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# Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?

AARTI GUPTA\*

## INTRODUCTION

With its completion in January 2000, the Cartagena Protocol on Biosafety became the first legally binding global regime governing the transnational transfer and use of genetically modified organisms.<sup>1</sup> The existence of this agreement is noteworthy, given persisting normative and scientific conflicts over potential harms (ecological, socioeconomic, or to human health) arising from the use of genetically modified organisms.<sup>2</sup>

As its central governance mechanism, the Cartagena Protocol calls for the “advance informed agreement” of an importing country before transnational transfers of genetically modified organisms. The notion of “advance informed agreement” has its genesis in the better-known concept of “prior informed consent,” which has been relied upon in the international realm to regulate trade in hazardous waste and restricted and banned chemicals.<sup>3</sup> However, in the case of genetically modified organisms, the very existence and nature of hazard remains

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

2. For a general introduction to the science of genetic engineering, as well as an analysis of risks and benefits associated with use of GMOs in agriculture, see generally ALAN MCHUGHEN, *PANDORA'S PICNIC BASKET: THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS* (2000). For a more critical perspective, see generally STEPHEN NOTTINGHAM, *EAT YOUR GENES: HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET* (1998). For a discussion of ecological concerns relating to use of GMOs, see generally JANE RISSLER & MARGARET MELLON, *PERILS AMONG THE PROMISE: ECOLOGICAL RISKS OF TRANSGENIC CROPS IN A GLOBAL MARKET PLACE* (1993). For a discussion of socioeconomic considerations, see generally Zemed Asfaw & Tewolde B.G. Egziabher, *Possible Adverse Socio-economic Impacts of Genetically Modified Organisms, in TRANSBOUNDARY MOVEMENT OF LIVING MODIFIED ORGANISMS RESULTING FROM MODERN BIOTECHNOLOGY: ISSUES AND OPPORTUNITIES FOR POLICY-MAKERS* (K.J. Mulongoy ed., 1997).

3. For an analysis of prior informed consent in the governing trade in chemicals, see Robert L. Paarlberg, *Managing Pesticide Use in Developing Countries, in INSTITUTIONS FOR THE EARTH: SOURCES OF EFFECTIVE INTERNATIONAL ENVIRONMENTAL PROTECTION* (Peter M. Haas et al. eds., 1993). For an analysis of the hazardous waste regime, see generally Jonathan Krueger, *Prior Informed Consent and the Basel Convention: The Hazards of What Isn't Known*, 7 J. ENV'T & DEV. 115 (1998).

heavily contested.<sup>4</sup> Under such circumstances, institutionalizing “advance informed agreement” entailed a sustained battle between potential exporters of genetically modified organisms, seeking predictability in trade, and potential importers, seeking flexibility and discretion in national decision-making. How have these competing objectives been reconciled within the Protocol’s governance mechanism of advance informed agreement?

In addressing this question, I focus on the *decision criteria* underlying advance informed agreement, i.e., the criteria upon which importer decisions about accepting or restricting genetically modified organisms are to be based. Three such decision criteria were debated during the Cartagena Protocol negotiations. These were sound science; the precautionary principle; and socioeconomic considerations. Their definitions, as well as their relationship to one another, remain heavily contested and transcend the issue of biosafety, since they have been disputed in other influential global fora such as the World Trade Organization (WTO), as well.<sup>5</sup> I examine below the nature of conflicts over decision criteria for advance informed agreement during negotiation of the Cartagena Protocol, the final compromise, and the implications for biosafety governance.

#### I. IMPLEMENTING ADVANCE INFORMED AGREEMENT: DISPUTES OVER DECISION CRITERIA

During negotiation of the Cartagena Protocol, potential exporters of genetically modified organisms were organized into the Miami Group, consisting of countries at the forefront of producing “living modified organisms” (LMOs).<sup>6</sup> This group includes the major LMO-producing and agriculture exporting

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4. See AARTI GUPTA, FRAMING “BIOSAFETY” IN AN INTERNATIONAL CONTEXT 5 (Belfer Ctr. for Sci. & Int’l Affairs, ENRP Discussion Paper E-99-10, 1999) (The term “advance informed agreement” results from precisely such conflict. It was insisted upon by the United States during negotiation of the Convention on Biological Diversity (CBD) in 1992 to avoid use of the term “prior informed consent” (given its association with hazardous substances) for GMOs.), at <http://environment.harvard.edu/gea/pubs/e%2D99%2D10.pdf>

5. The most prominent recent airing of disputes over these decision criteria within the WTO is evident in the transatlantic dispute between the United States and the European Union over trade in hormone treated beef. See, e.g., WTO, Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R (Jan. 16, 1998), at [http://www.wto.org/english/tratop\\_e/dispu\\_e/hormab.pdf](http://www.wto.org/english/tratop_e/dispu_e/hormab.pdf) [hereinafter *EC Measures*].

