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**Framing “Biosafety”
in an International Context:**

The Biosafety Protocol Negotiations

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The Global Environmental Assessment project is a collaborative team study of global environmental assessment as a link between science and policy. The Team is based at Harvard University. The project has two principal objectives. The first is to develop a more realistic and synoptic model of the actual relationships among science, assessment, and management in social responses to global change, and to use that model to understand, critique, and improve current practice of assessment as a bridge between science and policy making. The second is to elucidate a strategy of adaptive assessment and policy for global environmental problems, along with the methods and institutions to implement such a strategy in the real world.

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Publication abstracts of the GEA Project can be found on the GEA Web Page at <http://environment.harvard.edu/gea>. Further information on the Global Environmental Assessment project can be obtained from the Project Associate Director, Nancy Dickson, Belfer Center for Science and International Affairs, Kennedy School of Government, Harvard University, 79 JFK Street, Cambridge, MA 02138, telephone (617) 496-9469, telefax (617) 495-8963, Email nancy_dickson@harvard.edu.

FOREWORD

This paper was written as part of the Global Environmental Assessment Project, a collaborative, interdisciplinary effort to explore how assessment activities can better link scientific understanding with effective action on issues arising in the context of global environmental change. The Project seeks to understand the special problems, challenges and opportunities that arise in efforts to develop common scientific assessments that are relevant and credible across multiple national circumstances and political cultures. It takes a long-term perspective focused on the interactions of science, assessment and management over periods of a decade or more, rather than concentrating on specific studies or negotiating sessions. Global environmental change is viewed broadly to include not only climate and other atmospheric issues, but also transboundary movements of organisms and chemical toxins. (To learn more about the GEA Project visit the web page at <http://environment.harvard.edu/gea>).

The Project seeks to achieve progress towards three goals: deepening the critical understanding of the relationships among research, assessment and management in the global environmental arena; enhancing the communication among scholars and practitioners of global environmental assessments; and illuminating the contemporary choices facing the designers of global environmental assessments. It pursues these goals through a three-pronged strategy of competitively awarded fellowships that bring advanced doctoral and post-doctoral students to Harvard; an interdisciplinary training and research program involving faculty and fellows; and annual meetings bringing together scholars and practitioners of assessment.

The core of the Project is its Research Fellows. Fellows spend the year working with one another and project faculty as a Research Group exploring histories, processes and effects of global environmental assessment. These papers look across a range of particular assessments to examine variation and changes in what has been assessed, explore assessment as a part of a broader pattern of communication, and focus on the dynamics of assessment. The contributions these papers provide has been fundamental to the development of the GEA venture. I look forward to seeing revised versions published in appropriate journals.

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ABSTRACT

Controversy swirls around all aspects of the use of biotechnology in diverse sectors such as agriculture and medicine. This paper examines a multinational effort to formulate legally binding rules for "biosafety" or the safety considerations associated with trade in the products of modern biotechnology. Negotiations for a Biosafety Protocol under the Convention on Biological Diversity were begun in early 1996, and were due to be completed in February 1999 in Cartagena, Colombia. However, no agreement was reached, and this outcome was widely characterized as a critical failure. To ascertain failure, however, one requires a conception of success, yet what could "success" have meant in this case? What transnational rules, if any, could have garnered widespread legitimacy, in the climate of extreme contestation and value dissensus surrounding all aspects of biotechnology use and regulation? I address this question through exploring whether there was any shared understanding within this negotiation about what "biosafety" constituted, and what the scope and objectives of this international coordination effort were. In examining this, I map the divergent perspectives on biosafety within these negotiations, and explore the rationales (scientific, ethical, legalistic) used to justify narrower or broader conceptualizations of this still nebulous concept, as well as the potential for cross-communication across these in forging shared understandings. In particular, the paper examines whether a reliance upon scientific rationales to define the parameters of the problem has particular legitimacy in a transnational context requiring some form of cross-cultural communication.

The paper concludes that a shared understanding of biosafety was precluded within this negotiation: this was largely because, given divergent underlying beliefs about the nature, knowability and acceptability of risks posed by use of genetic engineering (narrowly or broadly construed), the objectives pursued within these negotiations by different contending parties were fundamentally incompatible with one another. While some sought *flexibility in decision-making* for genetically modified organisms through the vehicle of the protocol (a flexibility premised upon reliance upon a precautionary approach), others sought *predictability in decision-making* for genetically modified organisms (a predictability premised upon reliance upon sound science). This fundamental conflict over the *raison d'être* of a biosafety protocol proved impossible to transcend. I conclude by noting lessons from this case for transnational governance of decision-arenas characterized by high uncertainty and value conflicts—in particular, the need to reconceptualize the notion of "sound science" before it can serve as a legitimate norm of governance in such areas.

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List of Abbreviations

AIA	Advance Informed Agreement
CBD	Convention on Biological Diversity (1992)
EPA	Environmental Protection Agency, United States of America
FAO	United Nations Food and Agriculture Organization
GBA	Global Biodiversity Assessment (1995)
GEF	Global Environment Facility (UNDP, UNEP and World Bank)
GMO	Genetically modified organism
LMO	Living modified organism
OECD	Organization for Economic Co-operation and Development
PIC	Prior informed consent
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures (under the WTO)
SBSTTA	Subsidiary Body on Scientific, Technical, and Technological Advice under the CBD
UN	United Nations
UNCED	United Nations Conference on Environment and Development (1992)
UNIDO	United Nations Industrial Development Organization
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change (1992)
UNGA	United Nations General Assembly
WMO	World Meteorological Organization
WRI	World Resources Institute, Washington DC
WTO	World Trade Organization

1 INTRODUCTION: TRANSNATIONAL GOVERNANCE OF "BIOSAFETY"

Controversy swirls around all aspects of the use of biotechnology in sectors such as agriculture, medicine, and human genetics. The rapidly expanding use of biotechnology in these sectors has been accompanied by extensive debate over the moral, ethical, political, economic and environmental consequences of this use. There exist widely divergent and culturally mediated understandings about the nature, magnitude and distribution of the potential risks and benefits associated with use of this technology (Krimsky and Plough 1988, Shiva 1993, Rissler and Mellon 1993, Ravetz and Brown 1989). Debates and dissension about these have ebbed and flowed from the early 1970s, when gene-splicing was first successfully undertaken in the United States, and have been reflected in contentious national level attempts to regulate biotechnology through the 1970s and 1980s (Harlow 1986, Tooze 1981, Gottweis 1998).

The potential risks posed by use of biotechnology in agriculture and medicine are now regulated, to varying degrees, in most OECD countries, as well as in some developing countries (Wright 1994, Gottweis 1998). The most prominent transnational efforts at rule-making for biotechnology are the regional directives promulgated in the early 1990s by the European Union on the contained use and deliberate release of genetically modified organisms.¹ More explicitly international efforts have, until recently, been in the form of non-legally binding guidelines or consensus procedures for assessing safety in biotechnology, promulgated by organizations such as the Organisation for Economic Co-operation and Development (OECD) and the United Nations Industrial Development Organization (UNIDO), where a driving concern has been the need for coherence in rules to guide industrial activities in this area.²

I focus in this paper on one of the first multinational efforts to formulate legally-binding rules for "biosafety" or the safety considerations associated with biotechnology—the negotiation of a Biosafety Protocol currently underway under the auspices of the Convention on Biological Diversity (CBD). The objective of this negotiation is to devise rules for information sharing and decision-making regarding transboundary transfers of genetically modified organisms (GMOs). Its underlying premise is recognition of the need for "informed consent" of a receiving country prior to transfers of GMOs across national boundaries. In contrast to a number of other transnational coordination efforts, especially in the environmental realm, which focus on pollution reduction or damage mitigation as a way to ameliorate a perceived shared threat, this multilateral endeavor seeks to institutionalize consent or choice as the mainstay of international coordination in this area. Protocol negotiations were begun in early 1996, and were due to be completed in February 1999 in Cartagena, Colombia. However, no agreement was attained here, and this "collapse" in the negotiations was widely characterized as a critical failure. To ascertain failure, however, one requires a conception of success, yet what could "success" have meant in this case? What transnational rules, if any, could have garnered widespread legitimacy, in the climate of extreme contestation and value dissensus surrounding all aspects of biotechnology use and regulation?

This question highlights the challenges inherent in transnational governance of complex and highly contested decision-arenas such as biosafety, which are characterized by uncertain and unclearly understood risks and benefits, differing capacities to ascertain and manage potential risks or garner potential benefits, and distinct socioeconomic needs and priorities within which international coordination efforts have to occur. As a recent volume on biotechnology decision-making at national levels emphasizes, the "contested domain of biotechnological innovation has far-reaching implications for how concepts and practices of responsible governance can evolve", yet its somber conclusion is that "a governance semantics is absent (in this area), and in its absence governance innovation cannot be expected" (O'Mahony 1999:17). An absence

of a shared governance "semantics" is more likely yet at the transnational level, where a wider constellation of diverse interests and perspectives require mediation. While a number of studies have explored what the concept of governance in the international realm might mean (see, example Young 1997, Rosenau 1995), detailed analyses of the challenges of governance, understood as shared or mutually coherent ways of conceptualizing particular problem-areas, remains to be undertaken. Given the very recent arrival on the transnational agenda of the "biosafety" problem-area, the particular challenges it poses for governance have been little analyzed.

This paper examines the biosafety negotiations as an instance of a transnational governance effort in an area of high uncertainty and value contestation. In doing so, it explores, first and foremost, whether there was any shared understanding about what "biosafety" constituted, and what the scope and objectives of this international coordination effort were. I understand the term "shared understanding" as not necessarily denoting consensus, but rather as agreement about the direction in which to proceed or ways in which to continue dialogue. Shared understandings are, in turn, dependent upon how the parameters of a particular issue get defined or framed. Much recent research in international relations, and within the Global Environmental Assessment project, has pointed to the importance of *framing*, or drawing boundaries around complex nature-society interactions, as a way to facilitate shared understandings or governance of complex and multifaceted decision-arenas (Jasanoff 1987, VanDeveer 1998).

As these studies have shown, particular ways of framing or drawing boundaries around the nature of a problem serve to mobilize different interests and actor coalitions, legitimize distinct kinds of knowledges and expertise, and result in distinct solutions being devised. Studies of global governance, especially in the environmental realm, have examined how and why particular frames gain ascendancy or dominance over others, as well as the consequences of frame changes for international decision-making and action (Mitchell 1998, Iles 1998). As a study on "social learning" in the management of environmental risk notes, such changes can sometimes be in the direction of "complexification" of frames, or a broadening of the spectrum of cause-effect scenarios that merit international concern and action (Clark, van Eijndhoven, Jäger and Dickson, forthcoming). Such complexification, since it is counter to the tendency toward simplification and/or narrowing of difference upon which policy-making must rely, presents distinct challenges to transnational governance, depending partly upon the stage at which it occurs.

In the case of biosafety, distinct and competing frames have been co-existent from the start, with none dominant. Thus, drawing boundaries around the parameters of the problem in a way that will garner widespread acceptance or legitimacy has proven to be particularly difficult. Furthermore, a variety of different rationales (legalistic, moral, economic, scientific) are deployed in the attempt to hegemonize one or another of these competing frames. In the paper, I examine the various rationales relied upon by different actor-coalitions in positing divergent understandings of biosafety, as well as the extent to which dialogue across these is both feasible and essential in forging shared understandings.

In particular, one strand of inquiry in studies of global governance has been whether *science* has particular legitimacy as a discourse that is valid across widely divergent cultural contexts (Jasanoff 1996, 1998; Mitchell 1998, Wargo 1996). Much GEA research has examined the role of allegedly "objective" scientific input and advice into decision-making for transnational environmental governance regimes, such as those for climate change or acid deposition (Biermann forthcoming, Clark 1999, Farrell and Keating 1998, Connolly *et al.* 1998, Iles 1998). Given the contested rationales deployed in the biosafety discussions, an important question in this case is whether scientific framings can facilitate or give legitimacy to transnational norm setting, in a way that moral, ethical or social arguments may not. Perspectives on this question vary, with some claiming that scientifically-sound standards can provide the only universally legitimate "language" and basis for decision-making in contested areas such as biosafety, which are

characterized by vastly differing normative positions and value conflicts. Others view the push toward solely science-based decision-making as a disingenuous attempt to ignore deep-seated differences in belief-systems in such areas. As Brian Wynne suggests in an examination of the contested area of transnational hazardous waste regulation:

"the conventional regulatory language of rationality (derived from science) artificially reduces structural uncertainty and latent conflict to technical imprecision... [A] lack of control...is concealed by the scientific language of manageable uncertainties" (Wynne 1987: ix).

