, notwithstanding its unplanned character and the fact that the so-called moratorium *preceded*, in part at least, conclusive confirmation of the empirical substance of knowledge gaps – the alleged “moratorium” itself was *based on* an assessment meeting the criteria of

---

<sup>82</sup> *Hormones*, Report of the Appellate Body, at para. 163.

<sup>83</sup> *Id.* at para. 194.

<sup>84</sup> For a detailed description of scientific and regulatory developments in the EU around GMOs, see § IV.D.4(a) *infra*.

<sup>85</sup> *Id.*



Article 5.1.

**2. Risk assessment under the SPS permits qualitative factors**

The term ‘risk assessment’ in the SPS text and case law suggests that the EU GMO moratoria were based on risk assessment procedures appropriate to the circumstances. Specifically, the case law is clear that the ‘evaluation of likelihoods’ required in risk assessment under the SPS can involve qualitative factors such as values, framing, and cultural specificity; and may be expressed in non-quantitative terms.

The term risk assessment is defined in Annex A,4 of the SPS Agreement.<sup>86</sup> Although Articles 5.1-5.3 of the SPS agreement establish a number of required factors in a risk assessment, the Appellate Body in *Hormones* has made it clear that this is not an exhaustive list.<sup>87</sup> Further, the same opinion embraces the proposition that non-quantitative factors are relevant and legitimate considerations for risk assessment, stating that Articles 5.2 and 5.3 do not “exclude *a priori*, from the scope of a risk assessment, factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences.”<sup>88</sup> In a related vein, the AB made it clear that ‘risk assessment’ as it is defined by the SPS agreement does not require the scientific establishment of some sort of minimum threshold of quantifiable risk.<sup>89</sup> Likewise, the requirements of ‘harm identification’ and ‘likelihood’ evaluation required by Article 5.1 under *Salmon* do nothing to require rigid processes of quantification.<sup>90</sup> All these interpretations are consistent with social science analyses of the judgmental and context-dependent character of risk assessment.

**3. Risk embedded in the social system**

The SPS Agreement text uses the word ‘risk’ a number of times without specifically defining it. However, the Appellate Body has stated that risk should be “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

---

<sup>86</sup> The definition of risk assessment in Annex 4A of the SPS Agreement reads: “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 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.”

<sup>87</sup> The Appellate Body has stated explicitly that “there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list.” *Hormones*, Report of the Appellate Body, at para.187.

<sup>88</sup> *Id.* at para. 253 (j).

<sup>89</sup> “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.*

<sup>90</sup> In the *Salmon* case, *supra* note 6, the Appellate Body stated that “a 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.” Para. 121.

die”(emphasis added).<sup>91</sup> In other words, Member States are encouraged to consider how risk arises within patterns of human behavior and practice in societies. This point needs to be factored into evaluations of the adequacy of risk assessments.

Risks are always created and distributed in social systems, including the organizations and institutions that are supposed to control the risky activity.<sup>92</sup> As a consequence, the magnitude of a physical risk is, *inter alia*, a direct function of qualities and characteristics of the social relations and processes within those systems. This canonical finding from the social studies of risk has been borne out in recent cases. For instance, the official report on the Columbia space shuttle accident recognized the important role of NASA’s history, culture, and organizational realities. Indeed, the sources of risk *within the organizational structure* of the space program were emphasized as the investigation proceeded.<sup>93</sup>

The Chernobyl disaster demonstrated to risk assessors that the risks associated with nuclear power could no longer be evaluated outside the political and organizational structures in which they operate.<sup>94</sup> Experiences with BSE further illustrate how physical risk should not be viewed in isolation.<sup>95</sup> Similarly, it is now widely agreed that the risks of chemical pesticides cannot be adequately assessed without knowledge of how agribusiness, farmers, food producers, and consumers will use the pesticides and the products containing pesticide residues.

#### 4. The role of public deliberation in risk assessment

We have already stated above how expert committees within the United States regulatory system have emphasized public participation and stakeholder deliberation as central components of successful risk-based decisionmaking.<sup>96</sup> The SPS case law can and should be read to support this view, especially in the context of low certainty,

---

<sup>91</sup> *Hormones*, Report of the AB, at para. 187.

<sup>92</sup> See, e.g., U. BECK, *RISK SOCIETY: TOWARDS A NEW MODERNITY* (1992); C. PERROW, *NORMAL ACCIDENTS* (1984); *SOCIAL THEORIES OF RISK* (S. Krimsky & D. Golding eds., 1992).

<sup>93</sup> “The 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 accident.” NASA, *Columbia Accident Investigation Report*, Vol.1, at 9. Available at <[http://anon.nasa-global.speedera.net/anon.nasa-global/CAIB/CAIB\\_lowres\\_intro.pdf](http://anon.nasa-global.speedera.net/anon.nasa-global/CAIB/CAIB_lowres_intro.pdf)> (visited 4/29/04).

<sup>94</sup> LIBERATORE, *supra* note 53, especially at 225-247.

<sup>95</sup> In the BSE case, scientific advice to the UK government about the risks from BSE in British beef – from the Southwood Committee in 1989 and from the Spongiform Encephalopathy Advisory Committee (SEAC) from 1990 to 1995 – was predicated on the assumption that all the regulations would be, and were being, fully enforced. Because the official narratives were so reassuring, however, compliance and enforcement were often incomplete. When SEAC eventually learned of the scale of the enforcement deficit, its assessment of the risks from beef was revised. See Lord Phillips of Worth Matravers et al., *The BSE Inquiry Report* [hereinafter *BSE Inquiry Report*], at <http://www.bseinquiry.gov.uk/report/index.htm> (October 2000), at Executive Summary, §4, “Assessment of risk posed by BSE to humans.” This inquiry was announced in the UK Parliament on 22 December 1997, and set up on 12 January 1998, to establish and review the history of the emergence and identification of BSE and new variant CJD in the UK, and of the action taken in response to it up to 20 March 1996.

<sup>96</sup> See § III.C.1 *infra*.

low consensus knowledge of risks.

The Appellate Body’s conclusion that risk formulation should address “real world” situations in which people live, work and die – i.e., in sites of human practice and social systems – carries an important corollary: inclusion of these public voices as a component of ‘risk assessment.’ Scientific risk assessment often presumes radically simplified contexts of production in which complex organizational and behavioral factors are not fully accounted for. This provides rational support for giving greater practical standing to public knowledge and attitudes in risk assessment, so that real world factors in their variety and complexity can be adequately considered.<sup>97</sup>

Relevant public knowledge may include varieties of practical expertise, as well as everyday experience of how formal rules and regulatory norms are implemented in practice.<sup>98</sup> Neglect or non-recognition of such knowledge in risk assessment is not only a threat to analytic rigor and validity, but also adversely influences public attitudes to risk and trust in technology management.