6. GMOs are called “living modified organisms” in the Protocol. This change was insisted on by the United States to deflect attention from “genetic” modification as the focus of regulatory attention. I use the term “LMO” in the remainder of this essay to ensure consistency with Protocol usage. For a more detailed analysis of this language change, see generally Aarti Gupta, *Creating a Global Biosafety Regime*, 2 INT’L J. BIOTECH 205 (2000).

countries of Argentina, Australia, Canada, Chile, the United States, and Uruguay.<sup>7</sup>

A coalition of pharmaceutical, food, and agricultural companies, the Global Industry Coalition, supported the Miami Group in its push for predictability in LMO trade.<sup>8</sup> Other key actors in the Cartagena Protocol negotiations include the European Union, the “Like-Minded Group” of developing countries, and environmental and consumer safety groups.<sup>9</sup> Table 1 below summarizes the main divides over decision criteria during negotiation of the Protocol.

**Table 1: Disputes over criteria for importer decision-making**

<b>Miami Group</b>	<b>European Union</b>	<b>Like-Minded Group</b>
National decisions about LMO transfers should be based upon a <i>sound</i> scientific risk assessment <i>and should be compatible with the WTO</i>	National decisions about LMO transfers should be based upon a scientific risk assessment <i>and the precautionary principle; no deference to the WTO</i>	National decisions about LMO transfers should be based upon scientific risk assessment; the precautionary principle; <i>and on socioeconomic factors; no deference to the WTO</i>

As summarized in the table, a key divide between the Miami Group and the European Union has been over whether a scientifically sound risk assessment, as called for by the Miami Group and the Global Industry Coalition, should be the

7. See CLIVE JAMES, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH. APPLICATIONS [ISAAA], BRIEF NO. 8, GLOBAL REVIEW OF COMMERCIALIZED TRANSGENIC CROPS: 1998 iii-iv (1998) (In 1998, 27.8 million hectares were planted with genetically modified crops worldwide. Of this area, the United States contributed 74%, Argentina 15%, Canada 10% and Australia 1%. Mexico, Spain, France, China, and South Africa constituted the remaining, each with less than 1%. The main crops grown in 1998 were soybean (consisting of 52% of the global area), corn (constituting 30%), as well as cotton, canola and potato. The main genetic modifications were for herbicide tolerance (71% of all genetic modification) and insect resistance (21%). The growth in area devoted to genetically modified crops from 1997 to 1998 (from 11 to 27.8 million hectares) was concentrated in industrialized countries. Global sales from transgenic crops were estimated at \$75 million in 1995, \$235 million in 1996, \$670 million in 1997, and from \$1.2-\$1.5 billion in 1998.), [http://www.isaaa.org/publications/briefs/Brief\\_8.htm](http://www.isaaa.org/publications/briefs/Brief_8.htm).

8. Press Release, Global Indus. Coalition, Biodiversity Jeopardized in Cartagena Biosafety Negotiations (Feb. 16, 1999) (on file with author) (The Global Industry Coalition was established in 1998 and represents “over 2200 firms from more than 130 countries worldwide [and] includes companies from a variety of industrial sectors, including plant and animal agriculture, food production, human and animal health care, forestry and the environment.”).

9. See Aarti Gupta, Searching for Shared Norms: Anticipatory Global Governance of Biosafety (2001) (unpublished Ph.D. dissertation, Yale University) (on file with author) for a detailed analysis and history of the genesis of these negotiating alliances. See also Aarti Gupta, *Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety*, 42 ENV’T 23, 26 (2000) for additional analysis of the factors shaping the biosafety perspectives of these groups.

sole appropriate decision criterion, or whether the precautionary principle is also a legitimate basis upon which to make decisions about LMO transfer and use. This conflict is fueled partly by the increasing public opposition to genetically modified organisms in Europe.<sup>10</sup> The central justification offered by the Miami Group and the Global Industry Coalition for relying on sound science was that it provided the only objective and standardized basis for a global biosafety governance regime.<sup>11</sup> As stated emphatically by the Global Industry Coalition: “decisions under the Protocol . . . must be based on sound and objective science. To do otherwise, will severely undercut the effectiveness and integrity of the Protocol. . . .”<sup>12</sup>

A corollary to the call for sound science was that the precautionary principle was an ill-defined, nebulous concept that was open to abuse and could serve as a front to further protectionist or competition-driven trade agendas. Its status as a principle was also questioned by the Miami Group, who viewed it as a poorly defined *approach* to decision-making.<sup>13</sup> As one U.S. delegate noted, the precautionary approach, as articulated in the 1992 Rio Declaration,<sup>14</sup> was “so wide-open that you can drive a truck through it.”<sup>15</sup> Thus, as the Miami Group and industry argued, using the precautionary approach as a criterion for importer choice prior to trade in LMOs would make predictable global rules governing such trade unattainable.

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10. For an analysis of changing perceptions of LMOs in countries of the European Union, see George Gaskell et al., *Biotechnology and the European Public*, 18 NAT. BIOTECH. 935 (Sept. 2000).

11. For the perspective of a key Miami Group member, Australia, on the Protocol, see generally Austl. Dep't of Foreign Affairs & Trade, at <http://www.dfat.gov.au/environment/bsp>.