At first glance, much of the discussion surrounding biosafety can be seen as the attempt to *either highlight or ignore structural uncertainty and latent conflict*, often with recourse to the "scientific language of manageable uncertainties" as a strategy by which to ignore or minimize uncertainty and conflict. Such a "technicalization" of the debate can also be accomplished by attempts to delineate clear boundaries between the scientific and the political components of the debate. As has been widely noted in the science and technology studies literature, this boundary-drawing between the "political" and the "scientific" components of decision-making has long been relied upon as a legitimization strategy in domestic environmental decision-making, especially in contentious issue-areas characterized by uncertainty and value dissensus (Jasanoff 1987, 1990; Gieryn 1995). In the paper, I explore whether recourse to technicalization and/or boundary-drawing between science and politics is underway in the attempt to forge common understandings, and explore circumstances in which such processes might facilitate decision-making, versus those in which they merely mask uncertainty and conflict, and are thus not conducive to responsible governance.

The analysis in the paper utilizes qualitative research methods. These include participant observation, from attendance at three (out of six) Protocol negotiating sessions, analysis of primary documents and position papers circulated at these meetings, and reliance upon over 30 interviews with policy-makers and major groups associated with the negotiations. While I draw on the growing secondary literature in the area of biotechnology regulation for national-level developments, as well as for comparisons across different national contexts, it should be emphasized that the analysis in this paper is primarily focused on contestations over biosafety, as aired within the particular international forum of negotiations for a biosafety protocol. It is not an in-depth examination of how divergent perspectives emerge from larger political, economic, ethical and cultural concerns at national levels (for analyses of these complex interactions, especially for OECD countries, see, for example, Gottweis 1998, Wright 1994, Krimsky 1982). I focus, instead, on how such divergent perspectives become mobilized in processes of transnational communication, and the extent to which they can be mediated in forging transnational understandings of biosafety.

Section I of this paper identifies a few critical moments of convergences and faultlines in early debates on biosafety within the Convention on Biological Diversity, which established the parameters for debate in subsequent negotiation of the protocol. Section II explores the universe of concerns that the protocol negotiations have grappled with, and analyzes the main points of convergences and divergences in the perspectives of the main contending parties with regard to what "biosafety" should include. This section also discusses the rationales put forward in support of these divergent perspectives, and explores whether they allowed for cross-communication. Section III analyzes a few instances of shared understandings attained within the deliberations of the scientific and technical expert group, as well as the strategies by which this was made possible. In the conclusion, I explore the implications of a reliance upon such strategies for effective governance in this area, and discuss why a shared understanding of biosafety was precluded within these negotiations. I also speculate about what might be required to move beyond the current impasse in this contentious transnational governance effort.

2 EARLY DEBATES: CONVERGENCES AND FAULTLINES IN DRAWING BOUNDARIES AROUND "BIOSAFETY"

The earliest „framing“ battles over the potential risks posed by transfer of GMOs across national boundaries took place during negotiation of the Convention on Biological Diversity itself, which was completed in 1992. These debates occurred in the context of deciding whether or not to include a provision within the Convention which would call for a protocol on biosafety to be negotiated under its auspices at a later date. I explore here some critical moments in these debates, since they served to establish temporary boundaries around an understanding of biosafety within this forum.

Final agreement on a provision on biosafety, Article 19.3 of the CBD, signaled a temporary stabilization in understandings with regard to three critical components of debates surrounding international action on transboundary transfer of GMOs. These three issues were, first and foremost, the primary and highly contested question about whether GMOs posed unique risks at all, and thus needed to be singled out for attention; second, whether "prior informed consent" was the appropriate transnational governance mechanism in this realm, and third, whether the Convention on Biological Diversity was the appropriate transnational forum within which to pursue this discussion, and if so, which aspects of GMO risks³ were appropriate to address within this forum. Contestations over each of these questions served to define the parameters of concern and action relating to "transboundary" transfers of "genetically modified organisms" within the CBD in subsequent discussions.

2.1 Do genetically modified organisms pose unique risks? A shift from "GMS" to "LMOs"

In the early 1990s, when calls for a Biosafety Protocol to be negotiated under the Convention on Biological Diversity were first tabled, most experience with genetically modified organisms was concentrated within a few countries of the OECD, and especially within the United States (Wright 1994, James 1998). The proposal for a provision on biosafety within the CBD came first from Malaysia and was supported by most developing countries, the Nordic states and environmental groups (own interviews; Rajan 1997: 220). These groups argued that GMOs were novel biological entities, the use of which could pose unknown and unforeseeable hazards, especially in distinct socioeconomic and ecological contexts, necessitating, at the very least, information exchange and consent in this area. In viewing GMOs as potentially hazardous, many developing country delegates, especially from Africa, were drawing upon their experiences in the recently concluded Basel Convention⁴ on hazardous waste, which had addressed the problem of "dumping" of hazardous waste in developing countries. They emphasized their lack of capacity to assess or manage the potentially unique and novel hazards to biological diversity and human health that GMOs might pose, and voiced concern that they might become the testing grounds for release of genetically modified organisms produced in OECD countries, especially given the lack of a regulatory framework for biosafety in much of the developing world.

In keeping with the stance taken within its own domestic debates and regulatory outcomes on this issue, the United States objected strongly to the singling out of biotechnology as posing hazards which were unique or distinct from those that might be associated with the techniques of traditional breeding, already in widespread use (Rajan 1997, Wright 1994, own interviews). They argued that there was no scientific basis for the claim that GMOs posed unique hazards, whether ecological or pertaining to human health. Furthermore, recombinant DNA techniques allowed, if anything, for more precision and accuracy in

transfer of genetic material between organisms and, therefore, for more predictability and control over the outcome, than did the techniques of traditional breeding (COP-CBD 1995, Gottweis 1998, own interviews).

This "no unique hazard" narrative did not, however, receive wide endorsement within the CBD discussions, and in making this argument, the United States was virtually isolated, with support only from Japan and biotechnology industry groups (Rajan 1997). Japan's oft-reiterated view of the non-uniqueness of GMO risks was that:

"it has been widely considered that recombinant DNA techniques are an extension of conventional genetic procedures and that organisms produced by this technology present risks that are the same in kind as those posed by any other organism" (COP-CBD 1995: 9).

While this argument was being made by some OECD countries at the transnational level, debates on precisely the question of whether GMOs posed unique risks had also raged at national levels in Europe for at least the preceding half-decade (Gottweis 1998). While the European Union remained somewhat ambivalent about the merits of a biosafety protocol under the CBD at this time, national legislation dealing with the potential risks posed by GMOs had been elaborated in Germany and the UK by the late 1980s, partly in testimony to the fact that a precautionary narrative was gaining ascendancy within these countries. Moreover, as noted earlier, the EU had recently concluded two community-wide directives on contained use of genetically modified microorganisms and the deliberate release of genetically modified organisms. This effectively precluded their either taking or supporting the "no unique hazard" line of argument espoused by the United States within this multilateral context.

This stand-off on the critical issue of uniqueness of risk posed by GMOs resulted in the biosafety provision being one of the last to be resolved in the rush to complete negotiation of the CBD in time for its signing at the Earth Summit in 1992. The impasse was broken when the United States suggested substituting the phrase "genetically modified organism" with "living modified organism" as a way to make the provision dealing with a biosafety protocol acceptable to them (Rajan 1997, own interviews). In making this suggestion, they sought to underscore their claim that use of genetic engineering resulted in a product that was no more risky than one obtained through other means of modifying living entities, and thus, that "living" rather than "genetically" modified organisms should be the appropriate category of concern.

Thus, in the first major clash of differing perspectives on risk in this realm, agreement was forged through reliance on creative use of language or what has been termed a "boundary-ordering device"—terminology that all can interpret according to their own underlying worldviews, yet which allows dialogue to continue (Shackley and Wynne 1996). The newly coined phrase "living modified organism" served as such a "boundary-ordering device" around which agreement could cohere, even as differential interpretations of the term continued to persist. In an explicit rendition of this, Malaysia noted, during the Nairobi Final Act to sign the Convention on Biological Diversity, that "the delegation of Malaysia understands the term "living modified organism" to mean "genetically modified organism".⁵

While this linguistic maneuver did allow agreement to be forged even as underlying differences continued to persist, it also, however, signaled an entrenchment, in an international legal document, that the potential risks posed by use of genetic engineering merited separate regulatory attention. This was a significant departure from the position that the United States had continued to espouse in a domestic context through much of the 1980s. This legitimization of GMO risks as an issue meriting international concern and action influenced, in important ways, subsequent framings of the problem within the CBD. In particular, as I argue below, those with risk narratives that were counter to such an acknowledgment now had to try to circumscribe its practical implications. They sought to do so through invoking legalistic and procedural

rationales to support desired outcomes (such as a narrower framing of biosafety within the CBD) instead of merely reiterating a no-need-for-concern argument. Section II highlights the kinds of rationales relied upon to draw boundaries around the problem of "biosafety" in light of this initial framing battle and its temporary resolution.

2.2 Is prior informed consent merited in this realm? A shift from "PIC" to "AIA"

Again, drawing partly on their experiences within the Basel Convention on hazardous waste, and concerned with the spread of novel hazards to their countries, developing countries pushed for "prior informed consent" to serve as the linchpin of a future protocol governing trade in products of modern biotechnology. A much-publicized incident in Argentina in 1986, where a genetically altered rabies vaccine was field tested by a U.S. institute on an Argentinean farm without the knowledge or consent of the government (Rajan 1997: 179) provided much fodder for developing countries in their characterization of GMOs as another potential "dumping or testing of potentially toxic substances in the developing world" problem, akin to hazardous waste and chemicals. In making this demand for prior informed consent, developing countries implied a "moral imperative" for those with greater resources and experience in this potentially risky area to be responsible and accountable for their actions, at the very least through provision of information and solicitation of consent.

The United States stated its objection to use of this terminology in the context of genetic engineering, given the association of "prior informed consent" in the international realm with hazardous and restricted substances such as banned chemicals and hazardous waste. In keeping with the claim that GMOs posed no unique risks, the US noted that since GMOs were not intrinsically hazardous, nor were they banned in the country of export, they were wholly distinct from the category of concerns for which "prior informed consent" had been mobilized as a governance mechanism in the past. With developing countries pushing for it, however, supported by Nordic countries and green groups, and with the European Union not offering vigorous objection, it proved difficult to forestall this ethically framed demand for information and choice in this realm (own interviews, Rajan 1997).

Isolated on this question, and in a final-hour compromise, the United States again relied upon creative use of language to simultaneously maintain its "not intrinsically hazardous" narrative on LMOs, and yet concede to the majority demand for informed consent in this area. They proposed substituting the phrase "advance informed agreement" for "prior informed consent" which, while ostensibly identical in meaning, was intended to be devoid of the specific institutional history, if not the set of practices, associated with "prior informed consent" in other international fora. As in the case of the shift from GMOs to LMOs noted above, while this allowed for the multilateral dialogue to continue, it did at the same time entrench the recognition of the need for choice regarding GMOs within an international legal document. Again, this initial development shaped future discursive rationales in important ways. As I argue below, for those with risk narratives that went counter to the belief that informed consent was needed in this area, future framings had to, nonetheless, focus on circumscribing the nature and parameters of such consent, rather than questioning anew the need for it.

2.3 Does "biosafety" merit international action under the CBD?

Notwithstanding the tentative agreement on the need for "advance informed agreement" prior to transboundary transfers of "living modified organisms", the pertinence of instituting such a procedure

within the Convention on Biological Diversity, as opposed to an alternative international regulatory forum, was another contentious issue requiring temporary agreement before a provision for biosafety could be included within the CBD. This debate addressed perhaps the most basic question: what kind of problem (or opportunity) did "transfer of GMOs across national boundaries" represent? There was, at the time, no *a priori* reason to consider this primarily an environmental, as opposed to, for example, a human health, food safety, trade, property rights, or socioeconomic development concern. Its framing as one or the other would clearly determine its suitability to be addressed within a particular multilateral forum, with the reverse holding true as well, in that placing it within a given forum would shape the manner in which it would become framed or defined. Given that different international regulatory regimes have distinct mandates and objectives, along with distinct underlying philosophies and modes of functioning, each has more or less legitimacy with the various actors involved with defining biosafety within the CBD. Thus, in part, those who favored the CBD as the institutional forum for discussions of "biosafety" pushed for expanding the discussion here to cover as wide a variety of concerns as feasible, while those who preferred other institutional settings sought to narrow the CBD's coverage of biosafety, through invoking other multilateral fora as more legitimate avenues for particular discussions.

In early debates about whether "transboundary transfers of GMOs" were a legitimate concern for the CBD, the predominantly environmental ministry representatives negotiating the Convention agreed that the potential for adverse impacts on biological diversity from transboundary transfers of GMOs made this an appropriate issue of concern for the CBD. This minimum base line concern with potential "adverse impacts on biodiversity" was one with which all could agree, and it provided the pivot around which international coordination for biosafety could be developed within this forum. Given, however, that the CBD was one of the first legally-binding negotiations to discuss the issue of "transboundary transfers of GMOs" it was, from the start, a key battleground for broader contestations over the diverse nature of the concerns that could be subsumed within it. Early debates were characterized, therefore, by attempts to either include or exclude a range of other potential risks and concerns (beyond adverse impacts on biodiversity) within an understanding of "biosafety" within this forum.