### **5. Retaining democratic elements in regulatory process**

Public consultations on GMOs have been essential in contributing to the identification of risks as they arise in real world contexts. The need for public consultation on GMOs has been implicitly acknowledged in both the US and the EU, though perhaps not expressly articulated as such. Important changes of focus in EU and US risk assessment policy<sup>99</sup> have been the result of public controversy and sometimes accidental recognition of new risk questions, rather than the result of a supposedly determinate scientific process. To find that planned public consultations were not appropriately a component of risk assessments would be to undermine important democratic elements in the regulatory processes of Member States.

There are frequent mismatches between official risk assessment and public attitudes with respect to the framing of the risk issues to be addressed, but evidence indicates that public consultation is not antithetical to science. It is striking that when scientific review is allowed to range more freely in a domain like GM crops and foods, as in the 2003 UK GM Science Review,<sup>100</sup> which was not confined to case-by-case regulatory decisionmaking, the collective expert identification of areas of scientific uncertainty and concern converged with expressed public concern over such matters as unknown environmental and health consequences. These results underscore the importance of public review in securing robust and legitimate assessment of uncertainties.

---

<sup>97</sup> See, e.g., ECHOLS, *supra* note 20, at 154 (arguing that “consumers should be permitted to comment on the existence and seriousness of a possible hazard, to present research and otherwise help define the hazard,” and the public should be involved “in the design of the risk assessment, the judgements made concerning it and the subsequent discussion about whether to rely on it”).

<sup>98</sup> E.g., risk assessment of chemical pesticides, BSE transmission, and GM food-chain behaviors led to regulations, which were unrealistically demanding to implement and were violated in practice.

<sup>99</sup> See § IV.D.4 *infra*.

<sup>100</sup> GM Science Review, *supra* note 67, discussed in more depth in § IV.D.4(a) *infra*.

## C. Discrimination Disciplines

### 1. Introduction

GM and non-GM agricultural products are neither ‘comparable situations’ under Article 5.5 of the SPS, nor ‘like products’ under Article III.4 of the GATT. Finding a violation in the non-discrimination disciplines in both the SPS Agreement and the GATT requires that the challenged measure treats ‘comparable situations’ or ‘like products’ differently. Both discrimination disciplines are at play in this case, Article 5.5 of the SPS and Article III.4 of the GATT, require a threshold finding that genetically modified products are not meaningfully market-differentiated from traditional agricultural products. Since European, indeed US and world, agricultural markets differentiate between GM and non-GM, and since consumers in the EU have clearly demonstrated that they perceive and demand differentiation, the threshold condition of likeness for these discrimination disciplines is not met.

### 2. SPS Article 5.5 and GATT Article III:4

For a case to fall within the scope of Article 5.5, the Panel must find as an initial matter that there are “situations involving the same substance or the same adverse health effect.”<sup>101</sup> Without such ‘comparable’ situations, there can be no discrimination. The Appellate Body has not specifically addressed how such a determination should be made, although it has said that “the situations exhibiting differing levels of protection cannot, of course, be compared unless . . . they present some common element or elements sufficient to render them comparable.”<sup>102</sup>

There is a similar threshold issue when implementing Article III of the GATT. GATT Article III prohibits subjecting imported goods to taxes, levies, or other regulations in excess of those applied to ‘like domestic products’.<sup>103</sup> By contrast, regulatory differentiation is permissible when it distinguishes according to an origin-neutral criterion, such as physical characteristics, price, mechanisms of sale, etc. The legal judgment must be analyzed under the rubric of Article III:4. Regarding the Art. III.4 ‘likeness’ determination, the Appellate Body has recently affirmed that the proper criterion of likeness/difference should be derived from a 1970 GATT Working Party Report on Tax Adjustments.<sup>104</sup> These included, (1) the properties, nature and qualities of the products; (2) end uses of the products; (3) consumers’ perceptions and behavior; and (4) the products’ existing tariff classifications.

As applied to GMOs, these factors all favor a finding of ‘difference’ rather than likeness. While we consider end use of products and tariff classifications as weighing in this direction, it is the criteria of physical properties and consumer perceptions and attitudes that clinch this legal conclusion.

#### a. ‘Properties, nature and qualities’

GMO and non-GMO products differ in ‘Properties, Nature, Qualities’ as the WTO has defined them. In the *Hormones* case, the Appellate Body held that there might be a

---

<sup>101</sup> *Hormones*, Report of the AB, at para. 216

<sup>102</sup> *Id.* at 217.

<sup>103</sup> GATT Art.III:1-4.

<sup>104</sup> 2 December 1970, GATT B.I.S.D. (18<sup>th</sup> Supp.) at 97 (1972).

range of reasons why risks inherent in nature in the absence of any human intervention might call for a lower level of protection than risks produced or exacerbated by human intervention.<sup>105</sup> Breeding agricultural products using recombinant DNA (rDNA) techniques can be said to introduce at least four categorical and qualitative differences between GM and conventionally bred products:

- 1) Adaptive traits can be leap-frogged over vast phylogenetic distances to form radically new combinations of competitive features;
- 2) Sexual reproduction and traditional breeding are largely limited to exchanges of alleles (which are variants of genes), and exchanges typically demand substitutions and adaptive trade offs and compromises, but with rDNA this class of exchange-based trade-offs can be circumvented;
- 3) Sexual reproduction and traditional breeding cannot normally reprogram the large fraction of genomes that are functionally homozygous. But rDNA holds the potential to reprogram fundamentally important genetic programs that are normally protected against change;
- 4) Transgenes often have unusual genetic side effects, apparently when a host organism's editing and buffering systems do not recognize them and cannot correct or control them properly.