12. Posting of Dr. Helma Hermans, Executive Secretary Green Industry Biotechnology Platform, [sciwrico@wirehub.nl](mailto:sciwrico@wirehub.nl), to Observers to the CBD Meeting (Feb. 10, 1999, 12:51 p.m.) (on file with author) [hereinafter Posting from Dr. Helma Hermans]; see also Global Indus. Coalition, *Basic Requirements for a Successful Biosafety Protocol* (Feb. 1999) (position paper on file with author) [hereinafter *Basic Requirements*]; Press Release, Cartagena, Columbia, Global Indus. Coalition, *Biodiversity Jeopardized in Cartagena Protocol Negotiations* (Feb. 19, 1999) (on file with author).

13. For an interpretation of precautionary decisions as constituting an approach to decisionmaking rather than a principle, and arguments made by the United States in the beef-hormone conflict, see *EC Measures*, *supra* note 5. For more detailed analysis of the beef hormone case, and, more generally, for options to reconcile the trade regime's obligations with multilateral environmental agreements such as the Protocol, see also Frank Biermann, *The Rising Tide of Green Unilateralism in World Trade Law: Options for Reconciling the North-South Conflict*, 35 J. WORLD TRADE 421, 421-23 (2001).

14. Rio Declaration on Environment and Development, adopted by the U.N. Conference on Environment and Development, June 13, 1992, princ. 15, 31 I.L.M. 874, 879 (1992) [hereinafter Rio Declaration] (“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damages, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”).

15. Interview with Miami Group Delegate, in Washington, D.C. (Mar. 1999) [hereinafter Interview with Miami Group Delegate].

On the other hand, those advocating a precautionary approach, including the European Union and green groups, protested its characterization as antithetical to science.<sup>16</sup> Green groups, in particular, argued that sound science in contested areas such as biosafety was a science that was explicitly precautionary in the face of scientific uncertainties.<sup>17</sup>

While developing countries supported the European Union in its push to include the precautionary principle as a legitimate decision criterion, this conflict was primarily between the European Union and the Miami Group. For most developing countries, the key concern was inclusion of non-scientific socioeconomic considerations in the Protocol's decision criteria for advance informed agreement. The socioeconomic concerns voiced by developing countries, and supported by green groups, included new forms of dependencies on technologically advanced countries or multinational companies as a result of growing private ownership of transgenic seed. Concerns also included the possible effect on traditional livelihoods of growing reliance on LMOs in agriculture. In demanding that socioeconomic factors be included, developing countries and green groups argued that concerns over LMO transfers transcended narrowly-defined conceptions of harm that were assessable and quantifiable through technical risk assessments (even those that could account for scientific uncertainties).<sup>18</sup>

Most OECD countries and industry noted the extreme importance of socioeconomic factors in national decision-making about adoption of new technologies, yet insisted that such concerns were more suitably addressed

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16. For a recent clarification of the European Union's view on the precautionary principle and its implementation, see *Communication from the Commission on the Precautionary Principle*, COMM'N OF THE EUR COMMUNITIES (Feb. 2, 2000), available at [http://europa.eu.int/comm/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf).

17. For a detailed discussion of the relationship between "sound" science and precaution, see generally Nancy Myers, *The U.S. and the Precautionary Principle: An NGO Response in the Context of the Cartagena Protocol* (Dec. 2000), available at <http://www.sehn.org/rtdocs/1CCP.rtf>. See also The Science and Environmental Health Network (SEHN), <http://www.sehn.org> (giving a similar analysis).

18. See THIRD WORLD NETWORK, OPEN LETTER TO DELEGATES TO THE RESUMED SESSION OF THE FIRST EXTRAORDINARY MEETING OF THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY, ESSENTIAL ELEMENTS OF A BIOSAFETY PROTOCOL ¶ 7 (Jan. 24, 2000) (explaining that most green groups involved in Protocol discussions have emphasized the need for inclusion of socioeconomic impacts in the Protocol's decision criteria and stating that "socioeconomic considerations are an integral part of assessing the impact of GMOs . . . [which] could . . . impair or displace indigenous technologies . . . displace crops or exports and undermine a country's economy and cause social instability . . .") (text on file with author); see also WORLD WIDE FUND FOR NATURE, POSITION STATEMENT, FIFTH MEETING OF THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY (Aug. 1998) (on file with author).

through domestic regulations, rather than through a global governance regime.<sup>19</sup> In arguing against inclusion of socioeconomic factors as a criterion governing importer choice, a key concern for many OECD countries and industry was that such inclusion would conflict with multilateral trade obligations. As the Global Industry Coalition put it: “introduction of socio-economic considerations would erect unacceptable and inappropriate barriers to international trade, in conflict with countries’ WTO obligations.”<sup>20</sup>

These groups argued, instead, for the Protocol’s decision criteria to be compatible with the WTO’s science-based obligations governing trade in substances of contested risk. These obligations are contained in the trade regime’s Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which mandates that all national sanitary and phytosanitary standards relating to plant, animal, and human health and safety have a scientific justification to prevent their becoming unacceptable non-tariff barriers to trade.<sup>21</sup> The SPS Agreement does allow for provisional restrictions on trade in the event of insufficient scientific evidence of harm. In its understanding of precautionary decisions, article 5.7 of the SPS Agreement allows that:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information. . . . 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.<sup>22</sup>

Such precautionary measures are, however, to be maintained only on a provisional basis as more scientific data on risk is sought. Thus, the main thrust

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19. Interview with Miami Group Delegate, *supra* note 15.