One additional kind of adverse impact that was an important focus of these early debates was the concern with potential human health risks arising from direct consumption of GMOs and/or their products. Developing countries and green groups argued for inclusion of adverse human health impacts in an understanding of "biosafety" under the CBD. This was premised on their belief that use of GMOs in food could pose uncertain and potentially novel health risks (COP-CBD 1995). In justifying inclusion of this within the CBD, they argued that humans constituted an integral part of biological diversity, and therefore, that adverse impacts on humans fell within the mandate of the CBD. In light of this, they argued for the right to take such impacts into account in decisions regarding transboundary transfers of GMOs, in order to protect their citizenry from inadvertent exposure to potentially hazardous substances. One counter-response to this developing country framing of the need to include human health, offered by industry and premised upon the underlying belief that these products did not pose undue risks, was that there were vastly more pressing human health concerns facing the developing world, and that a focus of regulatory attention and scarce resources on "the nebulous risks posed by asparagus" or cookies made with genetically modified soya, seemed misguided (own interviews).

The dominant OECD response to this issue, however, was that while important, human health impacts were not appropriate to address under the CBD, and were more appropriately covered by other international fora, such as the Codex Alimentarius Commission⁶, a standard-setting body responsible for promulgating international food safety standards, or the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)⁷ of the World Trade Organization (WTO). As I argue below, the fact that adverse human health impacts from GMO use were now being regulated, to greater or lesser extent, in a number of OECD

countries (Gottweis 1998), meant that attempts to exclude such considerations from a broader understanding of biosafety had to rely upon legalistic and procedural arguments about the mandate and objectives of the CBD as an environmental regime, and invocation of other international fora as more legitimate, rather than from questioning the potential risks to human health posed by GMOs, per se.

2.4 Achieving temporary boundaries around "biosafety" within the CBD

The culmination of these early debates was the finalization of Article 19.3 of the Convention on Biological Diversity, which calls on Parties to the convention to:

"consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity" (CBD 1992).

Some temporary boundaries around "biosafety" were established through this provision, though these would constantly be subject to renegotiation and dissension in subsequent discussions. What this initial boundary-drawing around biosafety accomplished, however, was legitimization of the need for international action under the CBD to deal with potential risks to biological diversity posed by transboundary transfers of GMOs, as well as prior informed consent as the main governance tool in this area. The human health concern was addressed at this stage by reference to it in a provision within the CBD dealing with domestic-level obligations for biosafety, rather than within Article 19.3., which addressed international action in this area. This temporary resolution of a contentious issue is an example of arbitrary boundary-drawing between what is acceptable for international action, versus what is to be left for domestic decision-making, a strategy increasingly deployed as negotiations of a biosafety protocol commenced. This "resolution" left open, however, for continued future interpretation the highly contentious issue of whether genetically modified foods or pharmaceutical products intended for direct consumption by humans could legitimately be included within a protocol on biosafety under the CBD.

During these early debates then, while divergent perspectives on the nature, knowability and manageability of risks associated with GMOs continued to persist, initial common understandings about biosafety were achieved largely through a reliance upon use of boundary-drawing between the international and the domestic, and creative language and „boundary-objects“ around which differential understandings could cohere. Following achievement of these initial understandings of biosafety, the focus of debate and dissension shifted from *whether* there was a need for international action in this area to *which elements* (which LMOs, which adverse impacts of LMOs) to include or exclude within a protocol on biosafety, as well as *which decision-making criteria* (whether a reliance upon sound science or a precautionary approach) should form the basis for informed consent prior to transboundary transfers of GMOs. This latter dispute was not as much in evidence in the early debates, yet it took center-stage as negotiation for a biosafety protocol was launched under the CBD and, as will be seen below, constituted one of the main arenas where the battle to either technicalize (for those seeking narrowly circumscribed international obligations for biosafety), or to resist technicalization (by those seeking broader conceptualizations of the nature of the problem) was fought.

In the next section, I explore the universe of concerns confronting the negotiation of a biosafety protocol, when this process was launched under the auspices of the CBD in early 1996, following an interim period of debate about its necessity from 1993-1995.⁸ In particular, I examine the divergences and convergences in the perspectives of the main contending parties regarding what should be included under "biosafety", the

rationales (legalistic, scientific, economic, moral) put forward to justify or hegemonize differing understandings, and the potential for communication across them in this highly contested arena.

3 NEGOTIATING A BIOSAFETY PROTOCOL: THE UNIVERSE OF CONCERNS

In the early days of the Biosafety Protocol negotiations, a bewildering range of concerns was on the negotiating table, so much so that four (out of a total of six) protocol negotiating sessions leading up to the Cartagena meeting were characterized as the "pre-negotiation" phase. During this phase, various actors, with differing degrees of familiarity and experience with the issue of potential risks from transboundary transfers of GMOs attempted to ascertain or clarify their positions with regard to the many issues swirling around. The lack of shared clarity extended to the most fundamental concerns of the negotiation, including, for example, what constituted a "living modified organism"; what the risks associated with LMOs were likely to be in very distinct socioeconomic, ecological and cultural contexts; what methods currently existed by which to evaluate these risks; and what the potential drawbacks were of reliance upon such methods in transnational cooperative action on biosafety. This pre-negotiation stage served largely to make clearer the constraints, priorities and opportunities in the area of biosafety for countries at different ends of the biotechnology use, research and development spectrum. In so doing, it set the stage for the negotiations which began in earnest only in the second-last and last meetings of the Biosafety Working Group, in Montreal in August 1998, and in Cartagena, Colombia, in February 1999.

The main contending parties or actor-coalitions which were speaking as largely "one voice" by the time of the Cartagena meeting included (1) the Miami Group (consisting of the United States, Canada and Australia, as well as Argentina, Chile and Uruguay - most field testing and commercial production of GM crops is concentrated in the United States, followed by Argentina, Canada and Australia⁹); (2) the Like-Minded Group (consisting of developing countries, minus Argentina, Chile and Uruguay); and (3) the European Union. Two non-state actor-coalitions, with a strong presence, especially towards the end, included the Global Industry Coalition (the GIC) consisting of agricultural, food, and pharmaceutical companies¹⁰, as well as an international coalition of consumer safety and green groups.

Clearly, none of these groupings are homogenous in their beliefs or practices, and there are divergent perspectives on the risks and benefits associated with use of biotechnology within each. Notwithstanding this, however, there existed enough convergences of understandings such that relatively "coherent" views were advanced by each by the time of the Cartagena meeting. These positions with regard to excluding or including various elements from a definition of "biosafety" were driven, however, by a complex mix of social, economic, political, cultural and scientific interactions at national-levels and within each regional group. Mapping these dynamics in any detail is beyond the scope of this paper. Table A in the Annex presents, instead, a brief overview of a number of key factors which shape the understandings of "biosafety" put forward by the three negotiating alliances mentioned above.

3.1 Circumscribing the universe of options: defining "biosafety"

I examine the process of defining "biosafety" within these negotiations through the lens of three key elements of concern: (i) the category of LMOs to be covered by the Protocol; (ii) the adverse effects posed by use of LMOs to be included within the protocol; and (iii) the decision-making principles underlying

consent prior to the transboundary transfers of LMOs. Table I presents the universe of options debated within the protocol negotiations in each of these three areas.

TABLE I: THE RANGE OF OPTIONS IN DRAWING BOUNDARIES AROUND "BIOSAFETY"

LMOs to be covered by the Protocol and its informed consent procedures	Adverse impacts of LMOs to be covered by the Protocol	Decision-making principles underlying informed consent for LMO transfers
<ul style="list-style-type: none"> • All LMOs <i>and</i> products deriving from them; • All LMOs; • All LMOs, excluding LMO-based pharmaceuticals; • All LMOs, excluding LMO-based pharmaceuticals, and contained use; • All LMOs, excluding LMO-based pharmaceuticals, contained use, and LMOs for processing (commodities) 	<ul style="list-style-type: none"> • Adverse impacts on biological diversity; • Adverse impacts on human health (food safety concerns); • Adverse socioeconomic impacts in the agricultural sector 	<ul style="list-style-type: none"> • Sound science or the precautionary principle; • Can or cannot take „non-scientific“ socioeconomic factors into account • Deference to WTO obligations or not

These three categories are not independent of one another, instead they are explicitly interdependent, in that beliefs about, for example, which LMOs are to be covered under the protocol, are linked to beliefs about which adverse impacts of LMOs are legitimate to consider under the CBD. The table facilitates observations about a few critical areas of contention in defining biosafety, as well as reveals the breadth of perspectives at play within these discussions. Given this breadth of perspectives, various attempts to circumscribe what was to be covered under "biosafety" relied, as argued below, upon drawing often arbitrary boundaries between these various options, which were either be hard to maintain in practice or subject to constant contestation and differential interpretations.

3.1.1 LMOs to be covered under the protocol

Products derived from LMOs

One particularly contentious issue in this first category of concern was whether to include all entities that had been genetically modified *as well as* all products deriving from them, including processed and finished goods, whether they contained traces of the modified DNA material or not. The exact point of differentiation between a GMO and a product thereof was not immediately obvious, and elaborate diagrams were drawn up during the negotiations (by the scientific and technical group) to capture exactly at what stage, and according to what criteria, a genetically modified organism was no longer an organism, but had graduated to being a "product" derived from a GMO. The more contentious question was: at which stage in this process did such an entity no longer pose risks? As much writing on risks posed by GMOs suggests, and as was argued in these negotiations by developing countries and green groups, the exact point at which

an entity with novel, even if non-viable, genetic material no longer poses hazards to biological diversity or human health remains uncertain or unknown in the present context, given the lack of sufficient empirical evidence of long term impacts of GM-products in a variety of different settings (Rissler and Mellon 1993, Ravetz and Brown 1989). Thus, scenarios where products containing non-viable fragments of "living modified organisms" could potentially pose threats to human health or biological diversity could be envisioned, and remained the subject of contestation in protocol negotiations.

Given this, inclusion of the broad spectrum of entities termed "LMOs and products thereof" in the protocol was supported by developing countries and green groups. Since, in their view, the potential risks posed by GMOs versus those posed by "products thereof" could not categorically be differentiated, these groups argued for information exchange and consent as an essential prerequisite to transboundary transfers of the entire range of these products. They also noted, in response to the suggestion that such an inclusion was outside the mandate of the negotiating group, that the language of Article 19.3 in the CBD on "safe transfer, handling and use" of LMOs meant that *any use* of LMOs, including uses in commercial products, were intended to be covered under the protocol.¹¹

Most OECD countries, as well as industry groups, countered such arguments by noting that products deriving from LMOs did not come into contact with the environment. Since they did not, therefore, pose a threat to biodiversity, there was no need for their inclusion in the protocol. As stated by the Japanese delegation, the basic argument was that "products from LMOs containing non-viable genetic material should be kept outside the scope of the protocol...as their genetic components cannot be transmitted to other living organisms in the recipient environment under natural conditions".¹² However, in addition to potential disputes over this claim that non-viable genetic material no longer posed a hazard to biodiversity, this argument did not address the developing country and green group claim that adverse impacts on human health were also to be taken into account in considerations pertaining to "biosafety".

Given that the "no risk to biodiversity" rationale remained disputed, those opposed to inclusion of „products thereof“ also argued emphatically that inclusion of the vast and growing spectrum of commercial products manufactured using LMOs would impinge upon multilateral trade rules and would be logistically impossible to implement. As the Grocery Manufacturers of America, speaking for the U.S. food, beverage, and consumer products manufacturers, emphasized, inclusion of "products of LMOs" within the protocol would bring items such as household cleaners and paper napkins (manufactured from genetically modified timber) under the informed consent procedure of the protocol, pushing the whole exercise into the realm of the ludicrous, and overwhelming the capacity of importing countries to receive and respond to information about this wide range of products. It would, in sum, "impede the economic development of countries without any compensatory environmental benefit".¹³

As can be seen from the above, since the divide over this issue could not be mediated through arguments centered around the presence or absence of risk alone, which had to rely on contested boundaries between the riskiness of viable and non-viable genetic material, as well as contested boundaries between impacts on biodiversity versus human health, those in support of narrower framings of biosafety also evoked the need for a governing norm of *implementability* in determining the scope of international action on "biosafety" under the CBD. As will be seen further below, in many instances, norms of governance emphasizing autonomy, responsibility and accountability in decision-making for transboundary transfers of LMOs, advanced by developing countries and green groups, were countered by a norm of governance emphasizing implementability.