Such differences pose special challenges for risk regulation. In the words of trade scholars Howse and Mavroidis,

genetic engineering removes or alters many restraints or controls that limit variation in nature, resulting in a vast potential expansion of variants and the speed at which they occur. Reliance on long-acquired general knowledge of the properties of non-genetically modified foods might be reasonable given the EU's level of protection, whereas a requirement that specific investigation be undertaken with respect to GMOs may also be reasonable, given the same level of protection, in light of the greater degree of uncertainty and relative speed at which new organisms with unknown risk properties relative to specific ecosystems can be created.<sup>106</sup>

#### **b. 'Consumer attitudes and perception'**

The case for finding a difference between GM and non-GM foodstuffs is even stronger when one considers the outpouring of consumer activity on behalf of such differentiation, both in Europe and the United States.<sup>107</sup> In the EU, publics have shown strong resistance to using GM products.<sup>108</sup> They have determined, after ample public information and debate, that GM crops and foods should require special regulatory treatment. In particular, the criterion of 'substantial equivalence' has lost credibility as a reliable scientific measure of 'sameness' between GM and non-GM foods.

---

<sup>105</sup> *Hormones*, Report of the AB, para. 187. See also Howse & Mavroidis, *supra* note 10, at 367.

<sup>106</sup> *Id.* (Howse & Mavroidis) at 367.

<sup>107</sup> See Gaskell, *supra* note 25, 351-375, for an analysis of public opinion both in the US and the EU.

<sup>108</sup> Julian Kinderlerer, *The WTO Complaint – Why Now?*, 21 NATURE BIOTECHNOLOGY 735-36 (2003).

It is essential to point out, too, that in the United States the regulatory system demarcates GM from non-GM foods by means of ‘organic’ labeling requirements.<sup>109</sup> In this case, vigorous lobbying by environmental and consumer groups led to the development of organic labeling standards that exclude GM techniques. Many US consumers, when consulted in the more open manner typical of qualitative research methods, voiced their recognition of a basic distinction between GM and non-GM products. For instance, in studies by FDA researchers, consumers indicated that they regard GM foods as different in principle from conventional equivalents because GM foods harbor the possibility of long-term unpredicted effects beyond the capacity of existing scientific knowledge and understanding.<sup>110</sup>

#### **D. Provisionality (Article 5.7) and ‘Undue Delay’ (8, Annex C)**

Article 5.7 “is an obvious expression of permitted precaution.”<sup>111</sup> Under Article 5.7, a Member State may adopt a provisional SPS measure based on available evidence when it deems the scientific evidence insufficient to make a final decision, but only if it seeks more information and reviews the provisional measure within a reasonable time period. More specifically, Article 5.7, a ‘qualified exemption’<sup>112</sup> clause from Article 2.2 states that

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

In a similar vein, pursuant to Article 8, Members of the WTO 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* and in no less favorable manner for imported products than for like domestic products” (emphasis added).<sup>113</sup>

##### **1. “Where relevant scientific evidence is insufficient”**

In the November 2003 *Japanese Apples* decision, the Appellate Body explained that in order to invoke Article 5.7, Member States must establish as a threshold matter that “relevant scientific evidence is insufficient” for the purposes of the article. The AB 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 the risks as

---

<sup>109</sup> See National Organic Program, 7 C.F.R. Part 205. In the United States, the “organic” label has been the means by which consumers can choose to eat non-GM foods. See also, Mikael Klinton, *Arguments Surrounding Organic and Genetically Modified Labelling: A Few Comparisons*, 4 J. ENVIRON. POLICY AND PLANNING 247 (2002).

<sup>110</sup> *Id.*

<sup>111</sup> ECHOLS, *supra* note 20, at 109.

<sup>112</sup> *Japanese Varietals*, Report of the AB, at para. 80.

<sup>113</sup> SPS Agreement, Art.8 and Annex C(a).

required under Article 5.1 and as defined in Annex A to the SPS Agreement” (emphasis added).<sup>114</sup>

It is important to note here that what constitutes an ‘adequate’ risk assessment in the domain of GM products is precisely the issue of disagreement in *Biotech Products*, and has been a matter of intense scientific and public controversy over the relevant time period. Perhaps more importantly, as we explore more fully below, risk assessment methodologies in the biotech area have themselves been evolving in the United States, Europe, and at the international level over this period, so that an overly rigid approach to what constitutes an ‘adequate assessment’ in this area would rest on thin authority.

As further illustration of this point, only in July 2003 – after many years of debate – the Codex Alimentarius Commission agreed on risk assessment principles for biotech products in July 2003 (see part 4(c)(i) below). If the Panel were to decide that sufficient scientific evidence existed for an ‘adequate assessment of risk’ in the time period under review, they would be ignoring the fact that new potential risks were identified as a result of ongoing scientific experiments, participatory procedures, and regulatory experiences. The development of risk assessment techniques and collection of new scientific data over this time period are discussed below.

## 2. “On the basis of available pertinent information”

The term ‘pertinent information’ – like all treaty language in the WTO agreements — should be interpreted in accordance with its “ordinary meaning.”<sup>115</sup> The *Oxford English Dictionary* defines ‘pertinent’ as “pertaining or relating to the matter in hand; relevant; to the point; apposite.”<sup>116</sup> Contextual language is also important for treaty interpretation.<sup>117</sup> The first sentence of Article 5.7 clearly differentiates ‘pertinent information’ from the term ‘relevant scientific information,’ implying that ‘pertinent information’ is a broader category than ‘relevant scientific’ information.

Judges should look at whether Member State authorities consulted information that was ‘pertinent to’ or ‘related to’ the issue at hand, i.e., how safe is GM food for health and environment. Due to the low certainty of the science and novelty of risk analysis techniques at that time, the EU ‘moratorium’ and indeed Member State bans should be deemed legitimate under this prong, i.e., based on ‘available pertinent information’ within the understanding of the SPS Agreement. A broad array of sources of pertinent information were available at the time of the alleged moratoria, including existing domestic scientific studies, studies from the United States, the previous mistakes of science-based governmental regulatory bodies (as in the BSE case), contingencies surrounding the implementation of regulatory practice, and well-publicized cases of industrial errors and malpractices in the GM sphere, such as the StarLink and

---

<sup>114</sup> *Japanese Apples*, Report of the Appellate Body, at para. 179.

<sup>115</sup> *Vienna Convention to the Law of Treaties*, Art. 31(1): “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.”

<sup>116</sup> OXFORD ENGLISH DICTIONARY, 3<sup>rd</sup> edition (2004).

<sup>117</sup> See language of *Vienna Convention*, Art. 31(1), supra note 115.