20. Posting from Dr. Helma Hermans, *supra* note 12; see also *Basic Requirements*, *supra* note 12. For similar industry perspectives, see generally Biotech. Indus. Org., *The Biosafety Protocol: An Overview*, at <http://www.bio.org/food&ag/bspoverview.html> (last visited Jan. 14, 2002).

21. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1A, 69 (1994) [hereinafter SPS Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/docs_e/legal_e/15-sps.pdf). According to the SPS Agreement, “[m]embers shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence. . . .” *Id.* art. 2.2.

22. *Id.* art. 5.7.

of the SPS Agreement's science-based obligations is to ensure that national health and safety decisions are justifiable based on a scientific risk assessment.

The scientific validity of national health and safety measures is to be demonstrated through a formal risk assessment. The SPS Agreement addresses socioeconomic considerations only in including a limited set of "relevant economic factors" within the required risk assessment. These include "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risk."<sup>23</sup>

These are socioeconomic considerations relating to potential economic damage *resulting from* sanitary or phytosanitary harm. Broader considerations that are distinct from ecological or human health harm, such as the social need for a traded product that may pose risk, its public acceptability, or consumer opposition to it based on cultural or ethical grounds, are excluded from the SPS Agreement's science-based decision criteria.<sup>24</sup> As seen most prominently in the beef-hormone conflict, and as discussed later, implementation of such decision criteria has remained contested.

Similar disputes over decision criteria for advance informed agreement during negotiation of the Cartagena Protocol reveal clearly that the utility of having a global biosafety regime varied greatly for the different groups. While the European Union, developing countries, and green groups saw the global biosafety regime as a vehicle through which to institutionalize flexibility in decision-making about trade in genetically modified organisms (a flexibility deriving from national decisions based on the precautionary principle and/or socioeconomic considerations), the Miami Group and industry saw the regime as a vehicle through which to institutionalize predictability in decision-making about trade (a predictability deriving from decisions based on sound science). This ongoing conflict over the *raison d'être* of a global biosafety regime was reflected in conflicts over the decision criteria underpinning advance informed agreement.

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23. *Id.* art. 5.3.

24. See Wolfgang van den Daele, *Interpreting the Precautionary Principle: Political Versus Legal Perspectives*, in 1 *FORESIGHT AND PRECAUTION* 213, 220 (M.P. Cottam et al. eds, 2000) (noting the debate in the European Parliament in 1992 over a European Green Party proposal that new technologies pass tests not only of safety, efficacy, and quality but also a "fourth hurdle" of social need).

## II. THE OUTCOME: PRIVILEGING SCIENCE-BASED ADVANCE INFORMED AGREEMENT

The Cartagena Protocol's final compromise on decision criteria prior to LMO trade calls for importer decisions to be based upon a "scientifically sound" risk assessment; precautionary action in the face of scientific uncertainty about adverse impacts; and a very circumscribed inclusion of socioeconomic considerations.<sup>25</sup> As I argue below, such criteria can be interpreted as privileging science-based decisions about LMO transfers. In the remainder of this essay, I elaborate on how the decision criteria in the finalized Protocol privilege science and conclude with some implications for global biosafety governance.

In its call for sound science, the Cartagena Protocol mandates that LMO importer decisions be based upon a quantitative risk assessment. It further mandates that such risk assessments be "carried out in a *scientifically sound* manner . . . taking account of recognized risk assessment techniques."<sup>26</sup> The Protocol's understanding of what constitutes a scientifically sound risk assessment is contained in its Annex II. Importantly, it is conceded here that the criteria to be taken into account and the data to be generated in a quantitative risk assessment cannot be internationally mandated, given the diverse agroecological (and, as some would argue, socioeconomic) environments within which risk assessments are to be undertaken. Thus, the Protocol explicitly states that "the required information [in a risk assessment] may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment."<sup>27</sup> In recognition of this, the information to be evaluated in a risk assessment is listed in the Annex as "points to consider" rather than as mandatory criteria to be assessed in all cases.

This deference to context-based differences in risk assessment notwithstanding, there is still the stipulation that a risk assessment must be scientifically sound. Yet, in this normatively contested area, there is little agreement on what constitutes "sound" science. A striking illustration of this is provided by disputes over a key risk assessment principle—substantial equivalence—that currently underpins safety evaluations of genetically modified

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25. Protocol, *supra* note 1, arts. 10.1, 10.6, 11.6, 15, 26, at 1031, 1032, 1033-34, 1039.

