HARVARD UNIVERSITY

JOHN F. KENNEDY SCHOOL OF GOVERNMENT

Governing Biosafety in India: The Relevance of the Cartagena Protocol

Aarti Gupta

Global Environmental Assessment Project

Environment and Natural Resources Program

Belfer Center for Science
and International Affairs

2000-24

OCTOBER 2000

Belfer Center for Science & International Affairs

Governing Biosafety in India: The Relevance of the Cartagena Protocol

Aarti Gupta

2000-24 October 2000

Global Environmental Assessment Project
Environment and Natural Resources Program

HARVARD UNIVERSITY
JOHN F. KENNEDY SCHOOL OF GOVERNMENT

CITATION, CONTEXT, AND PROJECT ACKNOWLEDGEMENTS

This paper may be cited as: Gupta, Aarti. "Governing Biosafety in India: The Relevance of the Cartagena Protocol." Belfer Center for Science and International Affairs (BCSIA) Discussion Paper 2000-24, Environment and Natural Resources Program, Kennedy School of Government, Harvard University, 2000. Available at http://environment.harvard.edu/gea. No further citation is allowed without permission of the author. Comments are welcome and may be directed to the author at the Belfer Center for Science and International Affairs, John F. Kennedy School of Government, Harvard University, 79 John F. Kennedy Street, Cambridge, MA 02138; Email aarti_gupta@ harvard.edu.

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.

The Global Environmental Assessment (GEA) Project is supported by a core grant from the National Science Foundation (Award No. BCS-9521910) for the "Global Environmental Assessment Team." Supplemental support to the GEA Team is provided by the National Oceanic and Atmospheric Administration, the Department of Energy, the National Aeronautics and Space Administration, the National Science Foundation, and the National Institute for Global Environmental Change. Additional support has been provided by the Department of Energy (Award No. DE-FG02-95ER62122) for the project, "Assessment Strategies for Global Environmental Change," the National Institute for Global Environmental Change (Awards No. 901214-HAR, LWT 62-123-06518) for the project "Towards Useful Integrated Assessments," the Center for Integrated Study of the Human Dimensions of Global Change at Carnegie Mellon University (NSF Award No. SBR-9521914) for the project "The Use of Global Environmental Assessments," the Belfer Center for Science and International Affairs at Harvard University's Kennedy School of Government, the International Human Dimensions Programme on Global Environmental Change, Harvard's Weatherhead Center for International Affairs, Harvard's Environmental Information Center, the International Institute for Applied Systems Analysis, The Center for International Earth Science Information Network, the German Academic Exchange Service, the Heinrich Boll Foundation in Germany, the Heinz Family Foundation, the Heinz Center for Science, Economics and the Environment, the Massachusetts Institute of Technology's Center for Environmental Initiatives, a National Science Foundation Career Grant to Professor Daniel Schrag, the National Center for Environmental Decisionmaking Research, Yale's Department of Forestry and Environmental Studies, the University of Amsterdam's Department of Science Dynamics, the University of California at Irvine's School of Social Ecology, the University of California at Santa Cruz' Institute for Global Conflict and Cooperation, and the World Health Organization's Global Forum for Health Research. The views expressed in this paper are those of the author and do not imply endorsement by any of the supporting institutions.

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.

William C. Clark
Harvey Brooks Professor of International Science, Policy and Human Development
Director, Global Environmental Assessment Project
John F. Kennedy School of Government
Harvard University

ABSTRACT

The paper examines emerging global and national governance regimes for biosafety or the safe use of biotechnology in agriculture. The central concern is with examining the nature of the transnational-national interface in biosafety governance, i.e. the relationship between multilaterally negotiated rules and national-level biosafety decision-making. The paper examines the relevance of the recently concluded Cartagena Protocol on Biosafety, dealing with the transboundary movement of genetically modified organisms (GMOs), for biosafety governance in India. In its call for "informed consent" prior to transfer of certain GMOs, the Cartagena Protocol validates the need for national-level choice in biosafety decision-making. However, a competing imperative is standardization of rules governing such choice, in order to enhance predictability and reduce national differences in biosafety decision-making. I argue here that these potentially contradictory goals are reconciled in the Cartagena Protocol through reliance upon *a minimalist scope and ambiguous decision-criteria* for informed consent. In light of this, it is argued that the Cartagena Protocol can be relevant to national biosafety governance in three ways: first, it *legitimizes* the existence of domestic biosafety regulations; second, notwithstanding a minimalist scope, it *shifts the burden* for information sharing to producers of GMOs; and third, given ambiguous decision-criteria, it *leaves unchanged national discretion in GMO decision-making.* The paper then evaluates the likely relevance of such impacts for national-level biosafety governance in India, through examining the processes of biosafety decision-making and information sharing currently in place. I conclude with observations about the transnational-national interface, and the role for multilateral rule-making, in facilitating governance of contested decision-areas such as biosafety.

AUTHOR'S ACKNOWLEDGEMENTS

This paper has benefited from feedback and comments from many individuals. At Harvard University, I would like to thank William C. Clark, Robert Frosch, Sheila Jasanoff, Calestous Juma, Ronald B. Mitchell, Robert Paarlberg and Stacy VanDeveer for feedback at various stages of this research. At Yale University, Susan Rose-Ackerman and John Wargo provided timely input and encouragement. A special thanks to Frank Biermann for useful feedback on numerous occasions. Most important, however, I would like to express my gratitude to the many individuals in India who answered my queries - they are listed individually in the reference section. While each conversation furthered my understanding of biosafety in India, I want to thank, in particular, Dr. Gurinderjit Randhawa for the numerous ways in which she facilitated my research, and Dr. P.K. Ghosh and Dr. T.V. Ramanaiah for the many hours they took out of their busy days to discuss the status of biosafety regulation in India. I remain, of course, solely responsible for the analysis in the paper as well as for any errors. Support for this project is gratefully acknowledged from Harvard University's Global Environmental Assessment Project, Yale University Center for International and Area Studies, the Institute for the Study of World Politics (Washington DC), the Heinz Family Foundation (Pittsburgh PA), and Resources for the Future (Washington DC).

TABLE OF CONTENTS

1 INTRODUCTION 1
2 TRANSNATIONAL GOVERNANCE: THE CARTAGENA PROTOCOL 4
2.1 Informed consent: A minimalist scope 5
2.1.1 LMOs for deliberate release 5
2.1.2 LMO-commodities 6
2.1.3 LMOs for contained use 6
2.2 Informed consent: ambiguous decision-criteria 7
2.2.1 Science-based risk assessment 7
2.2.2 Precautionary decision-making 8
2.2.3 Socioeconomic considerations 9
3 NATIONAL GOVERNANCE OF BIOSAFETY IN INDIA 11
3.1 Use of genetically modified organisms in Indian agriculture 11
3.1.1 Public debate and concern surrounding biotechnology use in agriculture 11
3.1.2 The nature and extent of biotechnology research underway 12
3.2 The biosafety regulatory framework 13
3.2.1 The scope of the biosafety regulatory framework 13
3.2.2 Information required for biosafety assessment and decision-making 14
3.2.3 Consent–givers in the biosafety regulatory framework 15
3.3 Ensuring biosafety: controversies over use of genetically modified organisms 16
3.3.1 Regulatory approval for field testing transgenic cotton in India 16
3.3.2 Import of "terminator technology" into India? 18
3.3.3 Importing transgenic agricultural commodities into India 19
4 THE CARTAGENA PROTOCOL'S RELEVANCE FOR INDIA 22
4.1 The relevance of a completed protocol: legitimizing Indian biosafety regulations 22
4.2 The relevance of a minimalist scope: shifting the burden of action 23
4.2.1 Implications for India of the protocol's obligations for deliberate release of LMOs 23
4.2.2 Implications for India of the protocol's obligations for LMO commodities 23
4.2.3 Implications for India of the protocol's obligations for contained use of LMOs 25
4.3 The relevance of ambiguous decision-criteria: letting national discretion prevail 25
4.3.1 Implications for India of "sound scientific" decision-making 25
4.3.2 Implications for India of precautionary decision-making 26
4.3.3 The implications for India of socioeconomic considerations 27
5 THE PRIVATE-PUBLIC INTERFACE IN BIOSAFETY INFORMATION 28
6 CONCLUSION: MULTILATERAL RULES AND GOVERNANCE 31
REFERENCES 33
Interviews 33
Primary and secondary sources 35
TABLES 41
ENDNOTES 45

ACRONYM LIST

APHIS	Agricultural Plant and Animal Health Inspection Service, United States
CBD	Convention on Biological Diversity
DBT	Department of Biotechnology, Government India
EP Act	Environment (Protection) Act, 1986
EU	European Union
GEAC	Genetic Engineering Approval Committee
GMOs	Genetically Modified Organisms
LMOs	Living Modified Organisms
MEAs	Multilateral Environmental Agreements
MNCs	Multinational companies
MOEF	Ministry of Environment and Forests, Government of India
OECD	Organisation for Economic Co-operation and Development
RCGM	Review Committee on Genetic Manipulation
RFSTE	Research Foundation for Science, Technology and Ecology, India
TRIPs	Trade-Related Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization

1 INTRODUCTION

Transnational and national governance of newly emerging technologies, such as biotechnology, poses unique challenges. Increased use of biotechnology in sectors such as agriculture and medicine has been accompanied by conflict over the ecological, socioeconomic, political and ethical implications of such use (Rissler and Mellon 1993, Gottweis 1998, Shiva 1993). A central reason for conflict has been that biosafety governance has to be largely anticipatory, given scientific and normative uncertainties surrounding risks and benefits associated with dissemination and use of this technology. This paper examines emerging governance regimes at global and national-levels to ensure the safe use of biotechnology in agriculture. A main concern of the paper is the relevance of multilaterally negotiated biosafety rules for national-level governance. The paper analyzes international obligations contained in the recently concluded Cartagena Protocol on Biosafety dealing with transboundary movement of genetically modified organisms (GMOs). It then examines the relevance of these international obligations for biosafety decision-making in India, a key developing country and potential recipient of GMO transfers.

The Cartagena Protocol on Biosafety mandates the "advance informed agreement" of an importing country prior to the transboundary transfer of certain GMOs. The objective is to allow a receiving country to assess potential risks to biological diversity and human health from such transfers. Negotiation of the protocol was begun in 1996 under the auspices of the Convention on Biological Diversity and proved to be extremely contentious. Conflicting views on what it should accomplish led to a collapse in negotiations in February 1999 in Cartagena, Colombia. The protocol was finally concluded in January 2000 in Montreal, Canada. As of May 2000, it had been signed by 67 countries and the European Commission. It will come into force after 50 countries have ratified it, a process which can take from 1-3 years (UNEP 2000, interviews). Since the protocol is not yet in force, this paper cannot examine how its provisions are being implemented in India. Instead, in examining the transnational-national governance interface in this area, I focus on how the protocol's final obligations *compare with* currently existing Indian biosafety rules and practices. Thus, I examine whether the protocol's obligations exceed, fall short of, or serve to legitimize existing biosafety rules and practices in India. In doing so, I will draw conclusions about the role for multilateral rule-making in governance of contested decision-areas such as biosafety.

The paper finds that, in the face of persisting normative conflict, the Cartagena Protocol's final obligations are characterized, first, by a *least common denominator* or minimalist agreement and, second, by *constructed ambiguity* or openness to differential interpretations of key provisions. An important concern then becomes whether minimalist and ambiguous international obligations indicate an ineffective global regime. Writings in international relations on effectiveness of global environmental regimes offer a number of insights about the benefits of "least common denominator" international agreement (Haas, Keohane and Levy 1993, Weiss and Jacobson 1998, Victor, Raustiala and Skolnikoff 1998, Young 1999). As highlighted in these writings, such regimes can allow dialogue to begin, build trust and launch an incremental process of rule-making which can evolve into more stringent obligations later. In an influential early study, Levy, Keohane and Haas (1993) point to three ways in which evolving international regimes can help ameliorate environmental concerns. These three ways, designated the "3-Cs" by the authors, include raising national-level *concern* about the issue, enhancing the *contractual* environment, and building *capacity* to implement provisions of the agreement. However, while these might well be key functions played by an international regime, often such effects become relevant only after there is some shared international understanding about the nature of the problem being regulated.

In areas such as biosafety, which remain characterized by scientific uncertainties and value conflicts, it is precisely such shared understandings that are missing. In light of this, the implications of ambiguity in agreement, less examined in the international relations literature, deserves more sustained attention[1]. I use the term "ambiguity" here as distinct from "interpretative flexibility" which is a *sine qua non* of domestic administrative law. Clearly, as in domestic law, international regimes can also agree on broad objectives and leave their interpretation to be driven by context-dependent national differences. By ambiguity in agreement, however, I refer to ways of reaching agreement on centrally important concepts of a regime where fundamental normative disagreements cannot be mediated. In such instances, obligations which are open to differential interpretations allow *pre-existing distinct national approaches to persist*. This also highlights a relatively understudied dynamic of global governance: that international negotiations are often not just contestations over new obligations, which are to be implemented at national-levels, but rather contestations over whose preexisting and widely divergent domestic approaches will be internationalized through a global agreement.

If so, and if the implications of ambiguous and minimalist agreement for transnational governance are to be understood, it becomes necessary to analyze how approaches to risk and safety vary across different national contexts. Yet few comparative analyses of risk regulation currently exist. A vast interdisciplinary literature has, over the last 30 years, illuminated why "expert" versus "lay" perceptions of risk vary greatly in a domestic environmental decision-making context (Starr 1969, Johnson and Covello 1987, Brown 1989), and how such differences shape the nature and scope of domestic risk regulation regimes. While some comparative research has examined differing perceptions of risk and approaches to risk assessment across OECD countries (Jasanoff 1986), there exist almost no such comparative analyses across developed and developing countries, and even fewer studies of how differential understandings of risk in developing countries influence transnational risk regulation regimes and vice-versa. This paper begins to partially bridge such gaps through analyzing the relevance of the multilaterally negotiated Cartagena Protocol's biosafety obligations in the Indian risk regulation context.