Prodigene episodes in the United States.<sup>118</sup>

### **3. Members shall “seek to obtain the additional information necessary for a more objective assessment of risk”**

In the absence of a single criterion for absolute objectivity (reflected in the low certainty, low consensus status of GM science), a promising approach to minimizing the risk of *subjectivity* of judgment is through accommodation of multiple experiences of and perspectives on the phenomenon in question. In the case of the EU’s challenged ‘measure’, the alleged moratorium created the opportunity for informational triangulation between and across Member States, involving publics, experts and officials institutions. The series of actions described by the complainants as the *de facto* moratorium were designed in order to gather additional scientific information and to take stock of citizen opinions and attitudes.<sup>119</sup>

The UK case is especially instructive. The UK Farm-Scale Evaluations (FSE) of GM crops and a UK Government-funded study on GM crop gene flow and interaction with wild relatives exemplify how governments have used the additional time as an opportunity to seek additional scientific information. In 1998, the UK Government initiated a three-year (subsequently extended to a five-year) program of Farm-Scale Evaluations (FSE), with the prospect of generating new evidence on a selected range of indirect effects.<sup>120</sup> These studies were initiated as a result of the concerns of multiple actors in UK society – conservation agencies, NGOs, consumer bodies, etc. — about the appropriate scope of GM crop risk assessments.<sup>121</sup> Moreover, the subsequent creation of the Agriculture and Environment Biotechnology Commission (AEBC) in 2000,<sup>122</sup> with responsibility for advising the UK Government on strategic issues at the interface of public values and scientific knowledge, led to a formal three-pronged process of ‘public dialogue on GM crops’ in 2003. This involved a national public debate, a systematic review of the state of GM science, and an assessment of potential national economic implications of possible GM commercialization.

Collectively these processes have increased UK governmental understanding of both scientific and societal dimensions and uncertainties of GM crops developments.<sup>123</sup> 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.<sup>124</sup>

### **4. ‘Reasonable period of time’ and ‘undue delay’ require comparison**

Did EU authorities review the measure within a reasonable period of time and have they satisfied the ‘undue delay’ standard of Annex C? We submit that they have done

---

<sup>118</sup> See discussion of the StarLink and Prodigene cases in the United States, § IV.D.4(b) *infra*.

<sup>119</sup> See § IV.D.4(a) *infra*.

<sup>120</sup> UK Department for Environment, Food, and Rural Affairs (DEFRA), *The History of the Farm-Scale Evaluations* (August 2002), at <<http://www.defra.gov.uk/environment/gm/fse/background/history.htm>>.

<sup>121</sup> *Id.*

<sup>122</sup> Agriculture and Environment Biotechnology Commission home page is available at <<http://www.aebc.gov.uk/>>.

<sup>123</sup> UK Agriculture and Environment Biotechnology Commission (AEBC), *GM Crops?: Coexistence and Liability*, (November 2003), at <[http://www.aebc.gov.uk/aebc/reports/coexistence\\_liability.shtml](http://www.aebc.gov.uk/aebc/reports/coexistence_liability.shtml)>.

<sup>124</sup> *Id.*



so. The terms ‘reasonable’ and ‘undue’ are legal standards. It is a well-accepted tenet of jurisprudence that legal standards are meaningless without a comparison of what happened in the particular instance with what is believed to have happened in like situations.<sup>125</sup> The proper inquiry for WTO judges, therefore, is one that is comparative in nature: *in light of regulatory and scientific development within the United States and the international community*, does the pattern of regulatory behavior towards GMOs within the EU and its Member States *over this time period* constitute an ‘undue delay’ or an ‘unreasonable period of time’?

**a. Ongoing regulatory and scientific development in the EU**

The alleged moratorium has been subject to ongoing scientific review and regulatory discussion across EU Member states and scientific communities. Indeed, the development of a GMO risk assessment framework itself has been undergoing constant reevaluation and refinement through the period of the alleged moratorium.

In the period prior to the alleged EU moratorium, several circumstances had converged: (1) In the mid-1990s, the EU had already committed itself to amendment of the risk assessment provisions of Directive 90/220 on deliberate release of GM crops. (2) With the prospect of commercial growing and distribution of GM crops in Europe, public controversy in several Member States intensified in 1996-1999 around the issue of potential unintended environmental/health impacts, in the form of *indirect* effects from GM crops and foods. (3) These concerns were made especially acute by the experience of food-related controversies (most notably BSE in the UK) and official handling of these controversies.<sup>126</sup> In response, Member State governments recognized that the established risk assessment framework needed amendment in relation to, *inter alia*, indirect effects, post-market monitoring, and time-limits on consents.

Far from being a period of ‘delay’, the period from 1998 to the present has been one of intense social and scientific learning about GM and its implications within the EU. In this period, 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.<sup>127</sup>

The Farm Scale Evaluations (FSEs) in the United Kingdom have proven to be a very important contribution to the ecological impacts of growing GM crops outside of the

---

<sup>125</sup> See, e.g., HENRY M. HART & ALBERT M. SACKS, *THE LEGAL PROCESS* 157 (1958).

<sup>126</sup> *BSE Inquiry Report*, *supra* note 95.

<sup>127</sup> See, e.g., NATIONAL ACADEMY OF SCIENCE, *PEST-PROTECTED PLANTS* (1999); *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada: An Expert Panel Report on the Future of Food Biotechnology*, The Royal Society of Canada (2001); NATIONAL RESEARCH COUNCIL, *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* (2000); NATIONAL RESEARCH COUNCIL, *BIOLOGICAL CONFINEMENT OF GENETICALLY ENGINEERED ORGANISMS* (2004) (forthcoming); NATIONAL RESEARCH COUNCIL, *ECOLOGICAL MONITORING OF GENETICALLY MODIFIED CROPS: A WORKSHOP SUMMARY* (2001); NATIONAL RESEARCH COUNCIL, *ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION* (2002).

greenhouse.<sup>128</sup> The FSEs involved four years of farm-scale trials, carried out on 273 farms across Britain, at a cost of £5.9 million and involving more than 100 scientists.<sup>129</sup> On receiving the results, UK 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.<sup>130</sup>

The trials' primary purpose was to investigate ecological impacts of the distinctive herbicide regimes associated with four herbicide-resistant GM crops — beet, maize, and spring and winter oil-seed rape.

Findings from these recent studies extend the international GM-related science base significantly, and appear to have surprised everyone, not least scientists, the UK Government, and the GM industry.<sup>131</sup> For spring rape and beet, a substantial decrease in weed and insect biodiversity was found (compared with equivalent conventional crop management regimes) — with follow-on indirect food chain implications for insects including butterflies and bees, birds and other creatures.<sup>132</sup> 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 genetically 'block hybridization'.<sup>133</sup>

#### **b. Using US GMO regulation as a comparison**

The regulatory regime of GMOs in the United States and the international community as a whole has also evolved. Indeed, when the EU and US experiences are compared, it is clear that the GM assessment frameworks have been developing dynamically on both sides of the Atlantic throughout the period relevant to the present dispute. We

<sup>128</sup> 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 (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>>.