26. *Id.* art. 15, at 1033 (emphasis added).

27. *Id.* annex III, para. 6, at 1045.

organisms.<sup>28</sup> This term was coined by the Organization for Economic Cooperation and Development (OECD) in 1993 in an attempt to develop shared “concepts and principles” to underlie safety evaluations of genetically modified organisms.<sup>29</sup> The main premise of substantial equivalence is that the safety of a transgenic food should be assessed *relative to* existing comparable conventional foods, i.e. that the “substantial equivalence of a transgenic food is established by a demonstration that the characteristics assessed for the genetically modified organism . . . are equivalent to the same characteristics of . . . conventional foods.”<sup>30</sup>

This concept has fueled much debate since its elaboration in the early 1990s, even as it has been adopted by many OECD countries in regulation of genetically modified organisms.<sup>31</sup> Substantial equivalence has also been endorsed as an adequate scientific basis for safety evaluations of genetically modified organisms by international organizations such as the United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO).<sup>32</sup> A series of expert consultations organized by these two organizations has recommended that safety evaluations of transgenic foods be based on the concept of substantial equivalence.<sup>33</sup>

Significantly, however, the latest FAO/WHO Expert Consultation acknowledges that:

Several countries have used the concept of substantial equivalence as an important component of the safety evaluations of food and food ingredients derived from genetically modified plants. *They have found this approach to be scientifically sound and practical. Nevertheless, there has not been a universal*

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28. FOOD & AGRIC. ORG. OF THE UNITED NATIONS, BIOTECH. AND FOOD SAFETY: REP. OF A JOINT FAO/WHO CONSULTATION (1996), <http://www.fao.org/waicent/faoinfo/economic/esn/biotech/tabconts.htm> [hereinafter FAO 1996]; FOOD & AGRIC. ORG. OF THE UNITED NATIONS, SAFETY ASPECTS OF GENETICALLY MODIFIED FOODS OF PLANT ORIGIN: REP. OF A JOINT FAO/WHO CONSULTATION OF FOODS DERIVED FROM BIOTECH. (2000), [http://www.who.int/fsf/GMfood/FAO-WHO\\_Consultation\\_report\\_2000.pdf](http://www.who.int/fsf/GMfood/FAO-WHO_Consultation_report_2000.pdf) [hereinafter FAO 2000]; Eric Millstone et al., *Beyond “Substantial Equivalence,”* 401 NAT., Oct. 7, 1999, at 525-26.

29. OECD, SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY: CONCEPTS AND PRINCIPLES (1993), available at <http://www.oecd.org/pdf/M00007000/M00007573.pdf> [hereinafter OECD].

30. FAO 1996, *supra* note 28, at 22.

31. FAO 2000, *supra* note 28.

32. For the initial elaboration of this concept and early debates about it, see OECD, *supra* note 29, and FAO 1996, *supra* note 28. The latest FAO/WHO expert consultation on safety evaluations of transgenic foods contains a detailed account of recent debates on this issue. See FAO 2000, *supra* note 28.

33. FAO 1996, *supra* note 28.

*consensus on the application of this concept.* This has resulted in criticism that the approach does not provide a sufficient basis for safety and calls for national governments and international bodies to consider alternative approaches.<sup>34</sup>

However, the report concludes that: “[T]here [are] presently no alternative strategies that would provide a better assurance of safety for genetically modified foods than the appropriate use of the concept of substantial equivalence . . . [t]he application of the concept of substantial equivalence contributes to a robust safety assessment framework.”<sup>35</sup> Yet, continuing conflicts and critiques of this scientific tenet abound.<sup>36</sup> For example, a controversial and widely discussed article in the influential journal *Nature*, entitled “Beyond Substantial Equivalence,”<sup>37</sup> critiques continued reliance on substantial equivalence in safety assessments of genetically modified crops and foods. The authors question both the adequacy of the tests relied upon to establish equivalence and the underlying assumption that equivalence of transgenic with conventional foods can be established. Their conclusion, under the provocative title “an anti-scientific test,” states that:

Substantial equivalence is a *pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific.* It is, moreover, inherently unscientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit informative scientific research.<sup>38</sup>

Notwithstanding such persisting conflicts over scientific principles to regulate biotechnology, the Cartagena Protocol calls for a “scientifically sound” risk assessment as the central basis for LMO import decisions. Clearly, then, a call for “sound” science will not provide the predictability in trade desired by the Miami Group or industry. Moreover, the Protocol’s call for a scientifically sound risk assessment is strikingly similar to the SPS Agreement’s science-based

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34. FAO 2000, *supra* note 28, at 1 (emphasis added).

35. *Id.* at 20.

36. For an analysis of the disputed concept of substantial equivalence, see Millstone et al., *supra* note 28.

37. Millstone et al., *supra* note 28.

38. *Id.* at 526 (emphasis added).

obligations. Its interpretation in the new forum of the Cartagena Protocol is therefore likely to remain as contested as it has been in the SPS Agreement.