In addition to different understandings of risk, a related challenge to global governance of newly emerging decision-arenas such as biosafety is the scientific uncertainty and lack of empirical evidence underpinning different claims of risks and benefits. In the face of scientific uncertainties, science as a "neutral" mediator of conflict is rendered even more problematic than it might be in domains with fewer uncertainties. It is, in fact, a paradox of this era of late modernity, as noted by Ulrich Beck (1992) in Risk Society, that the very characteristics of uncertainty and complexity associated with technological risks necessitate increased reliance on scientific input, even as the ability of science to provide concrete answers is rendered more tenuous. A growing sub-set of writings in international relations have begun to focus on how agreement on technical components of a regime can be reached in the face of scientific uncertainties. More broadly, such writings address the role of science in facilitating international cooperation on environmental issues. Early analyses in this area suggested that scientific "epistemic communities" that crossed national boundaries were key to obtaining agreement in areas (such as ozone depletion) where technical input was imperative (Haas 1992). Subsequent analyses highlight, however, that in areas of scientific dissensus and conflict, "technicalizing" an issue is often resorted to as a means by which to minimize normative conflicts (Jasanoff and Wynne 1998, Jasanoff 1996). Again, however, the implications of attempts at such technicalization, especially of newly emerging issues such as biosafety, for developing country decision-making about risk remain underexamined.

One interdisciplinary effort has begun to focus on how globally negotiated understandings of particular environmental problems are differently received in distinct national contexts. These writings have examined the sources of credibility for different groups and countries of the currently proliferating "global environmental assessments" in international environmental regimes (for overviews, see Clark 1999, Jaeger 1998, Connelly et al 1998). As shown in such writings, internationally produced scientific assessments of environmental problems such as climate change or acid rain are very differently received,

and often perceived as illegitimate, in developing countries or economies in transition (VanDeveer 1998, Biermann 1999, Kandlikar and Sagar 1999, Miller 1998). In the case of biosafety, no "global biosafety assessments" exist. Instead, the Cartagena Protocol mandates the sharing of information generated within already existing national-level biosafety assessments. It also calls for new risk assessments to be undertaken at the national-level in a GMO-receiving country. In such a scenario, disputes over the role of technical input into decision-making center not so much around a "global assessment" but rather around what the protocol views as essential elements to be included in national risk assessments and the principles underlying such assessments. Examining whether these components of national risk assessments are globally standardizable, or whether they will necessarily remain open to differential interpretation, is an important component of the analysis undertaken here.

Section 2 of the paper analyzes the scope and clarity of the Cartagena Protocol's obligations governing GMO transfers. Section 3 examines the current biosafety governance regime in place in India. Section 4 analyzes the relevance of the Cartagena protocol for biosafety governance in India. Section 5 discusses the public-private interface in information sharing for biosafety. Section 6 concludes with reflections on the role for multilateral rule-making in decision-arenas characterized by scientific and normative uncertainties. The analysis relies on qualitative methods of participant observation, semi-structured interviews and document analysis. I have participated as an observer in the Cartagena Protocol negotiations from 1998-2000, and interviewed over 30 individuals associated with the negotiations. The research on biosafety in India is based on two months of field work conducted in December 1999, January 2000 and August 2000. This included collecting primary documents and interviews with over 35 individuals, including government regulators, agricultural scientists, non-governmental organizations and the private sector.

2 TRANSNATIONAL GOVERNANCE: THE CARTAGENA PROTOCOL

As noted in the introduction, the Cartagena Protocol on Biosafety, negotiated under the Convention on Biological Diversity, mandates the "advance informed agreement" of an importing country prior to the transboundary transfer of certain GMOs (called "living modified organisms" or LMOs here)[2]. The objective is to allow an LMO receiving country to assess potential risks to biological diversity and human health that could be posed by such transfers. I have examined in detail elsewhere the negotiating history of the Cartagena Protocol, including the manner in which the new and contested concept of "biosafety" has been framed in devising international obligations in this area (see Gupta 1999, 2000a, 2000b). Given the concern of this paper with the relevance of the Cartagena Protocol for national-level governance, this section provides only the briefest discussion of this early history. It focuses, instead, on analyzing the nature of the protocol's finalized obligations and examining how these might be relevant to national governance.

The demand for a biosafety protocol and for "informed consent" prior to GMO trade came originally from developing countries, led by Malaysia, during negotiation of the Convention on Biological Diversity in the early 1990s. While this developing country demand was supported by green groups and Nordic countries like Denmark, it was opposed by agricultural GMO producer and exporter countries such as the United States and Australia, as well as by biotechnology industry groups. Developing countries called for a biosafety protocol out of concern that they might become the testing grounds for what they perceived to be novel substances which they did not have the capacity to deal with. However, those opposed to a protocol argued that GMOs did not pose risks different from those associated with other techniques of genetic manipulation such as traditional breeding, and hence did not merit separate international regulation (Gupta 1999).

Although the European Union initially offered only lukewarm support for a biosafety protocol under the CBD, negotiations of the protocol have unfolded over a four-year period of expanding public concern in Europe over ecological and food safety concerns relating to genetically modified organisms. This has been accompanied by an escalating trade conflict between the United States and the European Union. A *de facto* moratorium has been in effect against entry of transgenic crops into Europe over the last two years, as the European Community has debated amendments to its regional directives on contained use and deliberate release of GMOs and has halted new approvals until such amendments are in place[3]. This has transformed what began largely as a developed versus developing country issue into a growing intra-OECD conflict, with repercussions for the scope and clarity of the protocol's obligations.

The evolving nature of the alliances in this negotiation is reflected in the fact that towards the end of the failed Cartagena meeting in February 1999, five distinct negotiating groups had emerged. These included the Miami Group, consisting of six agricultural exporting countries (Argentina, Australia, Canada, Chile, Uruguay and the United States); the European Union; the Like-Minded Group (developing countries, excluding Argentina, Chile and Uruguay); Central and Eastern Europe; and the Compromise Group, consisting of OECD countries that are not agricultural exporters nor part of the European Union (Japan, Mexico, New Zealand, Norway, Singapore, South Korea and Switzerland). While the Miami Group was concerned about the impact of the protocol on the agricultural commodity trade, the European Union was responding to increased public concern about import into the Union of genetically modified foods. The Compromise Group with its eclectic membership represented a mix of such concerns, since it included leaders in biotechnology research such as Switzerland and major agricultural importing countries such as Japan.

The central axis of conflict in protocol negotiations has been the push by LMO importing countries to have a broad scope for informed consent and broad national discretion in LMO decision-making. While a broad scope has been pushed by developing countries, the European Union has sought to ensure discretion in decision-making. On the other hand, LMO exporting countries of the Miami Group have argued for a narrow scope for informed consent, and limited science-based decision criteria, to ensure that trade in LMOs is not unduly curtailed (Gupta 1999, ENB 1999, 2000). These competing demands have been negotiated under the rubric of "informed consent" as the central governance mechanism of this regime. The protocol's obligations are examined below, with the scope of informed consent addressed in Section 2.1 and the consent criteria in 2.2.

2.1 Informed consent: A minimalist scope

The protocol's final obligations on the scope of "informed consent" (i.e. what should be included within it) represent a least common denominator agreement, given widely divergent demands in this area. Table I provides a summary and overview of divergent views on the scope of informed consent and the protocol's final obligations. The categories of LMOs debated for inclusion within informed consent were (a) LMOs for deliberate release into the environment; (b) LMOs for food, feed or processing (agricultural commodities); (c) LMOs for contained use; (d) LMOs in transit; (e) processed and finished products deriving from LMOs; and (f) LMO-pharmaceuticals. Developing countries argued initially for all LMOs and their products to be covered by informed consent. Their rationale was that all LMOs posed risks to biological diversity and human health and thus merited information-sharing and consent prior to transfer. Most OECD countries argued that only LMOs for deliberate release should be covered by informed consent, since this was the only category of LMO likely to pose threat to biological diversity.

As can be seen from the Table, only LMOs for deliberate release are to be covered by informed consent, the category that all agreed should be included. Other categories of LMOs have information-sharing as the primary international obligation, and LMOs-pharmaceuticals are excluded from the protocol altogether, as long as they are being addressed in other international fora. In order to assess the likely implications of this "least common denominator" agreement for national biosafety governance, I examine in more detail the protocol's obligations for three categories of LMOs: LMOs for deliberate release, LMO-commodities, and LMOs intended for contained use[4].

2.1.1 LMOs for deliberate release

The obligation for "advance informed agreement" prior to transfer of LMOs for deliberate release is the center-piece of the Cartagena Protocol and the most far-reaching change from the status quo (UNEP 2000, Gupta 2000a). The procedure is initiated by a notification of intended export of an LMO by an exporter to the competent authority of the receiving country. The notification has to include specific information about the LMO, as mandated under the protocol. The exporting country has to ensure that there is a legal requirement in place for accuracy of the information being provided. Importing countries have ninety days to acknowledge receipt of the notification and 270 days to make a decision (UNEP 2000: Art. 7-10). These obligations have the concrete impact of shifting the burden of responsibility for initiating action to exporters of LMOs, from a status quo where such responsibility rested with an importing country. More explicitly, it shifts the burden of responsibility for action from those desiring information to those in possession of it.

Thus, the obligation for informed consent prior to deliberate release of LMOs *shifts the burden of responsibility for initial action from the user/regulator to the producer of an LMO.* The protocol also encourages capacity building to assist recipients of information to assess its relevance to their national contexts, and to make decisions based upon such assessments. In mandating a set procedure and time-

frames for decisions, such as the 270 day limit, the protocol also attempts to harmonize and bring predictability to national decision-making about LMO transfers. The relevance of such obligations for national governance, to be explored in subsequent sections, will turn on how such shifts in burden of responsibility to share information and solicit consent relate to already existing biosafety rules and practices in particular national contexts such as India, and how attempts to standardize procedures and time-frames resonate with existing biosafety practices.

2.1.2 LMO-commodities

The protocol's obligations for LMOs for food, feed or processing (agricultural commodities) call for information sharing rather than solicitation of consent of an importing country. These obligations were contentious through the end, given the developing country demand to include such LMOs within the advance informed agreement obligation and Miami Group opposition to this demand[5]. The compromise calls for LMO producer countries to notify the Biosafety Clearing House (the institutional mechanism under the secretariat to share information) of domestic approval of a new LMO within 15 days of the approval being granted. A potential importing country can draw on this information to decide whether to restrict import of the particular LMO, which may enter international trade in the future. Countries can rely on their domestic biosafety regulations to make such decisions or use the protocol's procedure, whereby decision must be taken within 270 days of the domestic approval notification (UNEP 2000: Article 11).

These obligations serve, first, to validate a country's right to restrict import of LMO commodities under certain conditions. This is significant because, although countries have the sovereign right to take import restrictive decisions pursuant to their domestic regulations, such actions can be seen as inconsistent with obligations under World Trade Organization (WTO). International validation through the Cartagena Protocol of the right to restrict commodity imports under certain conditions makes it less likely that domestic decisions will be seen as counter to WTO obligations. The protocol's obligations also place the onus on LMO producers to provide information about LMOs that could potentially enter international trade to the biosafety clearing house (which might otherwise be less easily accessible to different groups) A key difference, however, between the protocol's obligations for commodities and those for deliberate release is that the onus of responsibility to initiate action relating to transfer of commodities *remains on importing countries*. The responsibility rests with an importing country to ascertain which LMOs, from those reported to the Clearing House, might pose risk in their particular national context, and to assess the nature and extent of such risk prior to taking a decision about import. As with deliberate release obligations, there are provisions for capacity building and technical assistance to assist countries with this procedure. The relevance of these obligations for national governance requires, again, examining prevailing practices of biosafety information sharing in particular national contexts such as India.

2.1.3 LMOs for contained use

The protocol's obligations for LMOs for contained use entail only information sharing about such LMOs to accompany all transfers (UNEP 2000: Article 6). However, in a concession to varied understandings of what constitutes containment in different national contexts, the protocol allows that "standards in the Party of Import" will determine which LMOs are to be considered for "contained"[6] use (UNEP 2000: Article 6, para 2). This deference to national differences is one of the most striking illustrations of how global efforts to standardize safety practices are necessarily limited by the fact that "safety" remains a context-dependent concept (i.e. it will depend upon varying capacities to ensure containment, for example). One outcome of the protocol's explicit deference to differing national understandings of containment is a reduced transnational predictability regarding the procedures governing transboundary movements of this category of LMOs. Given this (justifiable and inevitable) lack of standardization, the relevance of the protocol's obligation to share information about LMOs for contained use will turn on

national understandings of containment, the ability to ensure adequate containment, and the already prevailing practices in biosafety information generation and sharing for such LMOs in different national contexts.

2.2 Informed consent: ambiguous decision-criteria

In addition to mandating a minimum scope for informed consent, the protocol's final obligations are also characterized by ambiguity regarding the nature and "sound-scientific" content of the biosafety information to be generated, and the decision-criteria for consent. Disputes in this area during protocol negotiations centered around whether consent was to be based upon "sound" scientific evidence of harm posed by LMO transfers or whether countries had the right to restrict such transfers in the absence of scientific certainty of harm (i.e. whether precautionary decision-making was permitted). While the Miami Group argued for decisions to be based upon sound science, the European Union insisted that precautionary decision-making was essential in this area, given pervading scientific uncertainty about risks (UNEP 1999, ENB 1999, Gupta 1999). This dispute was tied to the contentious issue of the relationship of the protocol's obligations to multilateral trade rules, such as those of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). This agreement calls for national sanitary and phytosanitary measures relating to human, animal and plant health to be scientifically sound and allows for precautionary decision-making only on a provisional basis (for details see Wirth 1994)[7].

Developing countries supported the European Union on the need for precautionary decision-making for LMO transfers, yet this was clearly an issue over which the faultlines were deeper between OECD countries. For countries of the South, a main concern was inclusion of socioeconomic considerations in LMO decision-making. Developing countries argued that risks posed by LMOs went beyond quantifiable harm assessed through scientific risk assessments, even those that could account for scientific uncertainties. Key concerns relevant to LMO decision-making included whether widespread use of LMOs would fuel new forms of dependencies on technologically advanced countries or multinational companies, or affect traditional livelihoods. Most OECD countries opposed inclusion of socioeconomic considerations in LMO decision-making. They argued that such considerations varied greatly between countries and their inclusion would preclude predictable and harmonized international biosafety rules. The Cartagena Protocol's final compromises call for decisions about LMO transfers to be based upon a scientifically sound risk assessment. Also allowed, however, are precautionary restrictions on LMO transfers in the face of scientific uncertainty about adverse impacts posed by such transfers. Finally, socioeconomic impacts can be taken into account in decision-making, yet their scope is narrowly restricted. In discussing the relevance of these decision-criteria for national governance, I examine further below the clarity of each for LMO decision-making.