<sup>129</sup> Department for Environment, Food and Rural Affairs, U.K., (DEFRA), *GM Crops: Effects on Farmland Wildlife* (16 October 2003) at <<http://www.defra.gov.uk/environment/gm/fse/>>.

<sup>130</sup> Department for Environment, Food and Rural Affairs, U.K., (DEFRA), *Farm Scale Evaluation Results – Important New Evidence on GM Crops* (16 October 2003) at <<http://www.defra.gov.uk/news/2003/031016a.htm>>.

<sup>131</sup> Full results of the farm-scale evaluations are published on 16 October 2003 as a series of scientific papers in the journal *The Philosophical Transactions of the Royal Society* (Biological Sciences). Papers available at <[http://www.pubs.royalsoc.ac.uk/phil\\_bio/news/fse\\_toc.html](http://www.pubs.royalsoc.ac.uk/phil_bio/news/fse_toc.html)>.

<sup>132</sup> 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. TRANS. R. SOC. LOND. 1847–1862 (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. TRANS. R. SOC. LOND. 1863–1877 (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. TRANS. R. SOC. LOND., 1879–1898 (2003).

<sup>133</sup> M.J. Wilkinson, et. al, *Hybridization between brassica napus and brassica rapa on a national scale in the United Kingdom*, 302 SCIENCE 401-3 (17 October 2003).

note that throughout the world, GMO policy either remains politically contested, or enshrines a precautionary approach, consistent with low certainty, low consensus risks.

While often described as stable and unchanging, US policies with respect to risk assessment of GM crops, the technologies of risk assessment, and the GM products to be assessed have all changed over time. In particular, at least three major changes have occurred in US risk assessment procedures for GM crops and foods. The first two, known as the StarLink and Prodigene cases and described more completely below, involve changes in protocols brought about as a result of the behavior of people and companies in ways that did not conform to the assumptions of the initially developed risk assessment process. The third change occurred as a result of a lack of public confidence in the procedures adopted by the highly respected US Food and Drug Administration. As one legal commentator has noted, industry failures and changes in the regulatory approach to GMOs in the United States has created a credibility problem among US consumers.<sup>134</sup>

*i. Starlink case*

StarLink was a GM maize hybrid, containing the Cry9c protein from *Bacillus thuringiensis*, licensed to the Aventis CropScience corporation. Under US law, StarLink was at once a crop, a food, and a pesticide, requiring risk assessments by three separate agencies: the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). As a result of concerns raised about StarLink's potential allergenicity in humans, a 1998 ad hoc committee with representatives from USDA, EPA, and FDA determined that a 'split registration' would be granted: the maize was to be used in animal feed but not in human food.

In September 2000, Starlink DNA was discovered in a number of processed food products.<sup>135</sup> Aventis, USDA, EPA, grain elevator operators, food processors, and grocers became involved in a massive and costly recall. In light of this, the EPA called two Scientific Advisory Panel (SAP) meetings (in November 2000 and July 2001) to discuss 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 "does not eliminate Starlink Cry9c protein as a potential cause of allergenic reactions."<sup>136</sup> The EPA ultimately rejected Aventis's request for a tolerance exemption. As a result of this incident, the US government decided no longer to permit split registrations. This represented a marked change in risk assessment of

---

<sup>134</sup> Rebecca M. Bratspies, *Bridging the Genetic Divide: Confidence-Building Measures for Genetically-Modified Crops*, 44 JURIMETRICS J. 63, 74 (2003) (proposing confidence-building measures that focus on the environmental concerns that surround GMOs).

<sup>135</sup> William Lin et al., *StarLink: Where no Cry9C Corn Should Have Gone Before*, CHOICES 31-34 (Winter 2001-2002).

<sup>136</sup> U.S. EPA, FIFRA Scientific Advisory Panel, *A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Assessment of Additional Scientific Information Concerning Starlink™ Corn* (2001).

products that fall into more than one category, such as food and feed.

**ii. *Prodigene case***

The Prodigene case marks a second time that the US risk assessment procedures were reviewed and revised after experience with implementation. In this instance, the Prodigene Corporation received permission to engage in a field test of a genetically modified maize plant containing an insulin precursor, Trypsin.<sup>137</sup> The maize was planted in an unmarked field in rural Iowa, a state that is at the center of the ‘Corn Belt.’ The GM maize was to be used to produce pharmaceutical products. Part of the agreement with USDA, which approved the field trials, was that the field would be ‘rogued’ the following year so as to remove any volunteer plants.

In point of fact, the fields were not adequately rogued and an undetermined quantity of GM maize was harvested along with about 500,000 bushels of soybeans during the following season. USDA became aware of the problem and had the soybeans destroyed, thereby removing all potential for harm, but at considerable cost. In addition, the US Grocery Manufacturers Association and the National Food Processors Association expressed their concerns that future incidents be avoided.<sup>138</sup> In light of this mishap, USDA again decided to review its risk assessment process, requiring that future trials be conducted under far more controlled conditions.

**iii. *FDA Equivalence rules***

Currently, US food manufacturers are not required to notify FDA of genetic modifications unless they fail the test of “substantial equivalence.”<sup>139</sup> Put differently, determination of substantial equivalence, and the consequent lack of need for a risk assessment, is left to private sector producers. In January 2001 FDA proposed a rule which would have required food developers to notify FDA at least 120 days in advance of their intent to market food or feed developed through biotechnology and to demonstrate that the product is as safe as its conventional counterpart.<sup>140</sup> However, on advice of General Counsel, FDA has tabled this rule as not within the jurisdiction of the agency.<sup>141</sup> This formal conclusion does not speak to the need for or wisdom of notification.

**iv. *Post harvest risk assessment***

While the US has been doing field trials for some 15 years, it has not engaged in any post-harvest testing of GM crops. As a recent report from the Pew Initiative on Agricultural Biotechnology makes clear, the US has not conducted any systematic

---

<sup>137</sup> B. Hord, *The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination*, OMAHA WORLD HERALD (19 January 2003), 1d.

<sup>138</sup> S. Simon, *The Food Industry Loves Engineered Crops, but Not When Plants Altered to ‘Grow’ Drugs and Chemicals Can Slip into Its products*, LOS ANGELES TIMES (23 December 2002), 1.