As is increasingly clear, science alone cannot resolve fundamental value conflicts, notwithstanding continued calls to base decisions in normatively contested areas on science. In areas where the science itself is contested, a call for “sound” science is disingenuous, since it cannot resolve, on “objective” scientific grounds alone, the critical question of “whose” sound science.<sup>39</sup> The concept of sound science has been exhaustively analyzed and critiqued in recent years, not least because it is privileged as a basis for decision-making in the multilateral trade regime.<sup>40</sup>

A critically important component of this debate, which I explore next, is the relationship between sound science and the precautionary principle. The precautionary principle is becoming an increasingly important component of governance regimes dealing with environmental and human health and safety. Thus, a shared understanding of the precautionary principle would go a long way toward the development of transnationally legitimate governance precepts in contested areas such as biosafety.<sup>41</sup> Yet, as argued below, the Cartagena Protocol’s language on precaution does not as yet yield such a shared understanding.

The Protocol’s provisions on precautionary decision-making state that:

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

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39. For an analysis of how perceptions of the legitimacy (i.e., fairness) and the salience (i.e., relevance) of scientific input are as critical in determining whether science can influence policymaking as any shared perceptions of its “soundness” alone (i.e., its technical credibility), see generally INFORMATION AS INFLUENCE: HOW INSTITUTIONS MEDIATE THE IMPACT OF SCIENCE ASSESSMENTS ON GLOBAL ENVIRONMENTAL AFFAIRS (William C. Clark et al. eds., forthcoming 2002). See also Frank Biermann, *Big Science, Small Impacts—in the South? The Influence of Global Environmental Assessments on Expert Communities in India*, 11 GLOBAL ENVTL. CHANGE 297 (2001) for analysis of how global science may have minimal influence in India, if developing country concerns are not reflected or if developing country scientists do not participate in such global assessments.

40. See generally David Wirth, *The Role of Science in the Uruguay Round and NAFTA Trade Disciplines*, 27 CORNELL INT’L L.J. 817 (1994) (analyzing the science-based provisions of the SPS Agreement); Les Levidow & Susan Carr, *Unsound Science: Transatlantic Regulatory Disputes over GM Crops*, 2 INT’L J. BIOTECH. 257 (2000) (critiquing the concept of sound science as it relates to GMOs); AARTI GUPTA, *Sound Science in Global Governance of Biosafety*, in LOCALIZING AND GLOBALIZING: KNOWLEDGE CULTURES OF ENVIRONMENT AND DEVELOPMENT (Sheila Jasanoff & Marbeth Long-Martello eds., forthcoming 2002) (analyzing the call for “sound science” in the Protocol negotiations).

41. For an overview of debates on the precautionary principle, see generally INTERPRETING THE PRECAUTIONARY PRINCIPLE (Tim O’Riordan & James Cameron eds., 1994).

conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism . . . in order to avoid or minimize such potential adverse effects.<sup>42</sup>

This language has been hailed by the European Union, developing countries, and green groups as the first inclusion of the precautionary principle in the operational part of a global environmental agreement and one of the most noteworthy contributions of the Cartagena Protocol.<sup>43</sup> In contrast, however, the Miami Group and industry representatives have emphasized that the Protocol's language on precaution does not go further than the discretion already permitted to importers of risky products under the multilateral trade regime and its SPS Agreement.<sup>44</sup>

It is useful, therefore, to examine more closely the language in the Protocol to assess whether a shared basis for governance, generalizable to other anticipatory issues, is discernible here. Examining the Protocol's language on precaution reveals, first and foremost, that it does not operationalize *the* precautionary principle, as widely alleged, since no single universally shared version exists. Instead, the Protocol's language reflects a mix of existing understandings of precaution as articulated in other global fora, including Principle 15 of the Rio Declaration and article 5.7 of the SPS Agreement.

Comparing these various versions reveals that the Protocol's language on precaution is largely compatible with both Principle 15 of the Rio Declaration and article 5.7 of the SPS Agreement. Although these articulations are compatible, Principle 15 can be construed as setting a stricter standard for precautionary

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42. Protocol, *supra* note 1, art. 10.6, 11.8, at 1031, 1032.

43. See, e.g., *Montreal 2000: An Amazing Compromise*, 59 *COURRIER DE LA PLANÈTE* 7 (2001) (interviewing Christoph Bail, a lead spokesperson for the European Union during the Protocol negotiations); see also *THIRD WORLD NETWORK*, *supra* note 18.