2.2.1 Science-based risk assessment

In calling for science-based decision-making for LMO transfers, the protocol mandates that decisions be based upon a quantitative risk assessment. Such risk assessments are to be "carried out in a scientifically sound manner...taking into account recognized risk assessment techniques" (UNEP 2000: article 15 and Annex II). Recognized techniques, principles and methodologies for risk assessment are contained in the protocol's Annex II, now a concise two-page document yet one which was vigorously debated during negotiation of the protocol (ENB 1998, 1999). Importantly, the protocol's obligations on risk assessment concedes that the data to be generated in such assessments cannot be internationally harmonized, given the diverse agroecological environments within which they will be undertaken. As acknowledged in the protocol's obligations, in different risk assessments "the required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use

and the likely potential receiving environment" (UNEP 2000: 20, Annex II, para 6,7). In recognition of this, the information to be evaluated in a national risk assessment is listed under Annex II as "points to consider" rather than as mandatory criteria to be assessed in all cases.

Although the protocol's obligations acknowledge that data to be generated in a risk assessment will vary by context, they still mandate, as noted above, that such assessments be scientifically sound. However, the interpretation of what will be considered "sound" scientific criteria to be assessed will clearly *also vary* from context to context. This was evident during negotiations of the protocol itself, in deliberations by a group of scientific and technical experts from different countries to define key scientific concepts central to the emerging regime. As discussed in detail elsewhere, *cross-culturally valid scientific definitions* of key concepts such as "modern biotechnology", "living modified organism" and "receiving environment" for an LMO could only be agreed upon here through a reliance on ambiguous rather than technically precise or scientifically "sound" language (Gupta 1999: 22-25).

One such example illustrates the challenges inherent in standardizing or developing uniformly interpretable or global parameters for "scientifically sound decision-making" for LMO transfers. Scientists from different countries sought, for example, to define the ecological unit represented by the "receiving environment" for release of LMOs. Those arguing for a broad understanding of this term noted that a receiving environment should include not only the particular field into which an LMO was sown but also its surrounding areas, since these could inadvertently become receiving environments. The term "potential" was added to "receiving environment" to address this concern. However, this was seen as too broad by others, who argued that "potential receiving environment" for an LMO could be the whole planet. These scientists proposed the qualifier "likely" to address their concern. As a result, the ecological zone for which the scientifically sound assessment of adverse impacts from LMO releases is to be undertaken is characterized in the protocol as the "likely potential receiving environment" (UNEP 2000: Annex II, Article 1).

The ambiguity inherent in this formulation leaves it to the discretion of each national risk assessor to determine the scope of the receiving environment for an LMO. This openness to differential interpretations is perhaps unavoidable, yet the assumption underlying the call for scientifically sound decision-making is that such determinations can be made on the basis of universally understood or uniformly interpretable scientific criteria. This assumption was also revealed as problematic in attempts to develop a shared scientific understanding of the concept of "novelty" which underpins definition of a living modified organism. When divergent scientific understandings of novelty could not be reconciled, it was left unexplained, thereby allowing differential interpretations to persist (Gupta 1999). It is argued, from the above, that the call for scientifically sound decision-making in an arena where the science itself remains heavily contested will inevitably result in ambiguity and openness to differential interpretations, rather than standardized, uniformly interpretable criteria. Clearly, the implications of this for national-level governance, to be explored in subsequent sections, will turn on the nature of the decision-criteria currently being relied upon, as well as whose understandings of "sound science" currently prevail.

2.2.2 Precautionary decision-making

As noted, in debates over sound science versus precautionary decision-making, the protocol *legitimizes both* as necessary bases for decision-making about LMO transfers[8]. Thus, in addition to requiring a scientifically sound risk assessment, the protocol allows for potentially import-restrictive decisions in the face of scientific uncertainty about adverse impacts posed by LMOs (precautionary decision-making). The protocol's understanding of precautionary decision-making is included within its decision-procedures governing LMOs for deliberate release and LMO commodities (UNEP 2000: Articles 10.6 and 11.8)[9]. The language on precaution in the body of the protocol has been hailed as the first operationalization of

the precautionary principle in an environmental agreement. However, examining the language reveals that rather than operationalizing "the" precautionary principle (there is no universally shared version) it represents a mix of existing formulations in other agreements. As I have argued elsewhere, a comparison with other dominant renditions of precautionary decision-making, including Principle 15 of the Rio Declaration and Article 5.7 of the WTO Sanitary and Phytosanitary Measures Agreement[10], reveals that the protocol's language can be differently interpreted to both exceed and not exceed what is allowed for under existing agreements with relevance for LMO trade (Gupta 2000b: 221-223).

In particular, one reading of the language on precaution in the text of the protocol is that (in keeping with Article 5.7 of SPS) it takes a scientific risk assessment as its starting point. The language specifies that precautionary actions are justified when there is scientific uncertainty about "the extent" of an adverse impact posed by an LMO (but makes no reference to uncertainties relating to *whether or not* an adverse impact exists). This can be interpreted as requiring prior scientific documentation of the existence and nature of an adverse impact before precautionary action can be taken. In addition, however, the protocol also evokes Principle 15 in its preamble and objectives. The language of Principle 15 is again open to multiple interpretations. While it imposes a criterion of "cost-effectiveness" on precautionary actions on the one hand, it also states that "lack of full scientific certainty" should not preclude action to mitigate harm. Such references raise the specter of a zero-risk standard for some, since "full" scientific certainty about lack of adverse impact is seen as unattainable. In sum, the outcome is openness to multiple interpretations of the criteria which can trigger legitimately precautionary actions under the protocol.

The implications of ambiguity in this area remain important to assess in different national contexts, given the increased attention to the precautionary principle in the emerging global environmental governance architecture. While much debate on precautionary decision-making has occurred within OECD countries, the relevance of precautionary environmental health and safety standards for developing countries has been little examined. Even fewer studies have examined how precautionary decision-making is operationalized within national-level decision-making in developing countries such as India. The discussion on biosafety decision-making in India in subsequent sections will shed light on this much needed dimension.

2.2.3 Socioeconomic considerations

Finally, the protocol's finalized decision-criteria allow for limited consideration of adverse socioeconomic impacts in decisions about LMO transfers. Specifically, it allows countries to take into account "consistent with their international obligations, socioeconomic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity..." (UNEP 2000: Article 26). This is a narrow formulation insofar as it links the socioeconomic impacts that can be taken into account to impacts on biodiversity. This excludes considerations such as export substitution potential of LMOs, the loss of traditional livelihoods, or increased dependence on multinational companies, socioeconomic concerns voiced by developing countries. In addition, the proviso that decisions based on socioeconomic considerations are to be consistent with a country's international obligations (under the WTO) ensures that this concession to developing country concerns does not enhance national discretion beyond what the WTO already allows for. The question for transnational-national governance, evaluated in subsequent sections, is the relevance of such a narrow formulation for countries such as India, where socioeconomic considerations figure prominently in public debates about LMO use and are an important component of biosafety decision-making.

As the above analysis of the protocol's obligations reveals, its scope and criteria for "informed consent" are characterized by least common denominator agreement and by ambiguity. In particular, the *scope* of informed consent (what it should cover) is characterized by minimalist agreement, since only LMOs for

deliberate release are included. In turn, the *criteria* for consent, in particularly scientifically sound as well as precautionary decision-making, are characterized by ambiguity and openness to differential interpretations. I turn next to the relevance of these minimalist and ambiguous international obligations for biosafety governance in India.

3 NATIONAL GOVERNANCE OF BIOSAFETY IN INDIA

This section examines biosafety governance in India. Section 3.1 focuses on public concern about biosafety, the research on GMOs currently underway and the regulatory framework for assessing and managing risks associated with use of GMOs in agriculture. Section 3.2 examines recent controversies surrounding GMO use in India, which reveal how the regulations work in practice.

3.1 Use of genetically modified organisms in Indian agriculture

3.1.1 Public debate and concern surrounding biotechnology use in agriculture

Although little systematic research has been undertaken about public perceptions surrounding biotechnology use in India, it can be ascertained from media reports and interviews that public concern about GMO safety is not currently widespread. Instead, debate is concentrated amongst a few vocal critics and proponents of GMO use in agriculture. The critics include non-governmental organizations, prominent among them the Research Foundation for Science, Technology and Ecology (RFSTE), led by activist Vandana Shiva. Alliances between groups concerned with biosafety and intellectual property rights are likely when the two issues intersect, such as when patented seed is field tested to meet biosafety requirements. Opponents of seed patenting in India include a non-government organization, the Gene Campaign, launched by geneticist Dr. Suman Sahai in 1992 to oppose the trade-related intellectual property rights proposals in the Dunkel Draft of the Uruguay Round multilateral trade negotiations (Sahai, undated). Her campaign against the patenting of seed has received the support of highly influential farmers organizations, some of which are also opposed to transgenic crops (Telils 1993).

On the other hand, proponents of the use of biotechnology in agriculture include many leading public sector agricultural scientists and government regulators, especially at the Department of Biotechnology, whose mandate is to facilitate (but also to regulate) biotechnological research in India. Key private sector seed companies, with a history of involvement in developing hybrid seed, also emphasize the need for transgenic crops in Indian agriculture. Finally, the Supreme Court can be an influential player in the Indian biosafety debate, given the potential for public interest litigation to be brought against government regulators alleging non-compliance with national and international obligations to ensure biosafety.

Within these different groups, views about risks and benefits posed by GMOs are similar to those espoused elsewhere, i.e. they cover the spectrum of ecological, human health, food safety, ethical and socioeconomic concerns. However, the issues that have generated the most impassioned debate in India have less to do with ecological or food safety concerns and more to do with socioeconomic considerations arising from increased reliance on GMOs in agriculture. The socioeconomic concern voiced most often is that reliance on transgenic seeds will exacerbate small farmer dependence upon multinational companies and capital intensive agriculture. Groups who oppose use of biotechnology in agriculture often cast their arguments in overtly nationalist idioms, with slogans such as "Monsanto Quit India" and "bija satyagrah" (seed-related civil disobedience), evoking images of the anti-colonialist freedom struggle of the early 1900s (RFSTE 1998).

Socioeconomic concern over increased foreign dependence is linked to the always complex issue of food security in countries such as India. Food security in developing countries is evoked by supporters of biotechnology as a central reason to embrace transgenic crops, given the need to increase agricultural productivity in the face of a declining resource base. This claim is dismissed as disingenuous by

opponents, who point out that hunger is not necessarily related to insufficient food production. Notwithstanding rhetorical references to food security in the debate on GMOs, a concern with food security is clearly of immediate salience for a country where close to 70% of the population relies on agriculture for its livelihood, and a majority live below the poverty line. The as-yet unanswered questions turn on whether adoption of transgenic technology will help to ameliorate or will further exacerbate the multi-dimensional challenge of ensuring food security for all. Proponents of transgenic technology suggest that ensuring national food self-sufficiency (as one component of the larger food security challenge) is a goal that use of transgenics can contribute to (Paroda 1996). Such a goal was central to the decision to embrace green revolution technologies in India in the 1960s. However, opposition to transgenics is also couched in terms of the same need for food self-sufficiency, to be attained instead through freedom from foreign dependence (Shiva and Jafri 1998). As evident from these debates, the validity of the claim that developing countries stand to benefit from their adoption remains crucially dependent upon which transgenics will be developed and how suited they might be to developing country needs.

Furthermore, the less emphasized side of the same coin is that, notwithstanding which transgenics are developed, the *challenges of ensuring biosafety* are certainly likely to be greater in a developing country and tropical agriculture context. As noted by Eric van Dusen (2000), these challenges include the fact that crop genetic diversity in tropical agriculture is such that wild relatives and landraces tend to be intermingled, so that hybridization and gene flow is often harder to model; pests and pathogens exist in a complicated relationship with crop management systems in a smallholder context; abiotic stresses and heterogeneous growing conditions make new crop adaptation more difficult; and socioeconomic factors such as complex land tenure – technology interactions, small holdings, and the saving and mixing of modern and traditional seed make monitoring the use of transgenics more complicated. While such conditions are likely to make biosafety assessment and management vastly more challenging in a developing country context, it is precisely these regions of the world which have the least experience with monitoring for biosafety. Below, I examine both sides of the coin noted above for the case of India – the transgenics crops being developed, and the nature of the regulatory framework in place to ensure biosafety.

3.1.2 The nature and extent of biotechnology research underway

Table II provides a comprehensive overview of GMO research in Indian agriculture to date. As can be seen, both public sector Indian agricultural research institutes and private sector companies (most in collaboration with a foreign partner) are in various stages of developing and field testing transgenic crops in India. To date, research is underway for tobacco, rice, mustard, cotton, potato, tomato, brinjal, cauliflower, cabbage, chilli and bellpepper. Of the genetic modifications attempted, the vast majority are intended to confer pest resistance. This is highlighted by Indian scientists as a high priority, given greater biotic stresses of tropical agriculture (Rai 2000: 25). Another focus of genetic transformations has been production of higher-value hybrids for crops such as mustard. According to the largely private sector developers of this modification, such transgenic crops respond to a market opportunity and also meet a priority need, given that India currently imports large quantities of oilseeds (Mubashir 1999: 281). In addition, research mainly in the public sector is also underway on nutritionally altered transgenic crops, such as, for example, an effort to enhance protein content in potato (Rai 2000: 37), as well as a wide range of other applications such as moisture tolerant and delayed ripening crops (Expert Panel Report 2000).

While research on GMOs is expanding at a rapid pace in India, no transgenic crop has yet been approved for commercialization. As seen from the Table, contained field trials are underway or have been completed for tobacco (by the Central Tobacco Research Institute), mustard and tomato (by ProAgro-

PGS), cotton (by Mahyco), and brinjal and tomato (by the Indian Agricultural Research Institute). As of May 2000, Mayhco's transgenic cotton became the first crop to receive approval for further testing to assess for commercialization readiness (Economic Times 2000). Given that much GMO research is centered on crops and genetic modifications of importance in the Indian context, researchers from both the public and private sector feel justified in invoking food self-sufficiency as their rationale to support use of this technology, and to frame concerns over potential risks posed by transgenics within this larger context. However, even if transgenic crops and genetic modifications relevant to the Indian context are the focus of current research (a necessary first condition if the food security rationale is to hold), it remains equally important to consider the kind and sources of biosafety information being generated about such crops, the basis for decisions about their adoption, as well as the nature and accountability of the biosafety decision-process in place. These issues are examined below.