<sup>139</sup> See Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REF. 403, 426-432 (2002) (providing background on the “substantial equivalence” concept in US regulatory approach to GMOs).

<sup>140</sup> Food and Drug Administration, *Premarket Notice Concerning Bioengineered Foods*, 66 FED. REG. 4706 (proposed Jan. 18, 2001), at <http://www.fda.gov/OHRMS/DOCKETS/98fr/011801a.pdf>.

<sup>141</sup> E. Gersema, *FDA Opts Against Further Biotech Review*, ASSOCIATED PRESS ONLINE, 17 June 2003.

testing of the ingestion of foods produced from GM.<sup>142</sup>

This report further states that “the StarLink and ProdiGene cases have challenged the adequacy of postmarket oversight as currently practiced by the three regulatory agencies and have put the issue of postmarket oversight on the agenda of food system constituents, including government; the biotechnology, agricultural, and food industries; and the consumer and environmental advocacy communities.”<sup>143</sup>

### **c. Using International GMO Regulation as a Comparison**

#### ***i. Codex Alimentarius Commission***

Even within the “relevant international organizations” referred to by the SPS Agreement, thinking on the risk assessment of biotechnological products and how it fits within a broader risk analysis framework has been evolving. The Codex Alimentarius Commission (Codex) has been working on a recommended regulatory approach on GMOs for seven years,<sup>144</sup> and in July 2003, “Codex Principles and Guidelines in Foods Derived From Biotechnology,” were formally adopted.<sup>145</sup> The new recommended framework includes, *inter alia*, a “description of the donor organism,” a detailed “characterization of the genetic modification,” “evaluation of metabolites,” and an assessment of “nutritional modification.”<sup>146</sup>

The adoption of these principles and guidelines confirms that the international organization named by the SPS as responsible for setting base-line food safety standards<sup>147</sup> recognizes that the risk assessment of whole food products containing GMOs – or involving recombinant DNA in the production process – requires a new risk assessment framework. The fact that the Codex labored intensively for seven years before being able to agree on risk analysis guidelines for biotech products only confirms that the period of time under consideration has been active one of scientific and regulatory learning at the international and national levels.

#### ***ii. Cartagena Protocol***

On January 29, 2000, the representatives of 129 countries met in Montreal and adopted by consensus the Cartagena Protocol on Biosafety, an act capping over five years of negotiations regarding the international transport of “living modified

---

<sup>142</sup> Michael R. Taylor, Jody S. Tick, *Post-Market Oversight of Biotech Foods: Is the System Prepared?*, Pew Initiative on Food Biotechnology (April 2003), Executive Summary, at <<http://pewagbiotech.org/research/postmarket/>>.

<sup>143</sup> *Id.* at 2.

<sup>144</sup> See Anne A. MacKenzie, *The Process of Developing Labelling Standards for GM Foods in the Codex Alimentarius*, 3 AGBIOFORUM 203 (2000). The 23rd Session of the Codex, held in June/July 1999 in Rome, established the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (the Task Force) to develop standards, guidelines or recommendations for foods derived from biotechnology or traits introduced into foods by biotechnology. See Food and Agriculture Organization of the United Nations (FAO) news report, “Task Force analyses the risks of foods derived from biotechnology,” at <<http://www.fao.org/NEWS/2000/000304-e.htm>>.

<sup>145</sup> Codex Alimentarius Commission, *Report of the Twenty-sixth Session* (Rome, 30 June – 7 July 2003), para. 52; document available at <[ftp://ftp.fao.org/es/esn/food/princ\\_gmfoods\\_en.pdf](ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf)>.

<sup>146</sup> The Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, *Codex Principles and Guidelines on Foods Derived From Biotechnology*, available at *supra* note \_\_, at 9-18.

<sup>147</sup> See § III.A.2 *infra*; see especially SPS Agreement, *supra* note 4, at Preamble and Art. 3(2).

organisms” (LMOs), also known as “Genetically Modified Organisms.”<sup>148</sup>

The key provision of the Protocol is called the “advanced informed agreement” (AIA), under which an exporter must obtain the consent of the importing country before shipping certain GMOs to that country.<sup>149</sup> Article 4 of the Protocol describes the treaty’s scope and provides that the agreement shall apply to LMOs that may adversely affect the environment, “taking into account risks to human health.”

During the course of the Protocol’s negotiation, there was intense discussion over the scope and importance of the precautionary principle.<sup>150</sup> The final language appears in Article 10.6, and 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.

The centrality of the precautionary principle, which is also mentioned in Article 1 of the Protocol, suggests that “a reasonable period of time” under Article 5.7 of the SPS ought to be read expansively. Reasonableness should be read against the background of an emerging norm of precaution which entitles parties to take account of the ‘lack of scientific certainty’ in GM import decisions.

### **5. Conclusion on the issues of provisionality and delay**

The developing history of risk analysis of GMOs within the United States and the international community suggests that a simple model of risk assessment, one which may have been appropriate as a functional approximation in previous SPS cases before the WTO, is inappropriate to the case at hand. New issue-characteristics render the simple risk assessment model obsolete for the GM case, and justify a longer time period, and a more deliberate process-based, inclusive model of risk assessment for the development and implementation of regulatory solutions. The empirical experience outlined above for the UK, EU and US demonstrates the accidental manner in which the scientific framing of risk assessment may be demonstrated to require substantive changes to encompass previously unknown or ignored questions. This key reality is effectively denied in the conventional simple model of risk assessment, and this is not only scientifically unsound but undermines public legitimacy. Moreover what looks like “delay” in one regulatory culture may be “*bona fide* prudence” in another. Indeed, the rigid specification of a particular mode of risk assessment would tend to freeze the ongoing development (as visible in the United States as it is in Europe) of risk assessment science and policy in the GM area.

---

<sup>148</sup> 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 2-52 (2003).

<sup>149</sup> 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, at <<http://www.biodiv.org/biosafety/protocol.asp>>.

<sup>150</sup> See Stewart, *supra* note 148, at 16-22.

An overly rigid conception of proper risk assessment and regulation in this area could therefore lead to inadequate future risk assessments, put human populations or ecologies at undue risk, and undermine the legitimacy of the SPS agreement and the WTO more generally.

## V.

### REVIEWING RISK-BASED DECISIONMAKING AT THE WTO

#### A. Risk-based Regulations, Democracy and Judicial Review

As discussed in the preceding section, risk assessments and their integration into regulatory policies are value-laden processes, though the values involved often remain implicit. Democracies can and do differ in their assessment and management of risk, raising important concerns for supranational institutions like the WTO as they attempt to resolve regulatory conflict. Especially in light of recent legitimacy concerns and the so-called democracy deficit,<sup>151</sup> it is important to define what role WTO judges should play in scrutinizing the scientific bases of the food regulations.