44. Interview with Miami Group Delegates, in *Montreal* (Jan. 2000). For written statements on the key provisions of the Protocol, issued two weeks after finalization of the Protocol at the end of January 2000, see *OFFICE OF THE SPOKESMAN, U.S. DEP'T STATE, FACT SHEET: THE CARTAGENA PROTOCOL ON BIOSAFETY* (Feb. 16, 2000), available at <http://usinfo.state.gov/topical/global/biotech/00021601.htm>. The Fact Sheet states that "the language [on precaution] does not replace science-based decision-making nor does it authorize decisions contrary to a country's WTO obligations." *Id.* at (e). For a similar interpretation from another key Miami Group member, Australia, see also *DEP'T OF FOREIGN AFFAIRS & TRADE, ENV'T AUSTL., DISCUSSION PAPER: PREPARATIONS OF THE FIRST MEETING OF THE INTERGOVERNMENTAL COMMITTEE ON THE CARTAGENA PROTOCOL ON BIOSAFETY* (Oct. 2000), at [http://www.dfat.gov.au/environment/bsp/bio\\_sub/discussion\\_paper.html#outline](http://www.dfat.gov.au/environment/bsp/bio_sub/discussion_paper.html#outline).

actions than the Protocol, given its injunction that precautionary actions are to be taken (only) when “serious and irreversible” damage might result from inaction *and* when such actions meet an additional criterion of cost-effectiveness.<sup>45</sup> At the same time, Principle 15 also includes the concept of “full” scientific certainty, which is often equated with a “zero-risk” approach by opponents of this language, who argue that full scientific certainty about lack of harm is never obtainable.

A comparison with Principle 15 of the Rio Declaration is particularly relevant to evaluating whether the Cartagena Protocol’s inclusion of precaution can provide a shared basis for action. This is because there is a separate and explicit reference to Principle 15 in the Protocol’s overall objectives: “*In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms . . .*”<sup>46</sup>

Including two compatible, yet slightly distinct, versions of precaution within this one global regime allows for multiple and potentially conflicting interpretations about the legitimate triggers for precautionary action under the Protocol. Therefore, while it certainly provides flexibility in interpretation to importers of LMOs who wish to exercise precaution in allowing LMO transfers, it does not yet provide a common basis for action in this contested area. Although inclusion of this language in the Protocol is indeed a significant first step, its articulation here does not categorically shift the advantage to either the proponents or the opponents of reliance on precaution in governing transfers of LMOs. Rather, it ensures that the battle of interpretation will continue in this and other fora on a case-by-case basis.<sup>47</sup>

Notwithstanding the potential for multiple interpretations, however, the Protocol’s language on precaution contains one important and relatively unambiguous similarity to the multilateral trade regime’s understanding of precaution. As seen earlier from the language of the SPS Agreement’s article 5.7,

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45. See Rio Declaration, *supra* note 14, princ. 15, at 879.

46. Protocol, *supra* note 1, art. 1, at 1027 (emphasis added).

47. One difference between article 5.7 of WTO-SPS and the Protocol is that the SPS Agreement’s language emphasizes that precautionary decisions are to be provisional and should be reviewed within a “reasonable period” of time. SPS Agreement, *supra* note 21, art. 5.7. The Protocol’s version identifies no time frame within which precautionary decisions are to be reviewed and can thus be construed as allowing more flexibility to countries in taking import-restrictive actions in the face of scientific uncertainty. However, the SPS Agreement’s injunction to review actions within a reasonable period of time is sufficiently vague so as to make this distinction less critical.

the starting point of legitimate precautionary action in the trade regime is a science-based risk assessment. The Protocol's language can be read as a similar call for precautionary actions to be grounded in a quantitative risk assessment. This is evident from the emphasis in the Protocol's language on scientific uncertainty about the *extent* of an adverse impact posed by an LMO, rather than uncertainty about *whether or not* an adverse impact exists. This emphasis on the extent of an adverse impact can be interpreted as requiring prior scientific evidence of the *existence* of an adverse impact before precautionary action can legitimately be taken.

Thus, the language on precaution in the Cartagena Protocol can also be interpreted as not allowing countries to go beyond what is already permitted within the SPS Agreement's science-based obligations. It can be interpreted as privileging a quantitative risk assessment as the legitimate starting point for precautionary action, as does the SPS Agreement. Hence, the language on precaution can be read as privileging science-based importer decision-making prior to LMO transfers, in a manner similar to the call for a "scientifically sound" risk assessment.

This privileging of science is further reinforced by the manner in which socioeconomic considerations are addressed by the Cartagena Protocol. In its final compromise on this issue, the Protocol allows for very limited consideration of adverse socioeconomic impacts in importer decisions about LMO transfers. Specifically, it allows countries to "take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of [living modified organisms] on the conservation and sustainable use of biological diversity. . . ."<sup>48</sup>

This is a very narrow formulation in that it links socioeconomic impacts to impacts on biodiversity, in a manner similar to the WTO's treatment of socioeconomic factors in the SPS Agreement. This excludes many concerns of particular interest to developing countries, such as loss of traditional livelihoods or increased dependence on privately controlled seed. In addition, the proviso that decisions based on socioeconomic considerations are to be consistent with a country's international obligations ensures that the Protocol's allowance of socioeconomic factors does not go beyond what the WTO already permits. As the lead negotiator for developing countries, Tewolde Berhan Egziabher of

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48. Protocol, *supra* note 1, art. 26, at 1039.