Genetically modified pharmaceuticals

Contestations over the remaining possibilities regarding which LMOs were to be included centered around whether at least all LMOs (if not the non-viable products deriving from them) fell within the mandate of the negotiating group, or whether particular sub-categories of LMOs were also to be excluded from coverage by the protocol. While developing countries and green groups were in support of all LMOs being covered (given their support for the more inclusive category of LMOs and products thereof), the European Union and the pharmaceutical industry argued for exclusion of LMO-based pharmaceuticals, with the rationale that such products did not pose a threat to biological diversity, and therefore, were not appropriate to regulate in this forum. A corollary to this argument was that inclusion of pharmaceuticals within the protocol would hinder the widespread dissemination of the important benefits to be derived from these products. As the pharmaceutical giant Rhone-Poulenc Rorer framed it, given the lack of risk, excluding pharmaceuticals from the protocol was essential in order to "preserve access to medical treatments" and to avoid "significantly complicating deliveries of medical goods" to those most in need of them.¹⁴

In addition to the basic point of contestation over whether only adverse impacts on biodiversity were to be taken into account, this debate reflected another instance of contested boundary-drawing between categories that were often, in practice, hard to differentiate or subject to diverse interpretations. While in daily usage, pharmaceuticals might be easily distinguishable from "non-pharmaceuticals", in the case of genetically modified pharmaceuticals, however, it can remain unclear and open to differential interpretation whether, for example, bananas which have been genetically modified to serve as edible vaccines constitute an agricultural crop or a pharmaceutical product (own interviews). If such bananas were seen as an agricultural crop, they would be covered under the protocol, but if designated a pharmaceutical product, they might not. This provides a vivid example of the impact of attempting to draw boundaries around entities where, ironically, the use of modern biotechnology serves to explicitly break down previous conceptual divides (as evidenced by the new term "pharmaceuticals" in this area).

Contained use of LMOs

Most OECD countries and industry also argued for exclusion of the contained use of LMOs from the protocol's informed consent procedure, with the rationale, again, that LMOs destined for contained use would not be introduced into the environment, and thereby would not adversely affect biological diversity. As the debates and contestation over this revealed, the concept of containment could be narrowly or broadly construed—again through drawing boundaries around or defining it in relation to non-containment. Did containment mean enclosed physical structures, or could, for example, field tests of LMOs also be considered "contained use" since such tests were undertaken under experimental and controlled conditions? Defining contained use to include field tests would pose problems for countries, including most developing countries, with relatively less well-developed institutional regimes of control and oversight. This highlights, as do many of the other debates surrounding biosafety in this arena, the important insight from writing in science and technology studies that the "safety" of a product or technological innovation is dependent not only upon its physical design or characteristics, but equally upon the social context within which it is deployed (Jasanoff 1998:174). Thus, the "safety" of contained use of GMOs would be dependent, as much upon particular social, institutional and ecological contexts within which this use occurred, as upon particular mandated physical parameters of containment.

In addition to this, another point of dispute relating to contained use was whether the concept could be extended further to include biological, in addition to physical, containment. Thus, genetic modifications resulting in sterile seed, for example, (the much contested future possibility of "terminator technology") could also theoretically be exempt from the protocol's informed consent procedures, since it could be seen as a form of biological containment of the novel genetic material in an LMO. While sterile seed might be

produced for divergent reasons (mainly to serve as a form of technological patent protection) and could be objected to on different grounds, its efficacy in preventing gene flow through biological containment is, in any event, questioned by those wary of risk mitigation solutions which rely upon the same methods (the techniques of genetic engineering) in devising a solution, as those that produce the risks of concern in the first place. This is an example of what Gottweis observed, in his study of early national-level attempts in Europe to design technical risk regulation regimes for GMOs, whereby "hazards (were) being controlled by the technology that produced their possibility" (Gottweis 1998:104).

Dissension over the legitimacy of including or excluding contained use was reflected in different definitions of the term, from an earlier more explicit, but highly contested one, which stated that:

"contained use means any operation involving organisms which are controlled by physical barriers or a combination of physical and/or chemical and/or biological barriers which limit their contact with, or their impacts on, the potentially receiving environment, which includes humans" (BSWG 1999b:4)

to one which stated (much more ambiguously) that:

"contained use means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures which effectively limit their contact with, and their impact on, the external environment" (BSWG 1999; 5, article 3.b).

In this second definition, the containment could, at first glance, be seen as linked to a physical structure, yet the reference to "any operation" undertaken within such a structure could mean merely that the process of ensuring containment is undertaken within a facility or physical structure, but the containment itself is premised on the term "specific measures". This latter term is a vaguer formulation of the more specific earlier reference to "physical and/or chemical and/or biological barriers"- a formulation that left unclear whether, in fact, biological or chemical containment were included within this definition. In response to these debates, green groups noted the irony that, although contained use in laboratories was what first sparked concern over genetically modified organisms in OECD countries (Gottweis 1998, Wright 1994), some sought not only to exclude it from the purview of the biosafety protocol (which was ostensibly being negotiated for the benefit of developing countries, given their lack of domestic regulations or capacity in this area), but also to define this excluded category in the broadest possible way.

Agricultural commodities

Finally, a highly contentious issue, and another where creative boundary drawing was necessary, was whether or not genetically modified seed intended for processing (commodities) were to be covered under the protocol's informed consent procedure. Draft protocol language defined "commodities" as "LMOs intended for food, feed and processing" as opposed to those LMOs (which could be identical) but which were "intended for intentional introduction into the environment" (BSWG 1999: 7, article 5.2). Genetically modified commodities form a growing component of the global agricultural commodity trade in a few key crops, such as soybean and corn (James 1998). The major agricultural exporting countries, represented by the Miami Group, as well as industry, argued for exclusion of commodities from the informed consent procedure of the protocol, since they were intended for processing, and would not, therefore, come into contact with the environment. Again, as with products thereof, and contained use, an important corollary to this "no risk to biodiversity" argument, which remained contested, was that the structure and functioning of

the global agricultural commodity trade precluded, on logistical and implementability grounds, the coverage of agricultural commodities in a potentially onerous informed consent procedure.¹⁵

In arguing for inclusion of commodities under the informed consent procedure, developing countries and green groups pointed to the arbitrariness of a distinction between identical LMOs premised solely upon "intended use" (for processing, as opposed to for "intentional introduction" into the environment). Notwithstanding concerns about implementability noted above, these groups argued that excluding biologically viable LMOs from the informed consent procedure simply on the basis of their "intended" use was unacceptable, since intentions could never be categorically enforced nor guaranteed not to change.¹⁶ In this battle over informed consent for LM-commodities, the European Union did not categorically oppose the developing country, though members privately stated that such a demand was unrealistic and unlikely to be adhered to (own interviews). They did, however, diverge prominently from the Miami Group in this particular attempt to narrow coverage of the protocol's information sharing obligations, by emphasizing the need for a labeling requirement for LM-commodities (if not an entire informed consent process) to facilitate knowledge about transboundary movements, and the consequent safe management, of such entities.

A position paper circulated by the green group coalition during one of the all-night sessions at the tail-end of the Cartagena meeting provided a vivid display of the breadth of biologically viable LMOs that would be excluded from the protocol's obligations for information sharing, as well as from the informed consent procedure, if contained use, pharmaceuticals and commodities were excluded. Entitled "What is Left In?" the paper listed examples of the LMOs that would be excluded, most of which were those that either currently did, or were the most likely candidates, to enter international trade or exchange. These included transgenic fish for aquaculture (since this was seen as contained use), any living modified organisms intended for greenhouse experiments, all genetically engineered fruits, vegetables and tubers intended for human consumption (including strawberries, potatoes, tomatoes, and squash), transgenic soya and maize intended for animal feed, transgenic canola for processing (which the paper noted was banned in France and Greece), and all genetically engineered micro-organisms intended for sewage treatment, the production of food enzymes, for use in yogurt, or for use in production of pharmaceuticals for humans.¹⁷

The rationale to exclude all such items was, as seen above, the primary one that even though these were all biologically viable LMOs (arguably the minimum set of entities that the protocol negotiations had been launched to regulate), they should be excluded because they would not be "intentionally introduced" into the environment, and thereby would not pose risks to biodiversity. While a narrowing of "biosafety" to mean adverse impacts to biological diversity remained heavily disputed (see below), it was also unclear, as argued above, whether the exclusions envisioned could indeed be managed in a manner which precluded contact with the "environment", given the premises and assumptions upon which they were based. In light of this, for developing countries and green groups, concern over not having international obligations in place to cover this wide range of LMOs superceded otherwise legitimate concerns about implementability, which would have to be addressed if the spectrum of LMOs noted above were included in the protocol.

An over-arching response and underlying argument, offered in defense of narrowly circumscribed international obligations for biosafety, was that broader conceptualizations were always possible through domestic regulations. The draft protocol thus explicitly acknowledges the sovereign right of all countries to refuse entry to any category of LMOs beyond those covered by the protocol. While this seems, at first glance, to be sufficient to address developing country concerns over exclusions, this suggestion is premised upon a series of assumptions, which were questioned by developing countries and green groups. These included assumptions about prior knowledge and experience with the categories of LMOs and products in production, as well as assumptions about similar capacities across countries to anticipate and address their risks through domestic regulations.

The key point of contestation, in whether the onus for action was to be internationally mandated or left to domestic discretion, was over the differential distribution of the burden of anticipating and acting upon potential adverse effects that would result. Developing countries pointed out that it was impossible to keep track of all LMO commodities and products being produced in various parts of the world that might potentially enter international trade, ascertain which ones might be transferred to one's country, carry out a risk assessment of this entity, and then based on sound scientific evidence of potential harm from this risk assessment, invoke domestic regulations to prevent the entry of such a product into one's country. Instead, they noted, if the protocol mandated international obligations for notification and consent prior to transfer of a broad category of LMOs, this would internationalize the burden of anticipating harm and/or initiating procedures for consent for these entities.

3.1.2 Adverse impacts of LMOs to be included in the protocol

Adverse impacts on human health

As seen above, much of the debate over which categories of LMOs to include within an understanding of "biosafety" centered around arguments over whether such entities posed a risk to biodiversity—in contraindication to whether or not they also posed risks to human health, which would have vastly extended the scope of "biosafety" within this international undertaking. While this debate had been underway since the start of the discussions within the Convention on Biological Diversity (see section I above), it remained a subject of contestation as well as conceptual confusion through Cartagena. Many OECD countries continued to argue that human health considerations relating to LMO use were more appropriate to consider in other international fora, and through domestic regulations. Given the insistence, however, on the part of developing countries that human health impacts needed to be taken into account, an agreement emerging towards the end of the Cartagena meeting called for inclusion of the phrase "taking also into account the risks to human health" wherever a reference to adverse impacts on biodiversity appeared in the draft protocol. Most OECD countries, especially the Miami Group, pointed to this as a major compromise to developing country demands for inclusion of human health within the protocol.

The meaning and relevance of this phrase remained, however, shrouded in some mystery, given the direction that other related debates were taking. If, as interpreted by developing countries and green groups, it meant taking into account the *direct* adverse impacts on human health from LMOs, then the exclusion from the protocol and/or its informed consent procedures of contained use, products of LMOs, pharmaceuticals and LMO-commodities would render such an interpretation of the phrase meaningless in practice, since these excluded categories were those most likely to raise human health and/or food safety considerations in the first place. With their exclusion, a reference to adverse human health impacts within the protocol could be made with impunity, since it would then relate only to the sub-set of LMOs that remained under the protocol's obligations. These would be mainly LMOs intended for direct introduction into the environment, where the implications for human health were not immediately obvious. Some OECD countries argued, in support of this "compromise proposal" on human health, that it was meant to indicate *indirect* (and not direct) impacts on human health, i.e. adverse impacts on human health caused by adverse impacts on biodiversity, since this was the only legitimate pathway for inclusion of human health within the CBD. This articulation adds further conceptual confusion to the contested boundary between adverse impacts on humans versus those on biodiversity, witnessed by the fact that no one could quite articulate what the indirect adverse impacts on human health, arising from adverse impacts on biodiversity, might be, and examples of these were not easily forthcoming.

Adverse socio-economic impacts

Developing countries and green groups also argued for the need to include possible adverse socioeconomic impacts on developing country agricultural sectors in an understanding of "biosafety" within the CBD. This was driven, in part, by concerns that the livelihoods of poor farmers and/or small-scale farming practices might be adversely affected if traditional seed varieties were replaced by LMOs. More generally, a concern, voiced by green groups, was that widespread dissemination and use of LMOs might fuel new forms of dependencies on a few large multinational "life-sciences" companies, given a concentration of ownership of proprietary LMO seeds within such companies (BSWG 1999, own interviews, position papers).¹⁸ As with human health considerations, many OECD countries and industry noted the extreme importance of socioeconomic issues in decision-making regarding adoption of new technologies, yet insisted that such concerns were more suitably addressed at the domestic level, rather than being included within an international understanding of "biosafety" under the CBD.