3.2 The biosafety regulatory framework

Genetically modified organisms are regulated in India under the purview of the 1986 Indian Environment (Protection) Act (henceforth, the EP Act). The broad objective of the EP Act is the protection and improvement of the environment. To meet this objective, the Act calls for regulation of "environmental pollutants" which are defined as "any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to the environment" (MOEF 1986). The broad definition of "environmental pollutant" was used by the Ministry of Environment and Forests in 1989 to issue rules to govern use of genetically engineered organisms under the EP Act. The 1989 "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells" (henceforth 1989 Rules) constitute the legally binding regulatory framework for GMOs in India (Ghosh and Ramanaiah 2000).

As evident from the title, GMOs are placed here in the same category as hazardous microorganisms and their regulation under the EP Act is justified by their alleged potential to be hazardous substances or environmental pollutants. Since the 1989 Rules call for guidelines to be developed to give them effect, biosafety guidelines were issued by the Department of Biotechnology under the Ministry of Science and Technology in 1990, and have been consistently revised and expanded in the last decade. Development of this regulatory framework dating from the early 1990s has been in response to the need for regulatory oversight of the growing domestic community engaged in biotechnology research in both the agricultural and pharmaceutical sectors. It was also in response to debates within the European Union about safe use of genetically modified organisms, during negotiation of regional directives on contained use and deliberate release of GMOs. The possibility that India might be a future importer of GMOs from OECD countries thus also spurred development of a domestic regulatory framework (interviews). The nature and extent of the regulations are explored in more detail below. Section 3.2.1 examines the scope of the regulatory framework, i.e. the categories of GMOs and the activities covered; Section 3.2.2 discusses information to be taken into account and the bases for decision-making; and Section 3.2.3 examines the decision-makers and the process of consenting to GMO use in India.

3.2.1 The scope of the biosafety regulatory framework

The biosafety regulatory framework consists of the 1989 Rules issued by the Ministry of Environment and Forests, as elaborated and revised by the 1990, 1994 and 1998 Guidelines issued by the Department of Biotechnology. These cover the entire spectrum of activities relating to genetically modified organisms. This includes "research involving genetically modified organisms, as well as genetic transformations of green plants, rDNA technology in vaccine development, and large-scale production and deliberate/accidental release into the environment of organisms, plants, animals and products derived

from rDNA technology" (DBT 1990: 1). Production facilities such as distilleries and tanneries which use genetically modified organisms are also covered (MOEF 1989: Art. 4a-d, p. 437-438).

The 1990 "Recombinant DNA Safety Guidelines" and 1994 "Revised Guidelines for Safety in Biotechnology" provide detailed guidance on containment and safe laboratory practices for GMOs in the agricultural and pharmaceutical sectors. They also, however, contain an important change from the 1989 Rules in their treatment of deliberate release of GMOs. While the 1989 Rules effectively banned such releases (permitting them only under special circumstances), the 1990 Guidelines permit them, with a shift in focus to assessing and managing ecological and health risks that might result[11]. This is similar to the evolution of GMO regulation in OECD countries such as the United States, where self-regulation by scientists in the early 1970s prohibited deliberate release and focused on ensuring safe use of GMOs in contained conditions, yet where the prohibition on release was revoked in a relatively short period of time (Wright 1992).

The 1998 "Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts" apply only to transgenics for use in agriculture (in contrast to the 1990 and 1994 rules which covered both the agricultural and pharmaceutical sectors). The latest rules add to the regulatory architecture by calling for toxicity and allergenicity data on transgenic plants and plant parts. They also clarify how the procedures governing import of genetically modified organisms *for research* are distinct from imports for *release or commercialization* (DBT 1998; Ghosh and Ramanaiah 2000). However, notwithstanding this comprehensive coverage, GMO use in India to date has occurred largely in contained conditions, with some deliberate releases in the form of experimental field trials. Approvals for commercialization of GMOs or food safety assessments of processed materials have not yet been required. Furthermore, no transgenic products have knowingly been imported into the country for commercial use. Thus, while the biosafety regulatory framework in India is broad in its coverage, its functioning in practice remains in a state of evolution and development.

3.2.2 Information required for biosafety assessment and decision-making

The information to be taken into account in assessing GMO safety is contained in the 1990, 1994 and 1998 Biosafety Guidelines. Information requirements are very similar to those in risk assessment models elsewhere. Indian risk assessment guidelines have drawn upon models used by the United States Department of Agriculture Plant and Animal Health Inspection Service (APHIS) as well as from biosafety guidelines elaborated by other OECD countries (interviews). Guidelines developed by international agencies, such as the Organisation of Economic Cooperation and Development (OECD) and the World Health Organization (WHO) have also served as models[12]. Information taken into account or required to be generated in a biosafety assessment includes details of the modified organism, such as description of the host; source of the transgene; characteristics of expression vectors, insertion genes and promoters; transformation methods; and a genetic analysis of stability and biochemistry of the expressed product. For laboratory use and greenhouse trials, information is required about backcrossing methods, germination rates, phenotypic characteristics, and toxicity and allergenicity potential in handling the modified organism. For field trials, information is required about germination rates, gene flow, invasiveness potential, possibility of weed formation, possibility of transfer of transgenes to near relatives, and toxicity and allergenicity potential. Also, data is to be generated on the long-term survivability of the novel organism, including susceptibility to diseases and pests, as well as a comparison between the modified and non-modified organism in pest susceptibility. Finally, data on comparative economic benefits of the modified plant is also required (DBT 1998, Ghosh and Ramanaiah 2000).

Although Indian evaluation criteria are not distinct from risk assessment models elsewhere, it does diverge from such models in one significant manner. As noted above, a recently added requirement in

safety assessments includes an agronomic evaluation of the transgenic crop to determine economic advantage to farmers. This addition to the 1998 Biosafety Guidelines now constitutes an integral component of the technical risk assessment, along with the ecological and human health safety evaluation. It is required before a "biosafety clearance" can be issued to a transgenic crop. The generation of economic viability data during the technical safety evaluation is centrally linked to the socioeconomic dimension to biosafety in the Indian context. This inclusion of socioeconomic data in the biosafety calculus is reflected, as well, in the recent decision in July 2000 to grant permission for large-scale field testing of Bt cotton in India (the first crop to receive such approval). Although biosafety protocols for large-scale testing are still being drawn up, data required to be provided in this case includes the "cost of transgenic seed, projected demand, and the area to be covered under transgenic cotton cultivation" (GOI 2000).

3.2.3 Consent–givers in the biosafety regulatory framework

An important component of national biosafety governance, the consent-givers, is examined next. This is left relatively unproblematized in transnational rule-making, where the state is seen as the legitimate national-level consent giver. However, often the consenting authority as well as the *process* of giving consent are the most contentious elements of national risk regulation. In India, much debate has centered around the legitimacy of consent givers for GMO use in agriculture. As per the 1989 Biosafety Rules, the authority to regulate GMOs is divided between the Ministry of Science and Technology and the Ministry of Environment and Forests. *Research* on GMOs is to be overseen by the Review Committee on Genetic Manipulation (RCGM) under the Ministry of Science and Technology's Department of Biotechnology. *Deliberate release and commercialization* of GMOs is to be overseen by the Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests. Although the functions of these two national biosafety committees now appear to be clearly delineated, the division of responsibility between them has been a source of much controversy. Disputes have centered around where the boundary between research and deliberate release lies and, in particular, whether field trials constitute a research activity or a deliberate release of GMOs into the environment, since, if the former, they would be regulated by the Department of Biotechnology, and if the latter, by the Ministry of Environment.

In addition to these national-level regulatory committees, every institution engaged in genetic engineering research in India is required to establish an Institutional Biosafety Committee. Furthermore, State Biotechnology Coordination Committees and District-Level Committees are to be set up to facilitate information exchange between the center and the states. The most recent addition to this institutional framework is a Monitoring and Evaluation Committee to oversee the agronomic evaluation of the transgenic crop during field tests and to monitor biosafety data generation. Finally, a Recombinant DNA Advisory Committee is to meet occasionally to review national and international developments in biotechnology and recommend appropriate biosafety regulations for India (DBT 1990, 1998). While this is an elaborate and participatory decision-making structure on paper, its functioning remains far from smooth, as discussed further below.

The composition and functions of the different biosafety committees are summarized in Table III. As seen from the table, the two central regulatory committees under the department of biotechnology and ministry of environment, the RCGM and the GEAC, both consist of scientists from public sector institutions as well as government representatives. Scientific disciplines represented include genetics, molecular biology and the agricultural sciences. There are, however, almost no social scientists and no members of the general public involved. Representatives from industry and non-governmental organizations can be invited to participate in their individual capacities as experts, although there is no formal requirement to involve them (DBT 1994, 1998, interviews), and petitions by NGOs to participate in particular sessions have in a few cases been turned down (interviews). Also, these two central committees, but particularly

the Department of Biotechnology's RCGM, are composed of public sector scientists who are themselves engaged in transgenic research. This results in the not unfamiliar situation of scientists regulating themselves rather than an autonomous agency regulating research in this area. Equally important, public sector scientists are also regulating their private sector counterparts, who are often further along in developing similar transgenic crops. As seen later, this public-private information sharing dynamic has implications for reliance on information sharing as a central risk mitigation strategy in this area.

The role of other relevant ministries in biosafety regulations, such as those of agriculture and health, remains ill-defined. It is unclear, for example, whether transgenic seed is to be governed under biosafety rules alone or whether and how the 1966 Indian Seed Act also applies. The ministry of agriculture is considering amendments to Indian seed legislation to cover transgenic seed. A particular concern is ensuring seed purity, i.e. ensuring that use of transgenic seed, if and when available, does not contaminate regular seed lines. This is an issue which the ministry of agriculture clearly sees as within its regulatory domain and outside the competency of the department of biotechnology or the ministry of environment (interviews). Another issue still to be resolved, yet with crucial implications for biosafety, is whether transgenic seed once de-regulated is to be treated as regular seed or whether it will require distinct seed varietal registration procedures from those in place for non-transgenic seed. Current varietal registration rules in India offer two routes for placing new seed on the market: testing of seed and certification of efficacy through "all-India coordinated trials" administered by the public sector agricultural research system, or the alternative option of "truthful" labeling of new seed to be placed on the market. The debate at the moment turns on whether the "truthful labeling" option, historically preferred by the private sector for speedy entry into the market, should be permitted for transgenic seeds or whether the all-India coordinated trials should be made mandatory (Singhal 2000, Katiyar 2000, interviews).

There is also little clarity to date regarding jurisdictional authority for human health and food safety concerns raised by GMO use in agriculture. The 1954 Prevention of Food Adulteration Act does not specifically cover transgenic entities. However, this is dependent upon how broadly food adulteration is understood and whether transgenic food additives can be considered adulteration (interviews). Again, the Ministry of Health is engaged in a process of internal consultation to determine its role in regulating transgenic food once available. While the health ministry is the lead ministry responsible for negotiating labeling requirements for genetically modified foods within the Codex Alimentarius Commission (a United Nations standard setting body jointly established by the Food and Agricultural Organization and the World Health organization), they have not been involved with regulation of GMOs under the Cartagena Protocol. At the domestic level, however, representatives from the ministries of agriculture and health are included in national biosafety regulatory committees. Thus, their concerns can, in principle, be accommodated during deliberations of these committees in regulating domestic use of GMOs in India.

3.3 Ensuring biosafety: controversies over use of genetically modified organisms

As seen above, there is a fairly strict regulatory framework to govern GMO-related activities in India in theory. Yet, how does it work in practice? A number of controversies in recent years regarding (a) approval to field test transgenic crops; (b) whether terminator technology was being imported into India; and (c) approval to import agricultural commodities containing GMOs; have clarified how existing rules work and have contributed to their evolution. The nature and role of these controversies in shaping the biosafety governance regime in India is discussed below.

3.3.1 Regulatory approval for field testing transgenic cotton in India

The question of how well the regulatory system works in India received sustained scrutiny in the wake of a public interest litigation filed by the Research Foundation for Science, Technology and Ecology

(RFSTE) in the Supreme Court of India against the Department of Biotechnology, the Ministry of Environment and Forests, the Ministry of Agriculture, Mahyco, i.e. Maharashtra Hybrid Seeds Company (an Indian private sector seed company), and Mahyco-Monsanto Biotech India Ltd (a joint venture established between Monsanto and Mahyco). The RFSTE alleged that improper authorization was given to field test Monsanto/Mayhco's transgenic Bt cotton in India, and that existing biosafety regulations did not adequately protect against adverse ecological and human health effects posed by such transgenic crops (RFSTE 1999, 1999b). While the "facts" associated with this field testing remain disputed, it can be ascertained from media reports that Mahyco acquired a Bt toxin gene from Monsanto in 1995, backcrossed it into Indian cotton crop varieties, and requested approval to field test its transgenic Bt cotton seed. During this same period, Monsanto acquired a 26% stake in Mahyco. Permission to conduct 40 field tests in 9 states was granted by the Department of Biotechnology's biosafety committee to Mahyco in 1998 (interviews, RFSTE 1998) but the tests have remained mired in controversy.

In the public interest litigation brought by the RSFTE, it is alleged that these field tests constituted a deliberate release into the environment, and hence consent should have come from the ministry of environment rather than from the department of biotechnology. However, those soliciting and giving approval, namely the private sector developers of the crop and governmental regulators, viewed the field tests as "experimental research in contained conditions" rather than as deliberate release. As a result of this controversy, an amendment to the Biosafety Guidelines now clarifies that the Department of Biotechnology's committee, the RCGM, has the authority to approve "small experimental field trials" limited to a total area of 20 acres in multilocations in one crop season, with any one location not exceeding one acre. Field trials exceeding these limits are to be considered large scale releases and would require approval from the ministry of environment[13]. Notwithstanding this clarity about who has jurisdictional authority over which trials, it is revealing that the department of biotechnology's authority to consent to field tests was challenged in the Supreme Court when it consented to field tests of what was seen as Monsanto's Bt cotton. Earlier approvals by the RCGM to field test domestically produced transgenic crops have not been challenged. The controversy over the appropriate consent-giving authority appears linked then to broader concerns of some NGOs over multinational control of transgenic crops in Indian agriculture, rather than to concrete evidence that the ministry of environment's biosafety calculus would differ from that of the department of biotechnology, which remains to be put to the test.