The understandings of risk and risk assessment that we have outlined carry significant implications for defining the proper role of judicial scrutiny of Member State regulatory decisions at the WTO. The understanding of risk assessment that we have outlined, which accords with the social science of risk as well as the empirical record, implies a judicial role that should emphasize procedural norms as a means toward rendering domestic (and international) administrative decisionmaking more transparent. Put another way, the science-based disciplines should not function as draconian enforcement of substantive standards that have been considered and rejected by Member State citizens. Rather, the review of science-related rules at the WTO should facilitate an international discourse of rational decisionmaking in the regulatory sphere.<sup>152</sup>

#### B. Enforcing the Transparent, Accountable, and Reasoned Use of Science

Harmonization of technical standards is a worthy goal, both in terms of international trade and international relations, and the SPS Agreement correctly interpreted supports this goal. Harmonization of technical standards is usually seen as a fundamentally objective process, requiring experts to agree on, *e.g.*, human toxicity estimates, precise definitions of ‘safe’ exposure levels, and social and organizational factors in risk. But research has shown that risk analysis and the standards they support “incorporate not only ‘objective’ assessments of technical evidence but also collective cultural judgments about the appropriateness of particular social roles, power relationships,” public attitudes and regulatory styles.<sup>153</sup> These observations

---

<sup>151</sup> See, *e.g.*, ROGER B. PORTER, PIERRE SAUVÉ, ET AL., EDS., *EFFICIENCY, EQUITY, AND LEGITIMACY: THE MULTILATERAL TRADING SYSTEM AT THE MILLENNIUM* (2001).

<sup>152</sup> This viewpoint has also been argued persuasively by Professor Robert Howse. See Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329 (2000), especially 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.”

<sup>153</sup> Hazardous waste risk analysis and management is an important illustrative case here. Even within the EU in the 1980s, problems in international standardization arose. Here the institutional approach to scientific-technical risk knowledge assumed that the varying technical risk-standards for different



entail an expanded notion of harmonization and a different view of the WTO's role in promoting convergent standards.

The proper goal of WTO judges as they assess the facts and law under the SPS agreement should be mostly procedural, not substantive. The Dispute Settlement Panel's appropriate role in reviewing the arguments of the parties is that of an administrative tribunal reviewing the adequacy of executive decision-making processes — not that of an adjudicatory body reviewing substantive scientific details within the parties' risk assessments. In scrutinizing Members' regulatory decisions, judges should be able to distinguish legitimate local forms of regulatory sensibility from protectionism by requiring reasoned and accountable decisionmaking that takes the presence, absence, and content of scientific evidence into account.

### C. Selection of Experts

Key to the implementing this procedural conception of the judicial role will be the appropriate selection of experts. How courts and regulators use scientific experts was a major issue in the technical decisions made during the 1970s in the US,<sup>154</sup> and remains a lively jurisprudential and policy issue today.<sup>155</sup> In all four prior cases under the SPS Agreement, the Panel sought advice from “experts” – in relevant sciences and risk assessment – to help guide their decisions.<sup>156</sup> The language of the text leaves to the discretion of the Panel the 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.<sup>157</sup>

When one looks at the present case in this empirical and historical perspective, it is

---

member-states' hazardous wastes classifications and treatment requirements could be harmonized across the member states through a purely technical negotiation of common technical criteria. In fact, incommensurable technical criteria reflected particular institutional and cultural realities, implying the need for more complex forms of negotiation and convergence between the waste-trading member states. See Ducan Laurence and Brian Wynne, *Transporting waste in the European Community: A free market?* 31:6 ENVIRONMENT 12 (1989); see generally, e.g., Sheila Jasanoff, *Harmonization – The Politics of Reasoning Together*, in THE POLITICS OF CHEMICAL RISK 173-194 (R. Bal & W. Halfman eds., 1998).

<sup>154</sup> See, e.g., SHEILA JASANOFF, SCIENCE AT THE BAR 42-92 (1995).

<sup>155</sup> 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”); see also, Union of Concerned Scientists, *Scientific Integrity in Policymaking: An Investigation Into the Bush Administration's Misuse of Science* (February 2004); U.S House of Reps. Committee on Government Reform – Minority Staff Special Investigations Division, *Politics and Science in the Bush Administration* (August 2003), at <[http://www.house.gov/reform/min/politicsandscience/pdfs/pdf\\_politics\\_and\\_science\\_rep.pdf](http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf)>.

<sup>156</sup> ECHOLS, *supra* note 20, at 142. See also, *Japanese Apples*, Report of the Appellate Body, at para. 163.

<sup>157</sup> Article 11.2, 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.

immediately obvious that the selection and use of salient expert knowledge is more than simply a routine matter. For example established bodies of scientific expertise may assume particular selective framing of the salient questions that may be incompatible with those of other equally qualified and relevant disciplinary subcultures.

Relevant expertise should not be unduly limited to the natural sciences. Specialist practice-based bodies of expertise such as say, farming expertise, may be salient to risk assessment in ways that are not covered by the expert knowledge of scientific disciplines.<sup>158</sup> Social scientific research knowledge may also offer specialist insights to risk assessment, especially concerning important social-behavioral variables. Professor 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.”<sup>159</sup> 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.<sup>160</sup>

Therefore, before the selection of experts, there should logically be a prior systematic review of the kinds of question that are relevant to the case, leading to deliberate identification of which bodies of specialist (or public) knowledge and input are necessary for a sound resolution of the issue. The proper selection of experts might to some degree offset perceived deficiencies in the national decisionmaking processes of the parties in the case.

#### **D. Use of Experts**

Furthermore, it is crucial that appointed experts not be afforded *greater* authority in matters of science policy than national authorities. 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 defense of scientific justification under Article 2.2, 5.1, and 5.7. For instance, the recent *Japanese Apples* AB report states correctly that Panels are “entitled to take into account the views of experts.”<sup>161</sup> More than this, the AB implied, would be to exceed the authority of both the appointed experts and the Panel. While it is true that Panels are afforded “discretion as trier of fact”<sup>162</sup> within the WTO’s dispute settlement system, this should not be taken to mean that WTO judges 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 its own zone of competence.

---

<sup>158</sup> See, e.g., Howse & Mavroidis, *supra* note 10, at 348: “following 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.