In responding to this attempt to draw boundaries around what was appropriate for international versus domestic rule-making in this particular context, developing countries and green groups noted the disjuncture between the perceived legitimacy of international consideration of "socio-economic benefits" from unhindered movement of LMOs across national boundaries (a premise of the multilateral trade regime), but the perceived illegitimacy of similar international consideration of "socioeconomic risks". In addition to the problematic argument that concerns being aired within the "biosafety" negotiations could, in principle, simply be addressed through elaboration of domestic legislation (discussed above), these countries argued that the national prerogative to do so was not, in fact, left untouched. Thus, if adverse socioeconomic (or human health) impacts were not endorsed as relevant to decision-making for transboundary transfers of LMOs under the protocol, taking them into account through domestic regulations to prevent LMO entries could be seen as counter to obligations under the multilateral trade regime of the WTO. This debate over socioeconomic impacts highlights not only the broader versus narrower conception of risks associated with GMOs prevalent within this negotiation, but also the real challenges inherent in devising transnational norms of governance for "biosafety" under conditions of divergent socioeconomic needs, capacities and priorities, as discussed further in the conclusion.

3.1.3 Decision-making principles underlying informed consent for LMOs

Sound science versus precaution

One of the central axes of dissent in defining "biosafety" and its governance was over the appropriate decision-making principle that should underlie consent prior to transboundary transfers of LMOs. This divide, essentially one over the appropriate norm of governance for LMOs, was a prominent intra-OECD one, in contrast to the largely North-South divisions over categories of products or adverse effects of LMOs to be included within "biosafety" discussed in the two sections above. The dispute over decision-making principle or norm of governance for LMOs centered around whether national-level consent for LMO transfers should be based upon what some called "sound" scientific criteria, or whether reliance upon a "precautionary" approach was merited in this realm. It reflected underlying divergences in beliefs over the nature, magnitude and knowability of the risks posed by LMOs. The Miami Group and industry called for all decisions under the protocol to be based upon "sound science", reflecting an underlying risk narrative emphasizing the knowability and familiarity of potential risks posed by LMOs. This understanding of risks was contested by those, including the European Union, developing countries and green groups, who argued that, while scientific input remained essential in this arena, risks posed by LMOs remained unclearly understood, and could be potentially irreversible. In light of this, and given the pervading scientific

uncertainty in this realm, the ability to exercise precaution (as a way to address this uncertainty) was seen as central to any governance regime for LMOs (BSWG 1998, 1999).

Thus, the dispute over sound science or precaution was, in essence, one over differing perspectives on the extent and nature of scientific uncertainty with regard to LMO risks, as well as how such uncertainty was best addressed. The central justification for the reliance upon "sound science", or as Australia put it, "scientifically rigorous decision-making" (without specifying what that entailed)¹⁹ was that it could provide the only objective, non-normative, and standardizable basis for a transnational governance regime for LMOs. As stated emphatically by the Global Industry Coalition, "decisions under the protocol must be based upon internationally agreed scientific principles. To do otherwise would severely undercut the effectiveness and integrity of the protocol".²⁰ A corollary to this argument was that the precautionary principle remained an ill-defined, nebulous concept, one that was open to abuse, and often served as a front to further protectionist or competitiveness driven trade agendas (own interviews). Its status as a "principle", moreover, was also questioned, with those countering it choosing to characterize it as only an "approach" and one that remained undeveloped. As one Miami Group delegate noted, the precautionary approach as formulated within the 1992 Rio Declaration²¹, ostensibly the best known articulation of it, was "so wide-open that you can drive a truck through it" (own interviews). Thus, as argued by this group, any entrenchment of precaution as the basis for decision-making for "biosafety" within the CBD would render a governance regime premised upon harmonized transnational rules impossible to achieve.

While remaining a contentious divide throughout, the proponents of "sound science" or "precaution" in these negotiations did not concretely elaborate what each might mean in practice in assessing and managing for biosafety. Instead, for the most part, they merely stated their belief about the need to base decision-making on one or the other. Moreover, the relationship between the two terms also remained contested and differently understood. In particular, since the need for scientific input into decision-making for LMOs was acknowledged by all, those advocating a precautionary approach protested its characterization as somehow antithetical to a "scientific approach" (own interviews). This questioning of an alleged dichotomy or a mutual exclusivity between these concepts was reflected in a green group position paper entitled "precise precaution versus sloppy science"²² which expressed its understanding of "sound science" in this area as a science which explicitly acknowledged the need for precaution. The proponents of sound scientific decision-making countered this by suggesting that the very exercise of negotiating a protocol represented an operationalization of the precautionary approach, given the uncertainty attaching to whether there was a compelling need for regulation of genetically modified entities to begin with, and therefore, that further calls for it within the protocol's concrete obligations was unnecessary.

This dispute over sound science and precaution was also closely related to whether consent decisions under the Protocol could be in contravention with WTO obligations. The Miami Group argued, emphatically, that decisions taken under the protocol should not be counter to WTO obligations (BSWG 1999, own interviews, position papers).²³ In particular, they stressed the need for consistency with the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures, which seeks to ensure that different national-level standards for plant and animal health protection do not become unjustifiable barriers to trade, by requiring that such standards be premised again, upon "sound science" (Wirth 1994). Those disputing this deference to WTO obligations pointed out that giving "sound science" primacy of place, as WTO agreements did, placed the burden of proof in justifying decisions taken under scientific uncertainty squarely upon those alleging harm, rather than on those alleging the absence of harm. In countering this trend, and in arguing for decision-making under the CBD to be premised upon precaution, these groups sought a reversal of this distribution of burden of proof, merited by the fact that this was an arena where unambiguous scientific evidence of harm may not be always be forthcoming.

"Non-scientific" socioeconomic factors

Contestation over decision-making principles for LMOs was further complicated by the demand, from those arguing for a broader conceptualization of risks posed by LMOs to include adverse socio-economic impacts (see above), to also then take such impacts into account in decision-making for LMO transfers (Asfaw and Egziabher 1997, position papers).²⁴ While the debate over "sound science" versus precaution was essentially one over the extent of scientific uncertainty in this realm and how it was to be addressed, i.e, it remained a debate squarely within the realm of "science-based" decision-making for LMOs, the desire for inclusion of socioeconomic considerations in decision-making clearly transcended this. In arguing against this, most OECD countries and industry offered the primary rationale that since such considerations varied from country to country, harmonized rules governing national decision-making for transboundary transfers of GMOs would be precluded by their inclusion in a transnational norm of decision-making for LMOs. They also argued, moreover, that such an inclusion would almost certainly conflict with multilateral trade rules. The Global Industry Coalition stated categorically that the "introduction of socioeconomic considerations would create unnecessary and unavoidable conflicts with WTO obligations, and be disruptive of trade...".²⁵

The call for inclusion of these factors reflected the fact, however, that perceptions of risk in this realm transcended technical conceptions of quantifiable harm, that could be assessed through scientific risk assessments (even those designed to account for scientific uncertainty). It reflected, in fact, a catch-all phrase, and therefore, an ambiguous and hard-to-pin down one, which encapsulated within it pervading concerns and value conflicts transcending the technical, including concerns over unequal access to or control over the "final resource frontier" of biological knowledge, ethical misgivings associated with use of this technology to control "nature" or be deployed in critical sectors such as medicine or agriculture, or culturally varied significance and concern attaching to changing food production patterns and processes.

The discussion above reveals a variety of attempts to draw boundaries around an understanding of "biosafety" within the CBD, as well as a number of competing rationales to justify these attempts. Table II summarizes these divergent understandings of biosafety. While these perspectives did not remain static or unchanging, and were the subject of continuous negotiation, the summary presented in the table highlights the nature and extent of the divergences and convergences with regard to biosafety within this negotiation.

It should be noted that, although the table summarizes only the positions of the main intergovernmental negotiating alliances, the perspectives of industry are almost identical, in their broad contours, to those of the Miami Group, while the positions of the green groups are largely congruent with developing country perspectives, as seen from the discussion above. This clearly indicates, as much social science and international relations literature has documented (for example, Wapner 1997), that governments are not the only relevant actors in international decision-making, and that environmental governance is shaped by complex interactions between states and sub-and supranational actor-coalitions, such as industry or green groups. A detailed examination of the causal interactions between these groups at national levels, and how these interactions have dialectically shaped negotiating positions, is beyond the scope of this paper. Clearly discernible, however, even from observations drawn mainly from the international arena represented by the CBD, are the largely similar perspectives on LMO- risks espoused by developing countries and most green groups on the one hand, and the biotechnologically advanced countries and industry groups on the other, with a resulting congruence in understandings of "biosafety" within this forum.

TABLE II: WHAT IS "BIOSAFETY" AND HOW SHOULD IT BE ADDRESSED?

MIAMI GROUP	EUROPEAN UNION	LIKE-MINDED GROUP
<p><i>Biosafety</i> is a concern with the potential adverse impacts on biological diversity from release into the environment of some LMOs</p> <p><i>the solution</i> is informed consent of the importing country; based upon scientific risk assessment; and compatibility with WTO obligations</p>	<p><i>Biosafety</i> is a concern with the potential adverse impacts on biological diversity and human health from the transboundary movement of some LMOs</p> <p><i>the solution</i> is informed consent of the importing country; based upon risk assessment and the precautionary principle; and with no deference to WTO obligations</p>	<p><i>Biosafety</i> is a concern with the potential adverse impacts on biological diversity, human health, and socioeconomic patterns in the agricultural sector, from the transboundary movement, handling and use of all LMOs and products thereof</p> <p><i>the solution</i> is informed consent of the importing country; based upon risk assessment, the precautionary principle, and socioeconomic factors; and enforced through a liability and compensation regime</p>

Table II lays out visually, the narrowest and broadest "framings" of what constituted "biosafety" for different contending parties within these negotiations. Thus, it can be seen that the Miami Group had the most narrowly circumscribed understanding of what "biosafety" should include for the purpose of rule-making within the CBD, while developing countries had the broadest conception of the universe of concerns that should be addressed. In addition to this, two central points of intra-OECD divergence are clearly apparent- whether sound science or precaution should form the basis of decision-making in this realm, and whether these decisions could be in contravention to WTO obligations. As can be seen, both these areas of divergence address the decision-making principles which should govern LMO transfers, rather than which particular categories of LMOs or their adverse effects are to be included within the protocol, issues emphasized by developing countries, but where OECD countries were largely in accord.

This congruence in the views of the European Union and the Miami Group, notwithstanding clearly divergent risk narratives reflected in the call for precaution or sound science as governing norm for LMOs, can be understood partly by the fact that particular categories of LMOs or adverse impacts were covered by national-level regulations in most OECD countries, to the extent they deemed necessary.²⁶ As delegates from the European Union noted, they "did not need a Biosafety protocol to protect themselves" from adverse effects of transboundary transfers of a broad spectrum of LMOs, since they had domestic and regional laws in place to regulate the concerns they deemed legitimate. This exercise was, they argued, largely being undertaken for developing countries, which lacked such domestic regulations. Given this scenario, it remained in their interest, then, not to endorse wider conceptualizations of "biosafety" than their domestic regulations mandated, in defining international obligations with regard to transboundary transfers of LMOs (own interviews).

Notwithstanding this desire not to exceed what domestic regulations called for with regard to "biosafety", debates over international obligations in this realm also sought, as seen from the discussion above, to exclude categories of concern that *were* considered legitimate to cover under domestic regulations. Table III summarizes the rationales put forward to justify inclusions or exclusions of particular aspects of biosafety from consideration under the CBD. The pictorial overview allows for a contrast of the differing rationales

relied upon for various inclusions or exclusions, as well as which groups invoked which kind of rationale to justify their views. In concluding this section, I analyze whether communication across these frames and rationales was feasible, and where the "unmediable" points of contention lay.

3.2 Boundaries and rationales for biosafety: the potential for cross-communication

From the discussion in the preceding section and the summaries in Table II and III, it is apparent that the rationales put forward for excluding a broader range of LMOs or adverse impacts of LMOs from the protocol were largely similar across the Miami Group and the European Union. Thus, in contrast to post-Cartagena media representations of the EU as a "bridge between the Miami Group and the developing countries" in these negotiations, there were a sub-set of developing country concerns which were uniformly opposed by both the Miami Group and the European Union, and very similar rationales were invoked for these exclusions. These included, as seen above, products thereof, contained use, pharmaceuticals, informed consent for commodities, socioeconomic considerations, and a liability and compensation clause for damage resulting from transfers of LMOs (BSWG 1999). In contrast to this, in critical areas of intra-OECD disputes, where the Miami Group and the European Union disagreed (over reliance upon sound science or precaution, deference to WTO obligations, and labeling for commodities), developing countries aligned themselves with the EU positions, since they were closer to their own demands. In this sense, the EU did indeed represent a middle ground between the desired exclusions or inclusions of developing countries versus the Miami Group, but the bridge metaphor seems somewhat misplaced, since the congruence in the positions of the EU and the developing countries was largely in those areas where the EU was in conflict with the Miami Group (BSWG 1999).