The public interest litigation also alleges that *only* central government approval was given for the field-testing, without consultation with regional and state governments and local communities. In some states, no State Biotechnology Coordination Committee mandated by the 1989 Biosafety Rules had been set up, and state and district-level authorities were unaware that transgenic cotton was being field tested within their territories. A state biotechnology committee was only established in the southern Indian state of Karnataka after the tests were well underway. Karnataka and neighboring Andhra Pradesh have been the site of protests by farmers against transgenic crops, spearheaded by the Karnataka farmers' union headed by controversial anti-globalization activist M.D. Nanjundaswamy (Hindu 1998, Hindustan Times 1998). Setting up a state biotechnology coordination committee in 1999 was portrayed by the Karnataka state government as a major step in enhancing vigilance over transgenic crops, even though such a committee was to have been established in the early 1990s according to biosafety regulations (Hindu 1998).

More generally, this highlighted that despite the laws on the books, in many cases the state and district-level committees called for are not yet in existence. Moreover, where they do exist, they do not necessarily include scientists conversant with the technology under consideration or its use in agriculture (interviews). From the perspective of private sector developers of transgenic crops, requesting state government approval has proved to be one of the most frustrating components of meeting biosafety regulatory requirements, also because there are no fixed times for state-level biosafety committees to meet. They meet on an as-needed basis, placing the onus on each GMO producer to convince the committee of the need for an expedited evaluation of their proposal for research or field-testing. In

response to such concerns, biosafety regulators defend the existence and intent of the center-state participatory approval structure, and note that the system will adjust and evolve as the first transgenic crops move through the regulatory pipeline (interviews).

In addition to consent-givers, the information to be generated and procedures for field testing the transgenic crop were also disputed in the RSFTE case. The public interest litigation alleges, for example, that a comparative study of pest incidence in transgenic and non-transgenic fields is mandated by biosafety regulations, yet no such data was generated (RSFTE 1999a). It also alleges that mandatory containment measures as outlined in the biosafety guidelines were not followed. Thus, it alleges that although isolation distances of 5 meters around plantings of transgenic material are required, such distances were not maintained (RFSTE 1999: 86). These allegations are disputed by the Department of Biotechnology (DBT 1999), yet they highlight potential constraints to field-testing transgenic crops likely to be faced in the Indian context. Thus, maintaining and monitoring 5 meter isolation distances in very small farmer holdings may not always be feasible, notwithstanding whether it is a technically adequate containment parameter.

Although the public interest litigation remains pending, it has already had a discernible influence on the biosafety governance regime in India. In addition to generating public debate, it has also clarified the functioning of the consent giving process for GMO field trials. As seen, following the filing of this case, there are now specific criteria for what constitutes "small scale experimental use" versus "large-scale deliberate release" of GMOs. However, its ultimate influence remains to be seen. Although the case was due to be heard in July 2000, a biosafety clearance was issued to the transgenic cotton in question by the department of biotechnology in May 2000. The Economic Times announced this development as "government gives biosafety approval to Monsanto's cotton" illustrating again that multinational involvement is the most newsworthy element in this debate, even though the transgenic crop could also be characterized as Mahyco's domestic transgenic cotton. The biosafety clearance allows this transgenic crop to become the first to be tested for commercialization readiness in India (ET 2000).

3.3.2 Import of "terminator technology" into India?

Together with debates over field-testing transgenic cotton, a period of sustained controversy in late 1998 and 1999 centered around the alleged testing of "terminator technology" in India. Called "gene protection systems" by its developers, this technology entails modification to a crop such that it produces sterile seed. The objective is to prevent farmers from saving transgenic seed for use the following year. This is defended by proponents of the technology as a necessary biological method of intellectual property protection and is attacked by opponents as depriving farmers of an age-old right to save, share and exchange seed (Science for People 1999). The origin of the allegation that terminator technology was being tested in India is unclear, yet it became tied to protests surrounding field testing the transgenic Bt cotton. This seems to be the result of a similarity in timing between the field tests and Monsanto's move in the United States to acquire the seed company Delta Pine Land and Co. which holds a patent on a type of terminator technology.

Following allegations that the Bt cotton being field tested contained terminator genes, farmers uprooted the crop in the southern Indian states of Andhra Pradesh and Karnataka. A period of media debate and questions in parliament finally culminated in an announcement by the Minister of State for Agriculture, Som Pal, that terminator technology was not being tested in India and that no imports of transgenic material containing terminator genes would be permitted into the country (Hindu 1998). In response to the controversy, Monsanto issued a "Statement in the Public Interest" in national newspapers to clarify what it termed as the misperceptions surrounding terminator technology. The statement noted that "terminator technology is not a reality anywhere in the world, including India". It also noted that such technology

differed from the Bt cotton tests, which entailed insertion of the Bt gene into Indian varieties of cotton to confer resistance to the cotton bollworm. The statement concluded with a section entitled "Monsanto's Promise" which stated that Monsanto "respects the Indian Government's position as outlined by the Honorable Minister of State for Agriculture Mr. Som Pal and unequivocally commits that it had never intended and will not bring inappropriate technology to India; (that it) promises to only bring technologies that increases choice and opportunities of farmers, (and that it) will only bring to India technologies that are thoroughly tested and approved by the Indian Government" (Hindu 1998a).

This controversy highlights the importance to developing countries of socioeconomic impacts from use of biotechnology in agriculture. Following this incident, Indian biosafety regulations now call for one mandated entry point into the country for all imports of transgenic material, whether for research, field testing or commercial use. This entry point is to be the National Bureau of Plant Genetic Resources (NBPGR) under the Indian Council for Agricultural Research. The NBPGR has traditionally been responsible for quarantine procedures for imports of (non-transgenic) live organisms. Following the terminator debate, the NBPGR has also been mandated by the Government of India to develop probes to detect presence of terminator genes, notwithstanding promises by multinational companies that they will not import this technology into India unknown to regulatory authorities (The Hindu 1998, interviews). This commitment of scarce resources to ensure that the capacity exists to monitor and prevent entry of such technology into India highlights the importance of concerns relating to dependency voiced by developing countries in this area. It also highlights the force of public opinion in shaping emerging biosafety rules.

3.3.3 Importing transgenic agricultural commodities into India

In addition to the controversies surrounding terminator technology and field testing of Bt cotton, a food safety scandal has also served to clarify the functioning of the biosafety governance regime. Following an outbreak of illness in New Delhi from contaminated mustard oil in 1998, the government authorized imports of soybean from the United States for processing into edible oil. Permission was granted by the Ministry of Agriculture, as per normal regulatory channels. A few watchdog groups alerted the media to the fact that genetically modified soybean had been imported into the country without the authorization of the ministry of environment, which is required to give regulatory approval for imports of genetically modified material. In responding to questions in parliament, the official stance of biosafety regulators was that no genetically modified material had been imported, a stance made possible by the fact that the soybean imports from the United States are not currently labeled "transgenic" nor are they segregated from non-transgenic soybean (interviews). Following this incident, the Ministries of Agriculture and Commerce are now jointly responsible to ensure that no transgenic commodities are imported into India (interviews). Although no formal amendments to the biosafety guidelines have been made to this effect, its implementation appears to require that exporters provide a written guarantee on a case-by-case basis that commodity imports do not contain transgenic varieties (interviews).

In conclusion, a number of trends pertaining to biosafety governance in India can be highlighted. As noted above, there is a strong sense amongst regulators and prominent agricultural scientists that research in transgenics should be encouraged. A growing number of public sector laboratories, institutes and agricultural universities are engaged in basic transgenic research (Expert Panel Report, 2000). At the same time, international concern, especially in the European Union, over genetically modified foods has tempered enthusiasm amongst regulators for an overly quick adoption of transgenic crops. Many public sector scientists engaged in transgenic research allege, however, that the concerns of a "well-fed" EU are distinct from those facing India, and that India cannot afford to be left behind or become dependent upon technology leaders in this area (interviews). As one public agricultural scientist put it "why should we look to the European Union's approach to genetically modified foods, why not model our approach on

that of China, which is embracing transgenic technology. That's the model we should follow" (interviews).

Also, as seen above, although those who oppose transgenic crops are few in number, they can influence the decision-making process through accessing a free press and relying on the unique role played by the Supreme Court in India, where a citizen can bring a public interest litigation against the government alleging that regulations are not being complied with. The private sector, meanwhile, remains wary of trying to influence perceptions about transgenic technology through direct communication with the public through the media, fearing that such communications might be perceived as biased (interviews). Intermediary institutions which can bring diverse groups together to address mutual concerns are only recently attempting to play such a role. Notable among these are the M.S. Swaminathan Institute in Chennai and the Tata Energy Research Institute (TERI) in New Delhi. TERI, for example, has organized a series of workshops to discuss contentious issues surrounding GMO use in the past year (TERI 1999, 2000). Such workshop proceedings serve as one of the few sources of printed information about biosafety views in India, and in that capacity fulfil a valuable function. At the same time, however, they can take on the air of "preaching to the already converted" amongst their participants (mainly agricultural scientists, regulators and private sector developers of transgenic crops) who might already be convinced about the need to deploy transgenic technology in Indian agriculture. Divergent viewpoints are few, and until recently, such workshops (despite their attempt to be "stakeholder dialogues") had little representation from farmers, a constituency largely missing from biosafety debates in India.

In general, despite the elaborate biosafety regulatory regime in place over the last decade, the challenges of monitoring for biosafety in the Indian context are only now coming to the fore, with the first approval for large-scale testing of a transgenic crop granted in July 2000 (GOI 2000, ET 2000). Thus, for example, as one public sector agricultural scientist acknowledges with regard to insect resistance management for Bt crops: "...it is [generally] recommended that as much as 20% of the cropped area should be maintained as a refuge. However, under Indian farming conditions, a 20% crop area as a refuge for susceptible insects is unthinkable. Most of our farmers have small land holdings of about one hectare. ...alternate strategies of resistance management need to be developed that are especially suitable to the agricultural systems of developing countries" (Raina 2000: 11-12). Yet what such alternate strategies should consist of remains unclear.

Furthermore, current biosafety regulations also allow only for "conditional" deregulation following completion of large-scale testing. Thus, some form of continued monitoring is envisioned during commercial growing of a transgenic crop, once deregulated. Again, however, it remains unclear whether and how particular conditions, such as mandatory isolation distances or refugia are either feasible or monitor-able on a large scale in the Indian context. It is also unclear whether and how transgenic seed can be segregated from non-transgenic seed, to ensure that preconditions attached to growing transgenic seed are being met. Since no transgenic crop has yet been approved or grown for commercial purposes in India, the biosafety governance system cannot necessarily be faulted solely on grounds that appropriate procedures are not yet in place. The concern rather is whether such procedures can be developed in a manner that will ensure biosafety.

As also seen above, although the consent-giving process is elaborate and participatory in principle, its working in practice remains in a state of evolution. In particular, a central element of consent-giving, the monitoring of data generated during safety assessments by producers of transgenic crops, remains particularly rudimentary. The "monitoring and evaluation" committee, established in 1998, visits a field site a couple of times a year for a few hours, visits that are pre-planned and usually organized by crop producers (although on paper the committee can visit at any time). According to a member of this committee, such a role is dissatisfactory, insofar as it serves a mere "policing" rather than a monitoring and evaluation function, with the main accomplishment only "to establish that the field sites actually

exist" (interviews). According to this view, adequate monitoring and evaluation would require, at least, more frequent and longer site visits during different stages of growth of a transgenic crop. It would also require taking samples away for independent testing, rather than merely reviewing data provided to the committee by producers of the crop. It would also require modifications in the composition of the committee, currently consisting of high-level scientists with managerial responsibilities, to also include junior scientists with the time and on-the-ground training to monitor diverse aspects of the field tests.

In general, as controversies surrounding GMO use to date, and the upcoming challenges of assessing safety during large-scale testing make clear, increased transparency in decision-making will be imperative to mediating conflicts over biosafety governance in India in the future. How do the Cartagena Protocol's rules and obligations for information sharing and consent prior to transboundary GMO transfers fit within this scenario? Do its provisions go further, fall short of or legitimize of existing biosafety rules and practices in India? The remainder of this paper explores the transnational-national governance interaction in this area and its implications for biosafety governance in India.

4 THE CARTAGENA PROTOCOL'S RELEVANCE FOR INDIA

In examining the implications of the Cartagena Protocol's rules and obligations for biosafety governance in India, a preliminary hypothesis emerging from the analysis of the Cartagena Protocol can be postulated. As seen in Section 1, the protocol's provisions are characterized by a minimalist scope and ambiguous decision-criteria. If so, it can be hypothesized that the rules and obligations of the Cartagena Protocol *will not change the prevailing status quo for biosafety governance in India.* Thus, with its minimalist scope, it is not likely to exceed the categories of LMOs requiring consent in Indian regulations; and with its ambiguous decision criteria, it is likely to leave national discretion in LMO decision-making unchanged.

This is at first glance a relatively uninspiring hypothesis, in light of the long drawn out and contentious nature of these multilateral negotiations. If the completed protocol leaves unchanged the scope and decision-criteria of domestic biosafety regulations, should such a regime be considered irrelevant or ineffective? Clearly, relevance and effectiveness have to be evaluated in light of the objective of a regime, especially from the perspective of a developing country and LMO importer such as India. If an original intent was to negotiate a regime which would defer to national differences in LMO decision-making, then in leaving domestic biosafety regulations unchanged (and in not limiting them) the Cartagena Protocol accomplishes this original intent. This can be construed as a measure of its "effectiveness" and by this measure, it succeeds. In examining this in more detail below, the relevance to India of three facets of the protocol's obligations are discussed. These include: the relevance of having a completed protocol (section 4.1); the relevance of its minimalist scope (section 4.2); and the relevance of its ambiguous decision-criteria (section 4.3).