<sup>159</sup> Howse, *Democracy, Science, and Free Trade*, *supra* note 152, at 2346-7.

<sup>160</sup> *Id.*

<sup>161</sup> *Japanese Apples*, Report of the Appellate Body, at para. 166.

<sup>162</sup> *Id.*

## E. DSU and Case Law Supports this Understanding of Judicial Role

The judicial standard of review established by the Dispute Settlement Understanding and interpreted by previous Appellate Bodies supports a procedural interpretation of the Panel’s review function. The ‘objective assessment of the facts’ set out by Article 11 of the DSU falls between total deference and a *de novo* standard of review.<sup>163</sup> The Appellate Body in *Hormones* made clear that Panels should be concerned about their own institutional competence in matters of science policy, stating that “many 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.” However, they have 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.”<sup>164</sup>

The ‘objective assessment of the facts’ standard ought to be applied to determine whether Member States followed a *legitimate process* of risk analysis, and whether their use of scientific evidence is plausible. The crucial question to ask is what exactly are ‘the facts’ to be assessed in the context of science-based decisionmaking? The appropriate facts to be assessed ‘objectively’ include those relevant to whether salient questions were deliberated and inclusively defined, required elements of a risk assessment were taken into account, available scientific evidence was considered, and decisions were reasoned in an accountable way. For instance, judges should investigate whether Members have conducted a more robust process-based form of risk assessment, considered scientific evidence in this light, and made a record of this consideration as part of the required risk assessment process. This interpretation of the judicial role would avoid well-documented problems of scientific competency at the WTO<sup>165</sup>, which would in turn strengthen WTO’s global legitimacy.

In sum, we support an understanding of the judicial role in the SPS context that is *procedural* and *deliberative* in orientation and tends to be sensitive to localized science-policy decisionmaking. This understanding is shared by a number of trade scholars.<sup>166</sup> It should be noted that this general orientation stays within the DSU

---

<sup>163</sup> In *Hormones*, the Appellate Body explicitly rejected a *de novo* review of the scientific knowledge underpinning a decision, stating “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*, Report of the AB, para. 117.

<sup>164</sup> *Id.*, citing *United States - Underwear*, Report of the Panel (25 February 1997) WT/DS24/R, at para. 7.10. See also, *Japanese Apples*, Report of the Appellate Body, at para 165 (rejecting a “total deference” standard of review when Panels look at the scientific findings of national regulatory authorities).

<sup>165</sup> 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, 622-3 (2000).

<sup>166</sup> See, e.g., Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUMBIA JOURNAL OF TRANSNATIONAL LAW 323-389 (2002); David Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT’L L.J. 817, 857-9 (1994); Howse, *Democracy, Science, and Free Trade*, *supra* note 152, 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 5, at 277-296.

language and existing interpretations thereof, without abandoning the necessary judicial task of striking down illegitimate regulations.

## VI.

### SUMMARY AND CONCLUSIONS

The foregoing sections of this brief have significant implications both for the resolution of this particular dispute and for the WTO dispute settlement process when confronted by similar issues in the future. Below, we summarize our principal conclusions and the main arguments in support of each.

1. With regard to the present dispute, there is as yet no rational basis for declaring that the EU's behavior conflicts with the terms of the trade agreement. The reasons for such an assessment include:

A. There is as yet no broad international consensus on what is at risk from GM crops and foods. Even knowledge of what GM crops are, in terms of their precise biological characteristics and properties, is subject to the scientific immaturity of the basic biological fields involved (e.g., over the precise control of gene-expression and protein-production). The whole issue is characterized by low certainty on facts and low consensus on technical approaches as well as values to be protected. The scientific basis for making the relevant determinations of hazard and risk is incomplete, inconsistent, and still evolving on both sides of the Atlantic.

B. Public deliberation designed to fill in some of the gaps in knowledge and values is still taking place, and the appropriate forms and venues for eliciting public inputs are still being designed and implemented. Without extensive public inputs, there is an insufficient basis for risk analysis, and indeed for resolving the threshold question of proper or improper differentiation between GM and non-GM products.

C. There are significant and legitimate differences in national judgments with respect to the appropriate degree of risk aversiveness under conditions of low certainty and low consensus, reflected in different approaches to adopting precautionary or risk-based approaches under these conditions. Nevertheless our argument is not conditioned upon prior acceptance of a precautionary approach, but is a function of a robust rational treatment of the issues and available natural and social scientific evidence.

D. International standards are not in place and international risk assessment processes are also evolving and incomplete.

2. The normative model of risk assessment proposed here – as an iterative analytic-deliberative process – takes account of the complex realities which have been gradually and increasingly manifest as regulatory science has grappled with issues of GMO risk, and indeed with other domains of risk. This model appropriately replaces established conventional models which reflect simpler assumptions that have proven to be inadequate, even counter-productive, for comprehending low-certainty, low-

consensus risk issues, of which GM is perhaps the most extreme example.

3. The model of risk assessment proposed here — as an iterative analytic-deliberative process — implies a model of the WTO dispute resolution process functionally more similar to administrative review of rulemaking than to substantive adjudication of competing factual claims. The Panel’s function, following this model, should be to ensure the procedural adequacy of disputed risk assessment and management processes on a case-by-case basis. The Panel’s role should not be to second-guess the substantive merits of particular decisions or conclusions. This conclusion is supported by the following considerations:

A. WTO panels do not have the institutional capacity to decide among different and plausible scientific alternatives of the kind presented in the GMO dispute. To perform such a meta-scientific role is actually to favor the set of tacit value-judgements constitutive of one party’s substantive risk-stance over those of the opposing party. To be seen to do this, however innocently, would be to erode the legitimacy of WTO as a key institution of international governance;

B. Historical examples from world regulatory systems suggest that the judicial review of primary standard setting is most effective when it holds standard-setting processes to appropriate procedural norms. Hence such review is also likely to be more effective and feasible in the context of global governance.

C. Procedural review will provide an effective secondary check on the quality of the decision-making justifying SPS measures, including both the quality of technical analysis and the quality of public deliberation underlying complex technical judgments.

D. Procedural review would respect the deliberative traditions of the Members, thus recognizing deep-seated political and cultural norms and reducing the perception of a democratic deficit at the WTO.

4. Such an approach to risk within the SPS Agreement, if implemented through the interpretation of existing agreement language, will help build public confidence in the Agreement, a confidence that is necessary for the WTO to exercise the authoritative, mediating, and trade-promoting functions it was designed to perform.