It can also be seen that the nature of the rationales for exclusions and inclusions of categories of LMOs and adverse impacts offered by developing and most OECD countries differed. Developing countries chose most often to invoke risk-driven choice, responsibility and accountability rationales (regardless of manageability, implementability or legality) to justify a broad conceptualization of "biosafety" within the CBD. They emphasized, first, the potential risk, broadly defined, posed by various activities relating to LMOs, as well as the unknowability and uncertainty element of such risk. In light of this, they emphasized their (moral, if not legal) right to information and choice, even in those instances where risk had not been unequivocally established. The over-arching argument was that they lacked the domestic capacity to control the potentially novel risk represented by transboundary transfers of LMOs, hence the

TABLE III: RATIONALES OFFERED FOR EXCLUSIONS AND INCLUSIONS FROM "BIOSAFETY"

JUSTIFICATIONS FOR EXCLUSIONS	MIAMI GROUP	EUROPEAN UNION	LIKE-MINDED
This is not appropriate to address at the international level	Socioeconomic considerations	Socioeconomic considerations	
This is not appropriate to address in this international forum	Pharmaceuticals; human health	Pharmaceuticals	
This is not within the mandate of the Protocol negotiating group	Products thereof; human health	Products thereof	
This does not pose risks to biodiversity	Contained use	Contained use	
This cannot be decided in the time available	Liability and compensation	Liability and compensation	
This does not pose risks to biodiversity and is too logistically complicated	<i>AIA or labeling for commodities</i>		
This is unoperationalizable and can be abused	<i>Precautionary principle</i>		
This will nullify the objectives of the Protocol, if included		<i>Savings clause (protocol should not be counter to WTO obligations)</i>	
JUSTIFICATIONS FOR INCLUSIONS	MIAMI GROUP	EUROPEAN UNION	LIKE-MINDED
This is necessary, given the potential risks and the lack of domestic capacity to monitor; it is also within the negotiating group's mandate			Pharmaceuticals; human health; products thereof; contained use
This is necessary, given the potential threat to livelihoods			Socioeconomic considerations
This is necessary to ensure accountability and responsibility			Liability and compensation
This is necessary for informed choice		<i>Labeling for commodities</i>	<i>Labeling and AIA for commodities</i>
This is necessary, given lack of scientific certainty in this area		<i>Precautionary principle</i>	<i>Precautionary principle</i>
This is necessary for decision-making across cultural contexts	<i>Sound science</i>		
This is necessary, to prevent unjustifiable barriers to trade	<i>Savings clause (protocol should not be counter to WTO obligations)</i>		

onus rested with those exporting it to provide information and allow for the possibility of informed consent. This was, in its essence, a moral imperative form of argument, premised upon a broad understanding of risk. This reasoning was countered by most OECD countries with legalistic claims that particular sub-sets of concern relating to LMOs were either unsuitable for discussion at the international level or outside the mandate of the biosafety negotiating group. For those sub-set of concerns that were suitable for discussion, the arguments emphasized implementability concerns, premised upon a narrower conceptualization of adverse effects.

One crucial exception to this, however, was in the intra-OECD divide over whether sound science or precaution was to form the basis for decision-making on transboundary transfers of LMOs, and whether such decision-making had to be compatible with the WTO's sound-science-based regimes. This dispute was squarely a risk-and-knowability conflict, rather than one fought on legalistic or procedural grounds. Here the divergent risk narratives between the Miami Group and the European Union came into sharpest conflict. In this dispute, which extended beyond just the biosafety protocol discussions (it is also underway within the WTO, and the Codex Alimentarius Commission's discussion of standards for genetically modified foods),²⁷ the biosafety protocol negotiations became another site at which the struggle over decision-making principles was fought, with the attempt on both sides to internationalize and legitimize the governance norm underlying their preferred domestic or regional approach to GMOs.

4 DRAWING BOUNDARIES BETWEEN SCIENCE AND POLITICS

As noted in the introduction, one critical tool often relied upon as a means for forging shared international understandings is delineating boundaries between the "political" decision-making arena, and "scientific" assessments or deliberations (Gieryn 1995, Jasanoff 1988). I explore briefly here the attempts to forge shared understandings about a set of issues relegated to the "scientific and technical group" within these negotiations. The issues with which this group was entrusted included definitions of key terms, hence it fell to this group to define concepts such as "living modified organism" and "modern biotechnology". These were critical components of a transnational decision-making regime for biosafety, and hence necessarily overtly political questions, yet in establishing this group, protocol negotiators emphasized repeatedly that it was meant to provide scientific input and advice to the political decision-making arm, and was not, in and of itself, engaged in negotiations. Throughout the discussions, member scientists repeated the refrain that they were "not here to negotiate" but to come to mutual agreement about complex technical issues in their capacity as scientists.²⁸ I focus here on four instances in which agreement was secured on contentious issues by various different means, with consequences for broad or narrow framings of "biosafety", and for responsible governance in this area.

4.1 *Defining a living modified organism: interpreting "novelty"*

Since defining the undefined category of an LMO would determine the spectrum of entities that the Biosafety protocol would cover, it was, as noted above, a political undertaking, notwithstanding its discussion within the scientific and technical group. As a biologist from a developing country noted, following a particularly protracted attempt to agree upon what an "organism" was—"just put 20 scientists in a room and we will have a definition of an organism in half-an-hour—we know what an organism is—but here there are other issues involved" (own interviews). I highlight here one particularly illuminating

aspect of the debate over a definition of an LMO—that dealing with its ostensibly "novel" nature, as compared to products derived from traditional forms of genetic manipulation.

While all agreed that the concept of "novelty" served as the linchpin of a genetically modified organism, and thus was an integral component of the definition, this key term was differently interpreted by participating scientists. While for some, especially Miami Group scientists, the term novel meant "unlikely to occur in nature", for others, including developing country and Nordic scientists, it meant "unknown to occur in nature" (BSWG 1998). While a seemingly subtle distinction, this was another example of a familiar battle—that to narrow or broaden the scope of entities that would fall under the purview of the protocol. Scientists supporting the interpretation of novel as entities that were "unlikely to occur in nature" emphasized that if the genetic modification were such that the resultant product was "likely" to occur in nature (even if currently unknown to do so), it should not be subject to scrutiny under the protocol, since it would not pose risks distinct from those associated with non-genetically altered organisms existent or likely to occur in nature. Thus, only LMOs that were unlikely to occur in nature should be of concern.

Those supporting the "unknown to occur" interpretation of novelty argued, however, that it was impossible to unequivocally state what was likely or unlikely to occur in nature, and that the only legitimate, non-subjective knowledge claim that could be made was whether something was known to occur in nature or not. Since premising the notion of novelty on likelihood was too subjective, the only alternative was to define novelty by the more "objective" criterion of "known to occur" in nature. This understanding of novelty captured a broader set of genetically modified entities within the definition of an LMO, since most genetic modifications were likely to result in organisms currently unknown to occur in nature. This would result, in effect, in a process-oriented definition of an LMO, whereby if the techniques of genetic engineering were used, the resultant organism would become defined as an LMO, regardless of how close it was biologically to organisms already existing or likely to exist in nature.

This divergence within the group over what constituted novelty was resolved, not through compromise or a narrowing of difference, but through deletion from the draft definition of an LMO of both contested interpretations of novelty. While an earlier version of the definition stated that:

LMO means any living organism that contains genetic material which has been modified by modern biotechnology and of which the resulting genotype is [unlikely] [not known] to occur in nature and can confer traits novel to the organism.²⁹

the final definition read that:

LMO means any living organism containing a novel combination of genetic material obtained through the use of modern biotechnology.³⁰

As in earlier attempts to draw boundaries around biosafety within the CBD, this "agreement" that LMOs are those that "contain a novel combination of genetic material" hid within it differential, unreconciled interpretations of the meaning of the critically important concept of novelty. This allowed dialogue to continue, which was symbolically and substantively important because an agreed definition of an LMO was necessary for the "political" arm of the negotiations to continue with its deliberations. It also, however, allowed for differential interpretations on whether an entity qualified as an LMO, and therefore, whether it would be covered under the protocol, to persist. This ambiguity in international standard-setting in this area of high contestation and uncertainty may be inevitable—the merits of such ambiguity in transnational governance of such areas is discussed further in the conclusion.

4.2 *Drawing boundaries around scale: "likely potential receiving environment"*

Another instance of determining boundaries around concepts shrouded in scientific uncertainty, dispute or indeterminacy was the debate over how to draw conceptual boundaries around the notion of the "receiving environment" of an importing country, into which LMOs would be transferred. This was, again, an important element in the larger process of drawing boundaries around the area of concern, since it would influence how far the information and consent obligations of the Protocol should extend (this time in a spatial sense). As in other examples, differences amongst scientists' views on "receiving environment" reflected broader versus narrower understandings of the disputed concept. Those, including developing country and Nordic scientists, in favor of a broader conceptualization sought to ensure that the term was not restricted to just the immediate vicinity of a receiving environment, such as, for example, a corn field into which genetically modified corn was planted, but would also be understood to cover adjacent areas, into which the pollen from such crops might reach. This concern was captured by the addition of the term "potential" to "receiving environment" to include a wider swath of surrounding areas which could unintentionally become receiving environments for LMOs.

As one Miami Group scientist noted, however, the "whole planet could be a 'potential receiving environment'—clearly we don't want to worry in Australia about corn planted in Asia" (own interviews). To reflect these concerns, this group of scientists suggested the modifier "likely" in front of "potential receiving environment"—as a way to narrow the scope of the phrase by imposing some (itself undefined) criterion of "likelihood" of a "potential" being realized. Thus, resolution of disagreement over the largely unbounded concept of "receiving environment" was agreement on the convoluted and equally ambiguous phrase "the likely potential receiving environment" of an importing country—as the area of concern for risk assessments and consent procedures to manage adverse impacts of transboundary transfers of LMOs. This particular boundary-drawing exercise relied on all-encompassing rather than minimalist language (as had the case of "novelty" above) yet it served the same purpose of allowing differential interpretations of the term to co-exist. While this may have unclear ramifications for effective management of risks or implementation of the protocol at later stages, it highlights the role of ambiguity, even in scientific formulations, in ensuring agreement in this realm.

4.3 *Deliberate release versus intentional introduction: language substitution*

The use of creative language to engender agreement was also in evidence within the scientific and technical group, as it had been in the more "political" components of the discussion. This was evident in the debate over the critically important concept of "deliberate release" of LMOs into the environment, since this was the activity that the protocol would unambiguously cover. While the term indicated some form of direct contact with the environment, and could be open to differential interpretations, it was replaced throughout the text of the protocol with the phrase "intentional introduction". While this was ostensibly identical in meaning to "deliberate release", this substitution sought, as had earlier instances with "prior informed consent" or "genetically modified organisms", to avoid importing the institutional history, and underlying norms and practices, associated with use of the term "deliberate release" elsewhere. As a member of the scientific and technical group later explained (own interviews), this substitution, proposed by Miami Group scientists, was explicitly intended to distance an understanding of direct contact with the environment, within the context of the protocol, from use of the term "deliberate release" as deployed in the EU's regional directive on this subject, with its own particular scope and mandate.

4.4 *Defining modern biotechnology: negotiated science*

One of the more illuminating discussions, which lasted well into the last days of the biosafety discussions in Cartagena, was the search for agreement on what constituted "modern biotechnology" (BSWG 1999b: 3). While this could be perceived, like a definition for "living modified organism", as falling most squarely within the realm of a scientific as opposed to a political discussion, a technical issue where scientists could quickly agree, it proved to be one where the perception of the scientific and technical group, providing consensual technical definitions to the political arm of the negotiation, most explicitly broke down. The point of contention was whether the techniques of cell fusion (which are heavily relied upon in some countries for genetic modifications undertaken in contained use and/or production of pharmaceuticals) were to be included within a definition of modern biotechnology, or whether these were to be considered part of traditional breeding techniques (BSWG 1998, 1999b, position papers).³¹

Four countries which took a strong position on this, Japan, the United States and Australia, as well as Brazil, argued that these techniques had been used for decades, and that there were no known adverse effects to biological diversity (or for that matter to human health) associated with them. Others, especially developing countries, noted that the term "traditional breeding" meant very different things in different contexts, that a familiar technique in one country could be novel in another, and that it might now be possible to use cell fusion in ways that would render it more squarely able to achieve outcomes more akin to those achieved through (other) techniques of modern biotechnology than might have been possible in the past. In the discussions that ensued, a "compromise" solution proposed by the co-chair of the technical group was to include within the definition of modern biotechnology the "fusion of cells beyond the taxonomic family" as a way to capture those uses of cell fusion which might explicitly cross species barriers in a manner similar to that accomplished by modern biotechnology.