4.1 The relevance of a completed protocol: legitimizing Indian biosafety regulations

At the very least, the Cartagena Protocol embodies within it a norm that LMOs require special regulatory attention. This was contested through much of the early stages of the negotiation, given divergent views on the uniqueness of risk posed by LMOs (see Gupta 1999 for a detailed discussion of this initial history). Furthermore, the protocol also legitimizes the restriction of trade in LMOs under certain conditions. Until the process of negotiating a protocol commenced in the mid-1990s, there was no explicit international norm on the need to regulate such trade. Thus, attempts in this period to restrict LMO transfers pursuant to domestic regulations could be seen as hostile to a *de facto* prevailing international norm of the unhindered transfer of such entities. The relevance of a completed protocol for the transnational-national biosafety interface is then that it serves first and foremost to *legitimize the existence* of domestic biosafety regulations.

Clearly, however, while the protocol lends legitimacy to domestic regulation of LMOs, can it simultaneously legitimize contradictory approaches to LMO regulation, embodied within different domestic frameworks? As seen in the previous section, conflicts between existing domestic approaches, in particular the intra-OECD conflict over decision-criteria, lay at the heart of contestation in this negotiation. This highlights the importance of examining the domestic sources of international obligations, an area of research recently gaining currency in the international relations literature (see Hanf and Underdal, forthcoming). Previous writings in this literature had tended to assume that international agreements mandate new rules and obligations, which are then to be implemented at the national level. However, in an increasing number of international negotiations, including biosafety, the source of conflict centers less around devising new obligations and more on whose already existing national approaches will be internationalized. How such conflicts are resolved will be crucial to the relevance of the final

agreement for distinct national contexts. Although internationalizing their domestic approaches was most characteristic of the intra-OECD conflict in protocol negotiations, it was also an important concern for India. Thus, Indian negotiators sought to ensure that a completed protocol would not limit the already existing scope or decision-criteria for biosafety governance in domestic regulations (interviews). The extent to which the protocol's obligations go beyond or fall short of scope and criteria for biosafety decision-making in India is examined next.

4.2 The relevance of a minimalist scope: shifting the burden of action

4.2.1 Implications for India of the protocol's obligations for deliberate release of LMOs

The centerpiece of the protocol's minimalist scope is the obligation on the exporting party to solicit consent of an importing country prior to deliberate release of LMOs. This obligation explicitly enhances national-level potential for biosafety governance in countries with no domestic regulatory framework in place. Its relevance for countries with biosafety regulations such as India turns on whether existing domestic regulations already call for informed consent for such LMOs. As seen earlier, the biosafety committee under the ministry of environment in India has to approve all imports of genetically modified material into the country, whether for research, deliberate release or commercial use. Thus, consent prior to transfer of LMOs for deliberate release is required even in the absence of a protocol. However, the protocol's obligation has the limited yet concrete outcome of shifting the onus to initiate procedures for consent onto producers of LMOs rather than leaving it to the vigilance and capacity of the domestic regulatory regime.

While this shift in the burden of responsibility should facilitate the functioning of the domestic regime, exactly who are the producers of LMOs upon whom this burden will fall and what is their jurisdictional location? While the protocol mandates obligations for "exporting" and "importing" countries (and "exporters" and "importers"), precedent to date suggests that an exporting country or a multinational company is not likely to directly transfer LMOs to an importing country, but rather will collaborate with a domestic partner in undertaking such transfers. This is the case in India, with the domestic partner to date being from the private sector. Thus, the few LMO transfers to date have occurred through collaborations or joint ventures between foreign and domestic private sector entities. Furthermore, it is the newly established joint venture or the domestic partner (such as ProAgro PGS or Mahyco in the Indian context) which has solicited consent prior to deliberate release of LMOs. In India, then, contrary to exporters or exporting countries soliciting consent, it is the *domestic private sector that is soliciting consent from domestic regulatory authorities*. In such a scenario, the externalization of the burden of responsibility to initiate consent procedures, identified above, is unlikely to change the prevailing status quo, since existing regulations already place this burden on the domestic entity soliciting consent.

4.2.2 Implications for India of the protocol's obligations for LMO commodities

The protocol's decision process for commodities serves to legitimize the possibility of domestic dissent from commodity imports. Yet, contrary to LMOs for deliberate release, it leaves the onus to initiate procedures for dissent on the importing country. The implication for developing countries is that the potential to restrict commodity transfers remains dependent upon having the institutional wherewithal to effectively use the information provided to the biosafety clearing house. Both this institutional capacity constraint and the size of an importing country market will influence the relevance of the protocol's decision-process for commodities for any given country.

Institutional capacity constraints are likely to be of concern in India if a case-by-case risk assessment of the many different LMO varieties that may enter the international commodity trade had to be undertaken, in accordance with the protocol's procedure. Given the burdensome nature of this requirement, it is more likely that developing countries will opt either to restrict import of all commodities that contain genetically modified varieties, or allow such imports with their diverse transgenic varieties. Such decisions will vary with the needs, capacities and agro-ecological and political considerations within different countries. As seen from Section 2, the controversy over import of transgenic soybean into India has clarified national policy towards LMO commodity imports for the present. The current policy calls for restricting imports of all transgenic commodities into India, with the Ministries of Agriculture and Commerce jointly responsible to ensure that such restriction is maintained (it is illustrative of the distinct biosafety decision-criteria in India that no risk-based rationale is offered for this broad-based restriction on commodity imports, to be discussed further in the section on decision-criteria below).

Although with the protocol's procedure on commodities, the burden of responsibility for initial action remains with domestic regulatory authorities, the protocol also mandates that documentation accompanying transnational commodity shipments state that they "may contain" LMOs. Although this provision does not go far enough to mandate segregation between LMOs and non-LMOs in commodity shipments[14], it is likely to affect the situation in India insofar as it will no longer be possible to import commodities which are not labeled and assume that they are LMO-free (as happened in the case of the soybean imports). The concrete effect of this documentation requirement, moreover, is to shift the burden of responsibility for ascertaining which shipments contain transgenic material from domestic authorities to the exporting entity. This will facilitate the current mandate of the ministries of agriculture and commerce to ensure that bulk agricultural commodity imports are transgenic-free.

The relevance of the protocol's obligations pertaining to commodity exports and imports need also to be considered in light of broader trends in the Indian commodity trade. In India, the seed sector remains heavily regulated, in keeping with a long history of disliking food imports, dating back to fears of food dependence in the early 1960s prior to launch of the green revolution. While restrictions on imports of vegetable seeds are now being lifted through amendments to existing seed legislation, both imports and exports of seed for major crops such as wheat and rice remain strictly limited. Oilseeds, such as groundnut, cotton, sunflower, canola and soybean can be imported, but only through agencies specified by the central government (Kapur undated: 16-17). In this context of an extremely restricted commodity trade, it is reasonable from the biosafety regulator's perspective to prevent entry of transgenic commodities into the country as long as there is public concern about such imports, and as long as there is no perceived urgent need for them. Equally reflective of this "pragmatic" rather than necessarily precautionary approach is that in the face of emergencies such as the recent Orissa famine, food aid (including transgenic commodities) was transferred into the country and distributed, notwithstanding NGO claims about biosafety regulations having been violated (RFSTE 2000).

When and if restrictions on commodity imports are lifted, the protocol's documentation requirements for such LMOs can aid in ensuring that entry of all such material is through the single institutional entry-point, the National Bureau of Plant Genetic Resources, mandated by Indian regulations. Finally, although the protocol's documentation obligations do not directly bear on consumer labeling, they will facilitate such labeling if and when mandated by domestic regulations (currently not the case in India, since no food-based LMO is acknowledged to be in commercial use and labeling is seen as hard to implement in the Indian context). In sum, while the developing country demand for informed consent prior to trade in commodities was not met, for countries with biosafety regulations already in place like India, the protocol's obligations can enhance the potential to manage transgenic commodity transfers according to such regulations.

4.2.3 Implications for India of the protocol's obligations for contained use of LMOs

Finally, comparing the protocol's obligations for contained use of LMOs with those in place in India reveals very similar disputes over where and how to draw boundaries between contained use and deliberate release. As seen earlier, the court case brought by the Research Foundation for Science, Technology and Ecology (RFSTE) against the government of India and private sector companies centered around whether field trials, for example, constituted a deliberate release or contained research. This controversy has clarified the boundary between containment and deliberate release for Indian purposes. Thus, field tests of upto 20 one acre plots in multiple locations in one growing season are now considered "small experimental trials for research" with tests exceeding this considered large-scale non-experimental deliberate release (DBT Addendum 1999).

It remains unclear, however, whether it is possible to designate even limited field trials as "contained" use. Developing country arguments during protocol negotiations that the capacity to ensure containment varied greatly by context remains salient for India. As the RSFTE court case alleged, even if the Bt cotton trials could be considered contained, this would require a 5 meter isolation distance (RSTFE 1999: 86, DBT 1999) which, as noted earlier, may not be feasible even for field tests, let along on a large scale in the Indian context. At best, ascertaining whether a field trial was biologically contain-able would require case-by-case assessment of the characteristics of the transgenic crop being tested, whether it has wild relatives in surrounding areas or whether it was being tested in a center of origin. It is striking that the Indian definition of containment i.e. the "one-acre plots in 20 locations" does not turn on any such ecological or risk-related considerations. Rather the impetus for this demarcation appears to be the need to ensure that the Department of Biotechnology's biosafety committee, the RCGM (which can only consent to experimental research in contained conditions) maintains control over field tests and biosafety evaluations of transgenic crops. With the protocol's deference to national understandings of contained use, the outcome for domestic governance of this category of LMOs remains unchanged. The only change, as noted earlier, is the mandatory information required to accompany LMOs transferred for contained use. Issues pertaining to such information sharing and consent criteria are examined next.

4.3 The relevance of ambiguous decision-criteria: letting national discretion prevail

4.3.1 Implications for India of "sound scientific" decision-making

The protocol mandates that consent decisions for LMO transfers have to be based upon a scientifically sound risk assessment. Risk assessments are also the centerpoint of domestic biosafety evaluations in India. Yet, what constitutes a scientifically sound risk assessment in the Indian context? Information to be generated in such assessments includes the minimum "points to consider" mandated by the Cartagena Protocol. Equally important, however, do Indian information requirements go beyond what is mandated by the protocol, to cover ecologically or socioeconimically specific concerns in the Indian context? One example is often highlighted by biosafety regulators in claiming that risk assessment in India is "even stricter than the best models elsewhere" (interviews). This is the requirement to assess allergenicity and toxicity potential from consuming transgenic plants for ruminants such as goats, seen as relevant to the Indian context.

Biosafety regulators argue that generation of such data reflects the stringency of domestic risk assessment, since such requirements are not an integral part of risk assessments elsewhere (interviews). This is seen, however, as unscientific by some producers of LMOs required to generate this data (at present mainly the private sector). According to them, this is scientifically untenable, given that adverse impact testing is usually undertaken for smaller animals, with extrapolations about those higher up in the

food chain. Such requirements are thus perceived by LMO producers as reflecting the regulators' need for the appearance of stringency rather than being a scientifically sound judgment that such data are necessary (interviews). This dispute reveals not only the differential interpretations of what is considered a scientifically sound risk assessment, but also that the protocol's injunctions cannot aid in mediating such conflicts. One outcome, then, is to leave national discretion with regard to sound scientific decision-making unchanged.

Differing "science-based" understandings of risks and benefits posed by LMOs are also evident from submissions to the Supreme Court by the plaintiff and defendants in the public interest litigation pending against field testing of transgenic cotton in India. The submissions by NGOs, government biosafety regulators and private sector producers of the transgenic crop reflect both the sources of information considered scientifically sound and authoritative, and the networks that these groups seek to align themselves with (RFSTE 1999a, 1999b, DBT 1999). Thus, government regulators rely, for example, on domestically generated information by Indian agricultural scientists to validate arguments about the need for transgenic cotton in India. The submission by the Department of Biotechnology thus refers to peer reviewed articles in Indian journals about the constraints facing cotton production. Monsanto's submission, meanwhile, consists of general observations about the need for biotechnology to feed a growing population in the 21st century and the benefits to be incurred from adoption of such technologies by developing countries. In legitimizing such claims, it invokes studies by international organizations such as the United Nations Food and Agricultural Organization (FAO) and the World Bank which make similar observations. Given that proclamations by Monsanto are often suspect for some in the Indian context, the company attempts to invoke "neutral" and authoritative data sources such as the FAO or the World Bank to validate its arguments.

In contrast, in justifying claims about risks posed by transgenic cotton, the Research Foundation for Science, Technology and Ecology (the NGO initiating the litigation) relies on reports in the international news media about the ecological and food safety hazards posed by transgenic crops. It also invokes the travails facing Monsanto in its OECD markets, including excerpts from the issue of the Ecologist magazine focusing on Monsanto which was withheld from publication in September/October 1998. Finally, data generated by scientific think tanks such as the Institute of Science in Society in the United Kingdom pointing to the hazards of transgenic agriculture is also presented. These differential sources of authoritative information emphasize that sound scientific determinations of risk remain varied and open to interpretation in the biosafety realm. It also emphasizes that the *source* of knowledge claims is critical to their perceived soundness. This is crucially important to a regime based on information sharing and is further explored in Section 5.

4.3.2 Implications for India of precautionary decision-making

While the "precautionary principle" is not explicitly mentioned in Indian biosafety regulations, the 1986 Environmental Protection Act under which LMOs are regulated calls for regulation of substances that "may be or tend to be" injurious to the environment (MOEF 1996). This suggests that unambiguous scientific proof of injury to the environment is not a prerequisite for regulation. Thus, regulating LMOs under this Act can itself be construed as precautionary. Furthermore, if precautionary decision-making is understood as going beyond scientific uncertainties about quantifiable ecological and health impacts, then the clearest precautionary actions on LMOs in India have been related to socioeconomic concerns. As seen earlier, these "socially precautionary" actions have included restrictions on imports of transgenic commodities following the soybean controversy, and restrictions on future import of terminator technology following the controversy about its alleged field-testing in India. In both these cases, there were no environmental or human health rationales offered for restrictions on imports. Instead, attention to the issue in the media rather than assessment of potential hazards to human health from transgenic

soybean fueled the decision not to import such commodities, whilst the terminator controversy was centrally concerned with socioeconomic issues of dependence on foreign technologies and farmer's rights.