Ethiopia, put it following a temporary collapse in negotiations for the Protocol in February 1999 in Cartagena:

The Miami Group and European Groups would not allow the use of socioeconomic variables even in risk assessment. The [draft article on socioeconomic considerations] is useless because it is qualified by the phrase “consistent with their international obligations” which means, in effect, that they have to give *priority to facilitating free trade*. Thus Southern nations are expected to accept whatever disruption genetically modified organisms might cause their societies and economies.<sup>49</sup>

The limited inclusion of socioeconomic factors in the Protocol further validates the claim in this essay—that science-based choice is privileged in this global regime. Such a privileging of science-based choice can be seen as akin to a problematic technicalization of what are fundamentally normative conflicts in the area of biosafety. One potentially far-reaching implication of such a privileging of science in global governance fora is that a broad range of concerns about the nature and consequences of technological change may have to be articulated by all groups in the language of technical risk. Although normative concepts such as justice, equity, fairness, or choice will remain key drivers in conflicts over global governance, they may increasingly need to be recast in the language of technical harm.

A striking example is provided by the rationales relied upon to regulate imports of transgenic agricultural commodities in India. In the global forum, developing countries, including India, justified the need for national choice prior to trade in LMOs by invoking concerns over risks to biodiversity or human health. However, the primary concern in India over imports of transgenic commodities are socioeconomic, rather than related merely to ecological or health harm narrowly defined. Yet, such broader national-level concerns over technological change were couched in the global arena in terms of risk in order to receive a hearing within global governance fora that privilege the language of technically

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49. Tewelde Berhan G. Egziabher, *Safety Denied*, OUR PLANET, June 1999, at <http://www.ourplanet.com/imgversn/102/viewpoint.html> (emphasis added).

assessable harm.<sup>50</sup> Such a privileging of technical risk assessment as a basis for national decisions is likely to have particularly important but as yet under-examined implications for developing countries, which rely relatively less on technical input into decision-making, and which have to consider diverse socioeconomic priorities in governing uptake and safe use of new technologies.

In anticipatory areas of technological change, then, where the science remains contested and uncertain, and where concerns about adoption and safe use of technologies transcend scientifically measurable harm, it remains important to go beyond science-based mediation of normative conflicts. In addition to scientific input, some form of social impact assessment should also be a critical component of anticipatory global and national governance regarding the safe uptake and use of new technologies.<sup>51</sup> While any call to assess the social impact of technological change appears to go against the grain of the fundamental premises of an increasingly globalized market system, its perils and its promise for anticipatory governance need to be explored.<sup>52</sup>

The ardent debates over the precautionary principle as a basis for decision-making in the Cartagena Protocol provide a precursor to the greater set of challenges inherent in agreeing to and implementing any form of social impact assessment as a basis for transnational governance. However, the multiple challenges inherent in this endeavor should not be reason enough to abstain from considering such governance innovations in the search for shared bases for action.

### III. WHY GLOBAL GOVERNANCE STILL MATTERS

In the final analysis, even though the biosafety area remains heavily contested, the rationale for anticipatory global governance regimes is clear: there is dire need for institutional and governance structures to co-evolve with technological changes that have transformative potential, rather than to follow in

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50. For a detailed analysis of the relevance of the Protocol for biosafety regulation in India, see Aarti Gupta, Belfer Ctr. for Sci. & Int'l Affairs, *Governing Biosafety in India: The Relevance of the Cartagena Protocol* (Oct. 2000), at <http://environment.harvard.edu/gea/pubs/2000%2D24.pdf>.

51. Some green groups have also called for such assessments. See, e.g., WORLD WIDE FUND FOR NATURE, *supra* note 18; see also Gaskell et al., *supra* note 10, at 938 (stating that "international debate and decision-making must go beyond evidence based solely on scientific risks. The moral and ethical dimensions of biotechnology that underlie public concerns need to be understood and taken into account.")

52. For detailed discussion of the innovative concept of "real-time technology assessment" to observe and influence the process by which social values become embedded in technological innovations, see David H. Guston & Daniel Sarewitz, *Real-time Technology Assessment*, 23 *TECH. IN SOC.* (forthcoming 2001).

their wake after changes have become entrenched or irreversible. Striking in this regard is Professor Roger Dworkin's statement about regulation of genetic engineering more than two decades ago. Writing in the late 1970s and critiquing the trend at the time of self-regulation by scientists of this emerging area, Dworkin stated that "our greatest need is for an institution that can anticipate problems before options are foreclosed."<sup>53</sup>

This urgent need remains more than two decades later. The critical function that the emerging biosafety regime serves, notwithstanding its limitations, is to provide an institutional context within which problems can be anticipated and options considered and exercised, rather than foreclosed through inaction. Even though shared governance precepts, such as the precautionary principle or socioeconomic considerations, remain contested, vague, and/or under-institutionalized, this very ambiguity and conflict suggests a pressing need to continue searching for shared understandings through the vehicle of global governance regimes.

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53. Roger Dworkin, *Science, Society and the Expert Town Meeting: Some Comments on Asilomar*, 51 S.CAL. L. REV. 1471, 1481 (1978).