In making this suggestion, the co-chair described this as a "qualified inclusion of cell fusion, as a compromise between including it and not including it". While this suggestion engendered much debate on its substantive content, the point of interest for this paper lies in responses to the co-chair's suggestion that "a compromise" was being sought in this realm. The scientist-delegate from the United States noted that "we take issue with the suggestion that we should try to find a compromise in such a technical discussion, let's go with what the science tells us" while the Brazilian delegate seconded this by emphasizing that "we are having a technical discussion, let's hear the scientific arguments". In response, the chair of the technical group noted, in one of the first and only explicit acknowledgments of this, that "we are, for the most part, a technical group, but at some point we are negotiating, and then we may no longer be on technical grounds" (observations, BSWG 1999b).

The final outcome of this also revealing, and somewhat ironic—with the co-chair's compromise formulation endorsed by the majority of scientists present, the few delegations who had expressed dismay at the lack of sole reliance on scientific arguments in defining biotechnology, signaled their acceptance to go along with it, with a qualifying footnote that their "acceptance of the inclusion of cell fusion" within the definition of modern biotechnology as formulated by the co-chair was "dependent upon resolution of the question of inclusion of contained uses and/or pharmaceuticals. If contained use and pharmaceuticals are included within the protocol, the cell fusion issue will have to be revisited" (CG-1 1999). Thus, notwithstanding their earlier argument that a technical definition was a wholly scientific endeavor, their subsequent willingness to go along with the formulation endorsed by the rest of the group was explicitly reliant on the outcome of the political debate over inclusion or exclusion of contained use of LMOs, and pharmaceuticals products, from the protocol.

This also reveals that if cell fusion had been excluded from the definition of modern biotechnology altogether, this would have accomplished the same purpose of excluding many of the entities modified using this technique in contained use conditions or for pharmaceutical production, even if contained use and pharmaceuticals were then later included within the protocol—revealing the multiple avenues, through scientific definitions or "political" decisions, for broadening or narrowing the scope of biosafety within these discussions. In part, the extremely close link between all disputed issues, and the ramifications of decisions in one area for a number of others, made for enormously complicated "chicken and egg" substantive and procedural problems in the negotiating process, not only, as witnessed above, between the scientific and other groups, but also between all discussions underway in parallel sessions.

4.5 *The efficacy of boundary-drawing between science and politics*

The four examples above show, first, that while scientific deliberations constituted an ostensibly important part of the biosafety negotiations, these deliberations largely reflected the risk narratives, views and positions espoused by the political alliances within this negotiating forum. This was quite evident from the coincidental alignment of divergent "scientific" viewpoints on all contested issues with the "political" faultlines evident in the rest of the negotiations. Notwithstanding this, however, the fact that a body of scientific experts was sequestered from the remainder of the negotiations did result in "agreement" over some critical components of the discussions. As seen above, these shared understandings were attained largely through reliance upon strategies such as the use of creative or ambiguous language—which could meet divergent objectives, while at the same time remaining scientifically tenable to the group.

The constraint of "scientific tenability" in fact served to circumscribe somewhat the overt alignment of scientific viewpoints with political affiliation, noted above. The endeavors of this group *were* both portrayed and perceived by the members themselves as an "objective" exercise (own interviews), given that participating members were molecular biologists and geneticists who spent a better part of their time, outside these negotiations, in research laboratories working with GMOs, and who cared about their legitimacy as scientists in this arena. A politically motivated claim which was seen as scientifically untenable (rather than merely disputed) could not, therefore, pass muster in this group, in a way that other ostensibly untenable claims could be both made, and remain on the negotiating table, in the more overtly political components of the negotiations. The measure of multinational and multicultural peer review that this forced upon the discussions did serve as a constraint to overt "politicization" or even collapse in the discussions. This is reflected in the fact that the scientific and technical working group did complete all tasks assigned to it, an achievement which was much touted in the last days of the negotiation, with members pointing out that "the only room where any progress was being made was where the scientific and technical group was meeting" (own interviews).

This relative success in reaching agreement or making "progress" was, however, less about forging consensual science or delivering objective scientific advice to the political decision-making arm, as most claims on behalf of scientific input into environmental decision-making suggest, but rather about the ability to use ambiguous or all-encompassing language as a way to forge agreement. In part, this is a result of the "science" in this realm remaining highly contested, precluding any hegemonized or authoritative rendering of scientific input, assessment or advice to the more overtly political arena, upon which decision-making is then to be based. The non-existence of a hegemonized rendition of the science perhaps renders a "negotiated science" in this realm more acceptable than it otherwise might be, especially to scientists themselves. Jasanoff (1990) observes that the defining characteristic of what she calls "good science" in contested arenas of policy-making may well be a science based, explicitly, upon negotiation and compromise, rather than one perceived either as "objective" or as distant from political discussions. As seen from the above

examples, and as discussed further below, it is likely that in the contested arena of biosafety, the outcomes of a transnational "negotiated science" may well be the ones to garner the most widespread legitimacy.

5 CONCLUSION: GOVERNANCE IN "BIOSAFETY" AND BEYOND

5.1 *A shared understanding is precluded: effective sovereignty as an axis of conflict*

"No core has been identified, but the exemptions are in place"—this frustrated comment of a green group representative toward the end of the Cartagena negotiations captures the essence of the international coordination exercise represented by the Biosafety Protocol negotiations to date. As analyzed in the preceding pages, this international governance effort undertaken in a climate of extreme scientific, cultural, political and moral dissensus was largely an elaborate and contentious boundary-drawing exercise, which attempted, in a variety of ways, to define a core shared concern around which international action on the nebulous concept of "biosafety" could cohere. While debate and dissension centered around various elements to be exempted from consideration, this process did not yield a shared core concern that would provide the basis for international coordination for "biosafety" within this forum.

The analysis in this paper suggests that a shared understanding of "biosafety" was precluded within these negotiations because, in the most basic sense, the utility of *having* a Biosafety Protocol, and therefore, the objectives pursued within its negotiation by different groups were fundamentally at odds with one another. This was linked in part, to differences in worldviews with regard to the nature, knowability, certainty and acceptability of risk (narrowly or broadly understood) posed by GMOs. Given such differences, while some, including the European Union, developing countries, and green groups, saw the Biosafety Protocol as a vehicle by which to institutionalize *flexibility in decision-making* regarding genetically modified organisms (a flexibility premised upon the ability to take a precautionary approach), the agricultural exporting countries represented by the Miami Group, as well as industry, saw the Protocol as a vehicle by which to institutionalize *predictability in decision-making* regarding genetically modified organisms (a predictability premised upon decisions being based upon sound science). This fundamental difference in views regarding the *raison d'être* of a Biosafety Protocol proved impossible to bridge.

This lack of a sense of shared vulnerability in this realm precluded the compelling need for concessions from all sides, but especially from those upon whom the burden of international obligations would fall most (in this case, the exporters of LMOs). In this lack of a sense of shared threat, the biosafety issue differs from other heavily contested transnational governance efforts (such as, for example, climate change—where disputes center relatively less on *whether* a problem exists, and more on how it should be mitigated, or who should be responsible for its mitigation). Neither can it be considered a case, merely, of a failed attempt to set technical standards for commercial activities, since perceptions of the nature of the problem, while contested, exceeded such a narrow understanding of its scope. Given this lack of a shared objective, whether mitigation of a common threat, or a technical harmonization of national standards, and in the absence of a "chernobyl" in genetic engineering, the objectives pursued within this international coordination effort became premised, I argue, upon the desire to enhance, as much as possible, national-level discretion with regard to LMO transfers. In contrast to possible intentional ceding of national sovereignty that would accompany attempts to mitigate a shared threat, or harmonize technical standards, this international effort became, rather, an attempt to enhance what Miller (1998: 174) has called "effective sovereignty" or a state's actual "ability to exercise authority, autonomy and control" in particular areas.

This is distinguished from "formal sovereignty" to which lip-service is routinely paid in international governance, yet which does not capture differences in state capacities to exercise control.

For developing countries, given their lack of domestic regulations for biosafety, enhancing effective sovereignty in this realm meant having internationally mandated information sharing obligations in place for the broadest possible set of products and adverse effects relating to LMOs. Enhancing effective sovereignty meant something different for OECD countries, most of whom regulated, as they saw fit, the products and adverse impacts of LMOs through their domestic regulations, and explicitly would not want to exceed what their domestic regulations would call on them to do with regard to transboundary transfers of LMOs. Instead, an enhancement of sovereignty for these countries meant internationalizing the decision-making principle or norm of governance (sound science or precaution) *underlying* their domestic regulations. Thus, both the Miami Group and the European Union sought to use the biosafety protocol as a vehicle by which to internationalize and legitimize their preferred norm of governance. This was also driven powerfully by the fact that the very same battle was underway within the multilateral trade regime as well. Entrenchment of one or the other principle within an international legally binding agreement such as the biosafety protocol would provide key ammunition in this on-going battle in other fora (in the absence of a resolution of the sound science-precaution divide within the protocol, if the provision calling for the primacy of the WTO sound-science-based regime were retained, it would achieve the same purpose). Thus, while the rhetoric that pervaded the biosafety negotiations was that this was an exercise being undertaken for the sake of developing countries, who "most needed a biosafety protocol", agreement floundered most on this basic intra-OECD battle over the appropriate norm of governance for LMOs.

5.2 The role of science in defining norms of governance for biosafety

Given this, what is the role that science played within these negotiations? In contrast to other instances of transnational governance, in particular in the environmental realm, where science often serves to validate particular framings of the nature of the problem in early stages of problem definition, a similar reliance on science was precluded in this area. As seen in this paper, this was the case for two main reasons—first, because the science in this realm remains heavily contested, precluding hegemonic interpretations of harm or absence of harm that can garner widespread legitimacy or validate particular conceptualizations of the problem; and second, because perceptions of the nature of the problem exceed scientific or technical renditions of measurable quantifiable harm, narrowly understood. In fact, as seen in the struggle over norms of governance in this area, the attempt to technicalize "biosafety" by calling for assessments and decisions pertaining to LMOs to be based upon "sound science" was itself a central point of dispute, rather than being able to serve as a strategy (as it might have in other instances) by which to minimize, marginalize or ignore dispute.

Examinations of the role of science in other highly contested arenas, such as, for example, hazardous waste management, have concluded that devising elaborate technical criteria is often undertaken, or is seen as most necessary, under conditions of extreme institutional uncertainty and lack of trust (Wynne 1987: 9). While both these conditions certainly prevailed within the biosafety negotiations, an essential third condition (necessary for such technical criteria to be elaborated, even if they are problematic), would be minimum agreement about the parameters of the problem for which such criteria were being developed. In the absence of this minimum agreement, the very act of elaborating technical criteria itself became a highly contested exercise.

This suggests again, as seen also from the discussion of the scientific and technical group above, that in highly contested arenas such as biosafety, in the absence of minimum agreement over the nature of the

problem, mediating conflict might require a reliance upon vague or all-encompassing scientific understandings, rather than a search for precision. This finding also obtains in at least one other disputed transnational governance effort which straddles contested perspectives on scientific harm, elaborated within distinct socioeconomic contexts. As Wynne (1987) notes for the case of hazardous waste regulation:

the viability of the regulatory process may actually depend upon the very opposite of intensification of science; it may require that some imprecision and ambiguity of formal regulatory standards and definitions be maintained, as an adaptive arena in which the contending parties can interact, negotiate, and settle and renegotiate the practical meanings as they go along (1987:9).

Thus, a transnational negotiated science, which explicitly allows for ambiguity, is likely to be the way forward in managing for biosafety. This lesson, evident from the "success" of the deliberations of the scientific and technical group, has not permeated the remainder of the biosafety discussions, as witnessed by the blanket call for "sound science" to serve as a basis for decision-making for LMOs. In its implied association with objectivity and authoritativeness, such a formulation of "sound science" is intuitively counter to the concept of "negotiation" and has the potential to be disingenuous, since it chooses to ignore that the "soundness" of the science in this realm is precisely a major point of contestation. Thus, in its current formulation, it runs up against the inevitable question of *whose* "sound science".

Clearly then, and especially because science and scientific rationales will continue to be relied upon in the attempt to manage risks posed by transboundary transfers of LMOs, a reconceptualization of "sound science" as deployed within these negotiations is an essential step in the search for responsible transnational governance in this realm. Such a reconceptualization would need to cover both the parameters of the science, as well as its place in the larger universe of economic, political and social concerns within which management of newly emerging technologies will occur. Instead of a blanket call for either "sound science" or "precaution" both of which remain heavily contested and by now loaded concepts, the needs of transnational governance in this realm might be better met by a "serviceable science"³²—one which acknowledges the structural uncertainty and element of unknowability inherent in this area, as well as which explicitly incorporates within it the need for negotiated understandings, discussed above.

The challenge of transnational governance of heavily contested areas such as biosafety remains how to forge norms of governance which can take account of diversity (not just scientific, but also economic, moral and cultural perspectives) while still allowing for some narrowing of difference, in ways that are conducive to genuinely shared understandings. A reconceptualization of "sound science" as discussed above is an essential step in this larger task of mediating value conflicts in this highly contested area.