4.3.3 The implications for India of socioeconomic considerations

In fact, a striking characteristic of decision-criteria for LMO use in India is the *fuzziness between sound scientific, precautionary and socio-economic considerations in such decision-making*. This is evident, for example, from the merging of scientific risk assessment with socioeconomic considerations in the requirement to generate economic benefit data during the "technical" biosafety evaluation of a transgenic crop. The requirement to demonstrate that a transgenic crop is both "environmentally safe and economically viable" (DBT 1998:6) is the clearest evidence of these interlinkages. This requirement can be seen as both "scientifically sound" (if scientific assessments include a broader conception of assessable impacts to include the socioeconomic) as well as "socially precautionary" thus effectively merging all three decision-criteria for consent.

While debate continues about whether socioeconomic concerns can be included in a risk assessment or whether they belong to a political risk management calculus, they have been included in both phases of decision-making in India, highlighting the problematic nature of this dichotomy in this context. Furthermore, the data to be generated is about socioeconomic *benefits* and not risks, muddying the categories still further. As regulators argue, a biosafety evaluation in the Indian context must, of necessity, include not just ecological and human health considerations, but also responsiveness to the needs, constraints and priorities of Indian agriculture (interviews), since these cannot be divorced from the biosafety evaluation. The Cartagena Protocol, on the other hand, maintains the demarcation between the technical and the political, with provision on risk assessment calling only for data to be generated on adverse ecological and human health impacts.

The compatibility of taking socioeconomic considerations into account in biosafety decision-making with obligations under the WTO were, as noted earlier, a central concern in protocol negotiations, and thus merit comment here. The compatibility with WTO of taking economic benefit data into account before approving an LMO for domestic use has not yet been put to the test in India, in part because such evaluations have to date been of domestically produced and not imported transgenic crops. However, resolution of the terminator controversy in India reveals that conflicts with the WTO over taking socioeconomic considerations into account *are likely to be preempted* by unilateral actions such as Monsanto's categorical "promise" that it "will only bring to India technologies that are thoroughly tested and approved by the Indian government" (The Hindu 1998a). Monsanto's statement was made notwithstanding whether such testing and approvals by the Indian government were in keeping with India's WTO obligations. Clearly, in highly contested areas such as biosafety, public acceptance or the "court of public opinion" is as critical a mediator of conflict as determinations of legal rights under the WTO. Notwithstanding the narrow inclusion of socioeconomic considerations in the Cartagena Protocol, then, national discretion to take such factors into account appears to be little affected.

5 THE PRIVATE-PUBLIC INTERFACE IN BIOSAFETY INFORMATION

The above analysis reveals that the Cartagena Protocol's provisions are relevant to Indian biosafety governance insofar as, despite their minimal scope, they provide for certain shifts in the burden of action from regulators to producers of LMOs, and in their ambiguous decision-criteria, they leave national discretion for LMO decision-making unchanged. However, what remains unproblematized in the protocol's focus on informed consent as its central risk mitigation strategy *is where such information is being generated, who controls it and who it is provided to.* In the case of India, as seen earlier, the domestic private sector is at the forefront of developing and testing transgenic crops and in generating biosafety data. It is also sharing such data with regulatory authorities composed of public sector scientists, many of whom are also engaged in transgenic research. This private-public dynamic in information sharing brings to the fore the important but less examined link between intellectual property rights (IPR) concerns and biosafety. Given that privately held information about transgenic technologies is revealed during the biosafety assessment process, two sets of concern arise: a concern with legitimacy for those on the receiving end of biosafety information, and a concern with ensuring confidentiality for those on the giving end.

For private sector generators of biosafety data in the Indian context, the confidentiality concerns can relate to the perceived lack of adequate domestic intellectual property laws, especially given that information is being shared with potential public sector competitors. This latter concern could be partly ameliorated if regulatory authorities in India were autonomous watchdog agencies instead of public sector scientists engaged in similar research. Confidentiality concerns can influence both the transgenic technology chosen to be deployed by the private sector and the biosafety assessment data that is shared. The impact on choice of technology is reflected in the fact that the private sector has chosen to focus largely, in countries such as India, on development of transgenic hybrids rather than open-pollinated crops, since intellectual property concerns are less salient for hybrids. Even so, all centrally important components and production processes in a transgenic crop (whether hybrids or open-pollinated varieties) are likely to be patented or considered "confidential business information". As noted by the general manager of ProAgro PGS (a private sector company at the forefront of developing transgenic crops in India), in any transgenic crop, the plant variety germplasm, the selectable marker gene, the novel gene's trait, promoter and coding sequence, the transformation technology and the gene expression technology are all patentable (Kapur 1999, figure 6), where permitted under intellectual property regimes.

In such circumstances, especially if patents have not yet been acquired, confidentiality concerns can impact the information that is willingly shared by private sector developers of transgenic crops. At a minimum, concerns over confidentiality can affect the information available to a broader public, even if it has to still be provided to biosafety regulators. Under such circumstances, the onus is even more strongly upon such regulators to ensure an accountable and participatory national-level biosafety decision-making process, a requirement that the Cartagena Protocol's deference to national "competent authorities" cannot ensure. The protocol briefly addresses the relationship between intellectual property concerns and biosafety in an article on "confidential information" which remained contested during its negotiation. While developing countries called for its complete deletion, the finalized article responds to GMO exporting countries' concern that information shared under the protocol should be kept confidential if so desired by its providers. Thus, it calls on importing countries to ensure that there are procedures in place to protect confidential information. In response, however, to the concern that confidentiality requirements can stymie an adequate biosafety assessment, the protocol also mandates that certain data, such as a "general description of the living modified organism" and "a summary of the risk assessment" cannot be considered confidential (UNEP 2000, Article 21).

This can be an important advance in contexts where even such limited obligations to share information do not exist. Especially in conjunction with the additional requirement that an exporting party must "ensure that there is a legal requirement for accuracy of information provided by the exporter" (UNEP 2000: 5) the Cartagena Protocol has the potential then to serve as an "international freedom of information act" or an international "right to know" law. This can be an important function in a realm where the legitimacy of information often depends upon its source. In India, biosafety data provided by companies such as Monsanto is often viewed as suspect by certain groups. If so, the protocol's stipulation that certain information cannot be considered confidential, as well as the obligation to ensure its accuracy, can serve as a reassurance mechanism.

What remains uncertain, however, is whether such shared biosafety information adequately reflect contestations over risk or contains the information necessary to undertake adequate risk evaluations elsewhere. A striking illustration of the potential hurdles to risk evaluation posed by the interface between biosafety and IPR concerns is contained in a recent media report on genetically modified trees. As the report notes, evaluating the risks posed by such trees is precluded by the fact that "it is impossible to say exactly what scientists are putting into trees. Although the Animal and Plant Health Services (of the United States) web site summarizes every application for field tests, many say 'CBI' for 'confidential business information' in the column that is supposed to describe the gene being studied and the organism that it came from" (IHT 2000: 5). The protocol's relevance for biosafety governance will clearly turn during its implementation phase on whether it provides for a more open sharing of information than is the case to date.

In countries such as India with evolving biosafety rules, another broad implication of the private-public interface in information sharing is that *standard-setting for biosafety* is being undertaken through close interaction between private sector providers of information and public sector regulators. As seen earlier, many amendments to Indian biosafety regulations have been in direct response to evaluating and authorizing the first field tests of transgenic crops, many of which have been privately developed. Private sector developers of such crops have therefore interacted closely with biosafety regulators in determining adequate safety parameters for field-trials (interviews). Thus, in India, seed companies such as Mahyco or ProAgro PGS have been involved *not only* with soliciting consent but also with development of standards for biosafety assessments.

This can again raise concerns about the legitimacy or stringency of the resultant biosafety standards, and would certainly do so if the transnational private sector alone were playing this role. As noted, however, most transfer and field-testing of transgenic crops in India is underway through collaborations with the domestic private sector and it is largely the domestic private sector which interacts with domestic biosafety regulators. Concerns over involvement of the private sector in biosafety standard setting appear to be less pronounced in such cases. Perceptions amongst biosafety regulators of the Indian hybrid seed company Mahyco, for example, are that of an established and respected company engaged in research relevant to Indian agriculture. In attesting to this, regulators point to the fact that Mayhco's chairman, Dr. Barwale, was recently honored by the government of India for his contributions to the agricultural sector (interviews). Notwithstanding this, biosafety regulators have sought to enhance the credibility of the data generated within the private sector, and the processes of biosafety assessment underway, through requiring that private sector field tests involve state-level agricultural university scientists (not only to monitor but also to participate in generation of biosafety data). They are also encouraging, and in some instances mandating, that toxicity and allergenicity testing of transgenic crops be undertaken by established public sector laboratories (GEAC 2000, interviews).

If credibility concerns can be addressed, involvement of the private sector in biosafety standard-setting can, in the Indian context, also be perceived as *a source of learning* for public sector biotechnological

research. This is especially the case in light of the declining resource base for public sector agricultural research. Since the domestic private sector is privy to the latest technological innovations yet is being regulated by public sector scientists, the learning resulting from field testing and data generation for transgenic crops is accessible to the public sector research establishment as well. Such learning can set the stage for public-private partnerships in the area of transgenic research, often advocated by public sector scientists and policy makers as a way to offset intellectual property hurdles and resource inadequacies (Mruthyunjaya and Ranjitha 1998).

In particular, the need for such partnerships can turn on the comparative advantage of the private sector in converting basic research to commercializable products desired by farmers (interviews). The public sector has tended to lag behind the private sector in this area, a situation that is likely to be exacerbated in the case of transgenic research (interviews). This is because, although the strength of the public sector lies in its ability to conduct basic research, the infrastructure required to commercialize such research, and in particular, to undertake biosafety assessments prior to commercialization, is currently either lacking or uncoordinated across public sector institutes. Thus, public sector transgenic research in isolation runs the risk of moving from one "basic research" project to another, with no long term perspective on how such projects fit into the larger agricultural research goal of ensuring food security for the neediest sections of the population.

A host of questions remain, however, regarding whether public-private partnerships in transgenic research are even desirable for developing countries, and how they can be designed so as to be mutually beneficial. Examining such questions is beyond the scope of this paper, yet suffice it to say that the implications of the *public-private interface* in biosafety assessment and standard-setting merits much more detailed examination than it has received to date. In particular, whether public sector learning in this area will work in favor of ensuring biosafety will depend upon the nature of the private-public interaction in biosafety standard-setting, and especially upon whether there are adequate mechanisms in place to monitor and ensure the credibility to a wider public of the biosafety data generated by the private sector. This is especially essential to examine, given that multilateral rules under the Cartagena Protocol are likely to *compliment* rather than serve as an alternative to more dominant vehicles of biosafety standard-setting and diffusion across national boundaries, such as international joint ventures and potential public-private partnerships.

6 CONCLUSION: MULTILATERAL RULES AND GOVERNANCE

This paper has identified three ways in which the Cartagena Protocol on Biosafety is relevant to biosafety governance in India. First, completion of the protocol *legitimizes the existence of* the Indian biosafety regulatory regime. Second, certain provisions of the protocol *shift the burden of action* in information generation, assessment and solicitation of consent from regulators to producers of LMOs. They also provide for enabling conditions such as capacity building to assist with implementation of already existing domestic regulations. Third, the ambiguity or openness to differential interpretations of the protocol's criteria for consent *leaves national discretion about LMO decisions largely unchanged,* even as shifts in the burden of action can allow this discretion to be more fully exercised. In concluding, I address what this transnational-national governance interface indicates about the role for multilateral rule-making in decision-arenas characterized by normative and scientific uncertainties.

A central challenge facing transnational governance and multilateral rule-making in such areas is the need to balance the often competing imperatives of standardization with a deference to national differences in a manner that is cross-culturally credible. In particular, this is a challenge for the sub-set of multilateral rule-making examined here, namely the intentional transboundary transfer of potentially risky substances. The question then is whether and how well multilateral rule-making can deal with this challenge. As seen in this paper, the Cartagena protocol, with its risk communication and consent strategy, balances these competing considerations through reliance on a limited scope and ambiguity in decision-criteria. One conclusion, then, is that minimalism and ambiguity will be *essential counterpoints* to standardization in issue-areas characterized by scientific and normative uncertainties. However, as also evident from the preceding discussion, biosafety represents a coming together of two central dynamics within which multilateral rule-making has to occur. Not only is it a decision-area characterized by normative and scientific uncertainties, it is also one where much risk related information is privately controlled. The implications of private sector control over information remain, however, largely unaddressed in this global regime. While this paper has briefly highlighted some implications of the private-public interface in information generation and biosafety standard-setting in India, more extensive examination of these questions is necessary, especially once the information sharing mechanisms of the Cartagena Protocol are in place.

Another important impediment to multilateral rule-making and its role in transnational-national governance is the fractured nature of the global rule-making arena. Thus, biosafety is being addressed globally within more than one multilateral forum, each of which is characterized by fundamentally different objectives and modus operandi. This has implications for the nature and stringency of the multilateral rules devised in any one multilateral forum, as evident from the need to continually address whether the obligations of the Cartagena Protocol under the Convention on Biological Diversity would conflict with multilaterally negotiated rules of the global trade regime. The protocol's resolution (or non-resolution) of this potential conflict is to assert the "mutual supportiveness" of these two regimes (Gupta 2000b). While this terminology remains open to interpretation, the need for mutual supportiveness can be an impediment to coherent multilateral rules in areas such as biosafety. Multilateral rule-making is hampered then by the fact that it occurs in piecemeal fashion in the global realm.

Given such limitations, the essentially process-oriented nature of multilateral rule-making remains important to highlight. The Cartagena Protocol is the first step in a governance regime for biosafety. Its continuing relevance will depend upon how it evolves in response to changing normative and scientific concerns in this area, and whether it can serve as an arena either for the development of shared norms and principles governing the transboundary trade in GMOs or in the absence of such shared norms, a forum

for legitimate airing of difference. If governance is understood as a process of striving for shared understandings, one indisputable outcome of this multilateral governance effort to date has been the attempt to move toward such shared understandings amongst its participants. Multilateral rule-making is most importantly then a "site for dialogue" a role that acquires the greatest salience in areas characterized by scientific uncertainties and value conflicts, since it is precisely shared understandings which are missing in such arenas. In the case of biosafety, multilateral rule-making through the Cartagena Protocol is underway at a stage when the technology being regulated is not yet fully entrenched nor is there a long standing body of empirical evidence either of risks or benefits associated with its transfer and use. While this can result in minimalist and ambiguous rules, it also ensures that a role for multilateral rule-making as a site for dialogue and arena for "norm-building" remains highly salient.