6 POSTSCRIPT: ACCOMPLISHMENTS OF THIS TRANSNATIONAL PROCESS

Some have characterized the biosafety discussions as a "vast miscarriage of resources and priorities" that has drawn attention away from concerns that the Convention on Biological Diversity might have addressed instead. As colorfully put by an industry representative, negotiation of this protocol represented a "great big flap and a ho-ha about what in fact is one of the brightest potential promises (i.e. biotechnology) in favor of biodiversity to ever come down the pipe" (own interviews). Notwithstanding other biodiversity-related concerns that could have been addressed under the convention, the accomplishments of this transnational dialogue on "biosafety" have, I argue, not been inconsequential.

First and foremost, it has served, as do many other transnational dialogues, as an extended capacity building exercise for those with less experience and familiarity with products of genetic engineering, a learning process with crucial bearing and relevance for the future. Especially for those who might most "need" biosafety rules, it has made clear the range of possibilities, together with their attendant implementability hurdles, for what could be included within domestic regulations on biosafety (or what can be demanded internationally). As a number of developing country delegates noted, even if this international forum will not endorse or include their concerns, we "now know what to put in our domestic regulations on biosafety" (own interviews). This impetus to elaborate domestic regulations for biosafety has and will continue to shape and circumscribe demands put forward in the negotiations until the present time.

This process of capacity building and transnational learning is also evident in the fact that the biosafety discussions within the CBD saw an increase in participation of representatives from other than environmental ministries towards the end, resulting in not just a multinational, but also a multisectoral dialogue. Notwithstanding where it occurs, such a multisectoral dialogue is essential to forging shared understandings in this hybrid decision-area, which sits at the cusp of economic, environmental, political and cultural concerns. This multisectoral dialogue is likely, again, to circumscribe and shape demands, and the rationales offered to support them, in transnational understandings and management of biosafety.

Clearly, all contentious issues surrounding biosafety will not be resolved within the forum of the CBD or the biosafety negotiations. In fact, they may well be resolved elsewhere first, with the multilateral trade regime as the most obvious alternative, before final agreement on a protocol is secured (negotiations are due to be completed by May 2000). Notwithstanding this, instead of being viewed as a source of embarrassment and irreparable harm to the reputation of the Convention on Biological Diversity or its institutional home, the United Nations Environment Programme, protocol negotiations to date can be seen as having furthered the cause of biosafety—however understood—in a number of important ways.

Most importantly, they have allowed for an environmental regime to weigh in on multinational debates about regulating an emerging and powerful new technology before it has become fully entrenched, a relatively unprecedented occurrence. This offers at least the option to shape the norms of governance adopted in this realm. They have also placed front and center the need to resolve potential conflicts between the obligations of countries under the WTO and multilateral environmental agreements (MEAs)—an issue which transcends biosafety, and one that has been on the transnational governance agenda for a while. Finally, the discussions have also highlighted the urgent need to resolve another crucial issue for transnational governance—how to clarify the still nebulous concept of precaution, since this is evoked so often as the preferred norm for managing hybrid decision-arenas with an environmental as well as a scientific component. Discussions in the protocol negotiations have served to dramatically highlight the challenges inherent in conceptualizing precaution in a way that can co-exist with transnational policy-making, which must necessarily entail some narrowing of difference as a basis for shared action.

NOTES

- ¹ Council Directive of 23 April 1990 on the contained use of genetically modified microorganisms (90/219/EEC); Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC) in the Official Journal of the European Communities, No L 117/1-27.
- ² Voluntary Code of Conduct for Environmental Release of Genetically Modified Organisms (GMOs), endorsed by the Informal Working Group on Biotechnology Safety, UNIDO/UNEP/WHO/FAO, 1991. Text on file with author.
- ³ While all claims about risks posed by GMOs remain contested, a variety of ecological and human health risks have been examined or posited in the literature. In the category of ecological risks are included concerns about the transfer of novel genetic material from GM-crops to wild relatives, especially in centers of diversity of major crops. If the genetic modification is intended to bestow herbicide or pesticide resistance to the modified crop, concerns relate to potential build-up of weed or pest resistance to the modification, with the potential for development of what have been termed "superbugs" or "superweeds" in the literature. Concerns pertaining to human health include the potential allergenicity to humans of novel genetic material in genetically modified crops or the processed products deriving from them. See, example, Rissler and Mellon (1993) and Nottingham (1998).
- ⁴ Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. Reproduced in Arif (1996: 417-447).
- ⁵ Declaration of Malaysia. Nairobi Final Act to Sign the Convention on Biological Diversity. Text on file with author.
- ⁶ The Codex Alimentarius Commission was jointly established by the United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO) in 1962 to develop international food safety standards. Its objective is two-fold: to protect the health of the consumer, as well as "ensure fair practices in the food trade" (Statutes of the Codex Alimentarius Commission, Art. 1, para a, reprinted in Codex Alimentarius Commission, Procedural Manual 5,1993, quoted in Wirth 1994: 825). Food safety standards promulgated by Codex are voluntary, and are intended to serve as guides to countries. These standards remained relatively obscure through the first few decades of the existence of Codex, until their endorsement within the WTO-SPS agreement (see footnote below) as legitimate international food safety standards which should be adopted by countries in the attempt to harmonize different national level food safety standards, and prevent them from becoming non-tariff barriers to trade. While most of Codex's activities have focused on the setting of standards for acceptable levels of pesticide residues and additives in food, it has also recently begun discussions on whether labeling of genetically modified food products should be required, and whether only science or also "non-scientific" criteria should also form the basis of standard-setting for GMO foods.
- ⁷ The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), completed during the Uruguay Round multilateral trade negotiations, which also culminated in the establishment of the World Trade Organization (WTO), is an explicitly science-based agreement designed to ensure that differential national „sanitary and phytosanitary standards“ (i.e. those concerned with human, animal and plant health) not become non-tariff barriers to trade. See detailed discussion of this agreement, and its science-based provisions, in Wirth (1994).
- ⁸ For discussions on a possible future biosafety protocol under the CBD in the interim period between finalization of the Convention, and launching of the Protocol negotiations, see, for example, ENB 1994 and COP-CBD 1995.

- ⁹ 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 transgenics were estimated at \$75 million in 1995, \$235 million on 1996, \$670 million in 1997, and from \$1.2 - \$1.5 billion in 1998. All data from James (1998).
- ¹⁰ As noted in its position papers, the "GIC represents over 2200 firms from more than 130 countries worldwide. Its membership includes companies from a variety of industrial sectors, including plant and animal agriculture, food production, human and animal health care, and the environment". Global Industry Coalition (GIC). February 1999. "Basic Requirements for a Successful Biosafety Protocol". Text on file with author.
- ¹¹ This argument was also made in a briefing-paper by the Third World Network, entitled "Products-thereof are *legally* within the scope of the protocol". February 1999. Text on file with author.
- ¹² Position of the Japanese Government toward a Protocol on Biosafety. February 1999. Text on file with author.
- ¹³ Grocery Manufacturers of America. "Commonly-asked questions and answers about the inclusion of "products thereof" in the Biosafety Protocol as it relates to food, beverages and consumer products". February 1998. Text on file with author.
- ¹⁴ Rhone-Poulenc Rorer. "Statement on Biosafety Protocol". February 1999. Text on file with author.
- ¹⁵ The hurdles to provision of detailed information on individual LMOs in bulk commodity shipments, as pointed out in industry non-papers, included the fact that the LMOs in these shipments were "co-mingled" with non-LMO seed, making it difficult to distinguish, for single transaction transfers, which particular LMOs were in any given shipment of grain. Moreover, given the way the commodity trade was structured, there remained no business link between the producer (farmer) of the grain, and its final exporter, making it almost impossible for the exporter to know and comply with the detailed information requirements on individual LMOs mandated by the informed consent procedure. See "Impact Analysis: an application of AIA to agricultural commodities". February 1999 (a non-paper distributed by a coalition of corn, soybean, cotton and oilseed producer/processor associations in the United States, as well as the Global Industry Coalition). Text on file with author.
- ¹⁶ Deliberations of the informal group on commodities, Cartagena. February 1999. Text on file with author.
- ¹⁷ "What is Left In?" Non-paper distributed by green groups. February 21, 1999. Text on file with author.
- ¹⁸ "Socioeconomic Considerations: recommendations from WWF". Worldwide Fund for Nature; and "Case Study on Evaluation of Socio-Economic Factors". Council for Responsible Genetics/Washington Biotechnology Action Council. February 1999. Texts on file with author.
- ¹⁹ Statement by Australia. Open-Ended Ad Hoc Working Group on Biosafety. 5th Meeting. Montreal. 17-28 August, 1998. Text on file with author.
- ²⁰ Global Industry Coalition, opus cit. 8.
- ²¹ Principle 15 of the Rio Declaration on Environment and Development states that: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". Text available in International Legal Materials, 31: 874, 1992.

- ²² Hartmut Meyer. "Precise precaution versus sloppy science—a case study". Working Group on Biodiversity. Forum Environment and Development, Germany. Third World Network Briefing Paper. 5th meeting of the BSWG, 17-29 August, Montreal. Text on file with author.
- ²³ See, for example, Statement by Australia, Open-Ended Working Group on Biosafety, 5th Meeting. Montreal 17-28 August, 1998. Text on file with author. Also available at <<http://www.dfat.gov.au/environment/bswg-5.html>>
- ²⁴ These different views on inclusion of socioeconomic considerations have been articulated throughout discussions of biosafety under the CBD and in negotiation of a Biosafety Protocol. For early discussions, see, in particular, COP-CBD (1995: 11): Annex I: Elements for the content of an International Framework on Biosafety, as well as non-papers by Australia, Switzerland, the United States, and Japan on elements of a Biosafety Protocol, circulated at the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity, Jakarta, November 1995. Texts on file with author.
- ²⁵ "Basic Requirements for a Successful Biosafety Protocol". Global Industry Coalition. February 1999. Item 4. Text on file with author.
- ²⁶ See Biotech Regulatory Developments in OECD Member countries, available at <<http://www.oecd.org>>
- ²⁷ See footnote 6 and 7 above.
- ²⁸ Deliberations of the Contact Group on Definitions, Montreal. February 1998, August 1998. Cartagena. February 1999. Texts of the deliberations on file with author.
- ²⁹ Contact Group I. Draft definition of LMO. 18 August 1998, 5 pm. Text on file with author.
- ³⁰ Contact Group I: Working Definition of LMO. 22 August 1998 (also, as the final definition, BSWG 1999: 6).
- ³¹ For arguments to exclude "cell fusion" see eg. "Comments for (sic) exclusion of "cell fusion" from the term "modern biotechnology" Japanese delegation. February 1999, Cartagena. For counter-arguments, see eg. "Definition of Modern Biotechnology: reasons for inclusion of cell fusion" Third World Network Briefing Paper, Dr. Hartmut Meyer. German NGO Forum Environment and Development. BSWG-6, Cartagena, February 14-19, 1999, and "Examples of cell fusions overcoming natural recombination barriers" NGO coalition position paper, Cartagena, February 14, 1999. Texts on file with author.
- ³² The use of the term "serviceable science" here is inspired by Sheila Jasanoff's call for "serviceable truth" in mediating policy controversies with a scientific component in *The Fifth Branch* (1990: 250).

ANNEX

Table A: National-level Factors Influencing Positions on Biosafety

NEGOTIATING ALLIANCES	AGRICULTURAL EXPORTER OR IMPORTER (including GM crops)	BIO-DIVERSITY	EXISTENCE AND CONTENT OF DOMESTIC LEGISLATION	STATE OF PUBLIC OPINION ON GMOs
MIAMI GROUP United States, Canada, Australia, Argentina, Uruguay and Chile	<i>Mainly exporters</i> , though also import significant quantities; field testing and commercial production of GM crops concentrated in these countries	Australia a mega-diverse island state	Varies – Canada and Australia have strict laws; the US regulates GM crops through existing legislation	Public concern concentrated in pockets, no widespread push to regulate GM crops more stringently
LIKE-MINDED GROUP Developing countries (minus Argentina, Uruguay and Chile)	<i>Mainly importers</i> , some large developing countries aspire to be both in the future; China is one of the major producers of GM-crops	Includes most of the world's mega-diverse regions, including the centers of origin for many crops	Developing regional frameworks and/or national legislation on biosafety – not yet widespread, but biosafety discussions have provided an impetus to do so	Growing public concern in some countries – including India and Malaysia; NGO lobbies active in this area
EUROPEAN UNION	At present <i>more importers than exporters</i> (GM-pharmaceutical industry well advanced)	Marine genetic diversity an important concern for some	Regional directives and national legislation covering all facets of trade, handling and use of GMOs	High level of public concern relating to food safety and field tests of GMOs; consumer demand for labeling

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Note: References to informal "position papers" are included within the endnotes

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