REFERENCES

Interviews

Ahuja, M.K. Ms., (previously) Head of Indian Delegation to the Biosafety Protocol negotiations 1998-99; (currently) Senior Resident Commissioner, Rajasthan. Bikaner House, Pandara Road, New Delhi.

Babu, Sarat Dr., Joint Director, Biodiversity and Biosafety Unit, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi.

Bajaj, Shavindra Dr., Regulatory Manager, Monsanto Enterprises Ltd. Agricultural Sector. 1016-1018 Vishal Towers, District Center, Janakpuri, New Delhi.

Bhatia, Sabhyata Dr., Fellow, Tata Energy Research Institute, Durbari Singh Block, Fifth Floor, Habitat Center, Lodi Road, New Delhi.

Chakravarty, Dolly Ms., Joint Secretary, Ministry of Agriculture, Krishi Bhawan, New Delhi.

Datta, Asis Dr., Chairman, (Biosafety) Review Committee for Genetic Manipulation, and Vice-Chancellor, Jawaharlal Nehru University, New Campus, Administrative Block, JNU North Gate, New Delhi.

Gautam, P.L. Dr., Director, National Bureau of Plant Genetic Resources, Pusa campus, New Delhi.

Ghosh, P.K. Dr., Scientific Advisor, Department of Biotechnology, Ministry of Science and Technology, CGO Complex, Lodhi Road, New Delhi.

Gupta, Deepak Mr., Chairman, National Codex Committee on Food Safety Standards, Ministry of Health, New Delhi.

Jacob, Ancy De. Ms., Legal Officer, ProAgro Seed Company, Ltd. Dhumaspur Road, Gurgaon, Haryana.

Jafri, Afsar H. Mr., Programme Coordinator, Research Foundation for Science, Technology and Ecology, A-60 Haus Khas, New Delhi.

Jain, S.C. Dr., Technical Advisor, All India Biotechnology Association, VIPPS Center, Masjid Modi, G.K. II, New Delhi.

Kapoor, R. D., Mr., National Regulatory Manager, Monsanto Enterprises Limited Agricultural Sector. 1016-1018 Vishal Towers, District Center, Janakpuri, New Delhi.

Khan, R.R. Dr., Member-Secretary, (Biosafety) Genetic Engineering Approval Committee, and Director, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi.

Khetarpal, R.K., Head, Division of Plant Quarantine, National Bureau of Plant Genetic Resources, Pusa Campus, New Delhi.

Khwaja, Rajen Habib Mr., Joint Secretary and Head of Delegation to Cartagena Protocol negotiations. Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi.

Kumar, Alok Dr. Manager, Biotechnology Regulatory Affairs, ProAgro-PGS India Ltd., Dhumaspur Road, Badshahpur, Gurgaon, Haryana.

Laroia, Gaurav Dr., Scientist, Council for Scientific and Industrial Research, 3/8 Shantiniketan, New Delhi.

Lakshmikumaran, Malathi, Dr., Fellow, Bioresources and Biotechnology Division, Tata Energy Research Institute, Darbari Singh Block, Habitat Place, Lodhi Road, New Delhi.

Malik, U.N. Mr., Secretary, All India Biotechnology Association. Vipps Center, Masjid Moth, G.K.II, New Delhi.

Mashelker, R.A. Dr., Secretary, Department of Scientific and Industrial Research, and Head, Council for Scientific and Industrial Research, New Delhi.

Mubashir, Ellora Dr., Regional Manager, Biotechnology Regulatory Affairs, ProAgro PGS India Limited, Dhumaspur Road, Badshahpur, Gurgaon, Haryana.

Narain, Sunita Ms., Center for Science and Environment, New Delhi.

Nyati, K.P. Mr., Head, Environment Management Division, Confederation of Indian Industry, India Habitat Center, 4th Floor, Core 4A, Lodi Road, New Delhi.

Parikh, Sanjay Mr., Advocate, Supreme Court. Office No. 102, New Lawyers Chambers, Supreme Court, Bhagwandas Road, New Delhi.

Pental, Deepak Dr., Professor, University of Delhi, South Campus, and Director, Center for Genetic Manipulation of Crop Plants, University of Delhi, South Campus, New Delhi.

Rai, Mangla Dr., Deputy-Director General and Head of Seed Division, Crop Sciences, Indian Council for Agricultural Research, New Delhi.

Raina, S.K. Dr., Principal Scientist, National Research Center on Plant Biotechnology, Indian Agricultural Research Institute, New Delhi.

Ramanaiah, T.V. Dr., Senior Scientist, Department of Biotechnology, Ministry of Science and Technology, CGO Complex, Lodhi Road, New Delhi.

Randhawa, Gurinderjit Dr., Senior Scientist, National Research Center on DNA Fingerprinting, National Bureau of Plant Genetic Resources, Pusa Campus, New Delhi.

Sahai, Suman Dr., Convenor, Gene Campaign, J 235A, Sanik Farms, New Delhi.

Sharma, Devendra Mr., Forum for Food Safety and Biotechnology, 96A Gautam Nagar (opp Kaka Booth, past Sudarshan Talkies), Near Yusuf Sarai. New Delhi.

Sharma, Manju Dr., Secretary, Department of Biotechnology, Ministry of Science and Technology, CGO Complex, Lodhi Road, New Delhi.

Sharma, R.P. Dr., Project Director, National Research Center on Plant Biotechnology, Indian Agricultural Research Institute, Pusa Campus, New Delhi.

Shiva, Vandana Dr., Director, Research Foundation for Science, Technology and Ecology, A-60 Hauz Khas, New Delhi.

Singh, R.B. Dr., Chairman, (Biosafety) Monitoring and Evaluation Committee, and Chairman, Agricultural Scientists Recruitment Board, Indian Council of Agricultural Research, New Delhi.

Tiwari, Sandhya, Deputy Director, and Head of Biotechnology, Confederation of Indian Industry, 23 Institutional Area, Lodi Road, New Delhi.

Tyagi, Akhilesh K. Dr., Head and Programme Coordinator, Department of Molecular Biology, University of Delhi, South Campus, New Delhi.

Tyagi, R.K. Dr. Senior Scientist, National Facility for Plant Tissue Culture Repository, National Bureau of Plant Genetic Resources, ICAR, Pusa Campus, New Delhi.

Vaish, Vinod Mr., Chairman, Genetic Engineering Approval Committee, and Special Secretary, Ministry of Environment and Forests, CGO Complex, Lodhi Road, New Delhi.

Primary and secondary sources

Beck, Ulrich (1992) *Risk Society: Towards a New Modernity* (London: Sage Publications).

Biermann, Frank (1999) *Big Science, Small Impacts—in the South? The influence of International Environmental Information Institutions on Policy-Making in India* (ENRP Discussion Paper E-99-12, Kennedy School of Government, Harvard University, Cambridge, MA).

Brown, Jennifer (1989) *Environmental Threats: perception, analysis and management* (London: Belhaven).

Chayes, Abram and Antonia H. Chayes (1993) "On Compliance" *International Organization* 47, 2: 175-205.

Clark, William C. (1999) editor. *Research Note on "Designing effective assessments of global environmental issues: towards a conceptual framework for learning from experience"* by Global Environmental Assessment Faculty and Fellows,Kennedy School of Government, Harvard University, Cambridge, MA.

Connolly, Barbara, and Alex Farrell, Wendy Franz, Jill Jaeger, Terry Keating, Robert O. Keohane, Ronald B. Mitchell and Stacy VanDeveer (1998) *Institutions Working Group Theme Paper Information and Governance* Unpublished draft. Kennedy School of Government, Harvard University, Cambridge, MA.

DBT [Department of Biotechnology] 1990. *Recombinant DNA Safety Guidelines*. Ministry of Science and Technology, Government of India, New Delhi.

DBT [Department of Biotechnology] 1994. *Revised Guidelines for Safety in Biotechnology.* Ministry of Science and Technology, Government of India, New Delhi.

DBT [Department of Biotechnology] 1998. *Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts.* Ministry of Science and Technology, Government of India, New Delhi.

DBT [Department of Biotechnology] 1999. *Counter Affidavit on Behalf of The Union of India-Respondent No. 1 to the Writ Petition*. Supreme Court of India, Extraordinary Original Jurisdiction, Civil Writ Petition No. 71/1999. Text on file with author.

Dhillon, B.S. and G. J. Randhawa (2000) *Evaluation of Transgenic Crop Varieties for Biosafety and Agronomic Performance- Some Considerations*. Paper presented at the Biosafety Training Seminar, National Bureau of Plant Genetic Resources, August 14-27, 2000. Text on file with author.

ET [Economic Times] (1998) "Seeds of a Bitter Harvest: with the terminator looming large on the horizon we need to review our strategies" Guest column, AT Dudani *The Economic Times* August 23.

ET[Economic Times] (1999) "Fields of genes: the next green revolution is underway" *The Economic Times* April 11.

ET [Economic Times] (2000) "Government Gives Biosafety Approval to Monsanto's Cotton" *The Economic Times* 9 May.

Finnemore, Martha and Kathryn Sikkink (1999) "International norm dynamics and political change" in Katzenstein, Keohane and Krasner, eds. (1999: 247-277).

Ghosh, P. K. and T. V. Ramanaiah (2000) "Indian rules, Regulations and Procedures for Handling Transgenic Plants" in *Journal of Scientific and Industrial Research* (Vol. 59, February, pp. 114-120).

Ghosh, P. K. (2000) *Genetically Modified Crops in India with Special Reference to Cotton* Silver Jubilee Lecture Series, Delivered June 23, 2000. Indian Society for Cotton Improvement (Mumbai: Central Institute for Research on Cotton Technology).

Ghosh, P.K. (2000) "Genetically Modified Crops in the Context of India and Developing Countries" in *New India Digest*, forthcoming.

GOI [Government of India] (2000) *Large-Scale Field Trials for Transgenic Cotton Allowed* Press Release, Government of India, 20 July (Press Information Bureau: New Delhi). Text on file with author.

Gupta, Aarti (1999) *Framing "Biosafety" in a Transnational Context: the Biosafety Protocol Negotiations under the Convention on Biological Diversity* (ENRP Discussion Paper E-99-10, Kennedy School of Government, Harvard University, Cambridge, MA) Available at <http://environment.harvard.edu/gea>.

Gupta, Aarti (2000a) "Governing Trade in Genetically Modified Organisms: the Cartagena Protocol on Biosafety" in *Environment*, Vol. 42, No. 4. 23-33.

Gupta, Aarti (2000b) "Creating a Global Biosafety Regime" in *International Journal of Biotechnology*, Vol. 2, Nos. 1/2/3: 205-230.

Haas, Peter (1992) "Banning chorofluorocarbons: Epistemic community efforts to protect the stratospheric ozone" in *International Organization* (Vol. 46, No. 1187-224).

Haas, Peter M., Robert O. Keohane and Marc A. Levy (1993) *Institutions for the earth: sources of effective international environmental protection* (Cambridge: MIT Press).

Hampson, F.E. and J. Reppy, editors (1996), *Earthly Goods: Environmental Change and Social Justice* (Ithaca: Cornell University Press).

Hanf, Kenneth and Arild Underdal (forthcoming) *The domestic Basis of International Environmental Agreements* (Aldershot: Ashgate).

Hindu (1999) "Terminator technology vital for farmers' interests" in *The Hindu* January 13.

Hindu (1999) "Officials welcome seed trials by Monsanto" in *The Hindu* January 14.

Hindu (1999) "Monsanto justifies trials in India" in *The Hindu* February 23.

Hindu (1999) "Debates over Monsanto's field trials" in *The Hindu* February 24.

HT [Hindustan Times] (1998) "Terminator stares India in the face: deadly seed may sneak into the country, warn social scientists" *The Hindustan Times* 21 August.

IE [Indian Express] (1999) "Monsanto puts terminator on hold" *Indian Express* June 10.

IHT [International Herald Tribune] (2000) "Genetically modified trees: a blessing or danger for the world?' *The International Herald Tribune*, Frankfurt, 4 August.

Jaeger, Jill (1998) "Current thinking on using scientific findings in environmental policy making" in *Environmental Modeling and Assessment* 3, 143-153.

Jasanoff, Sheila (1986) *Risk Management and Political Culture: A comparative study of science in the policy context* (New York: Russell Sage Foundation).

Jasanoff, Sheila (1996) "Science and Norms in Global Environmental Regimes" in Hampson and Reppy 1996, 173-197.

Jasanoff, Sheila and Wynne, Brian (1998) "Science and Decision-making" in Steve Rayner and Elizabeth D. Malone (editors.) *Human Choice and Climate Change* Vol One: The Societal Framework (Columbus: Battelle Press).

Johnson, Branden B. and Vincent T. Covello (1987) *The Social and Cultural Construction of Risk: essays on risk selection and perception* (Holland: D. Reidal Publishing Company).

Kandilikar, Milind and Ambuj Sagar (1999) "Climate Change research and analysis in India: an integrated assessment of a South-North Divide" in *Global Environmental Change* 9:2, 119-138.

Kapur, Arvind (undated) *Globalization and the Seed Distribution System: the Impact of Globalization and of Domestic Market Reforms on the Seed Distribution System in Developing Countries* . ProAgro PGS unpublished manuscript. Text on file with author.

Kapur, Arvind (1999) "Opportunities in Agricultural Biotechnology" in TERI (1999: 80-92).

Katzenstein, Peter, Robert O. Keohane, and Stephen D. Krasner, eds. (1999) *Exploration and Contestation in the Study of World Politics* (Cambridge, MA: MIT Press).

Katiyar, R.P. (2000) "Seed production technology in relation to transgenics" Paper presented at the Biosafety Training Seminar, National Bureau of Plant Genetic Resources, New Delhi, August 14-27, 2000.

Mashelkar, R.A., (1999) *Economics of Knowledge* 16th Dr. C.D. Deshmukh Memorial Lecture, India International Center, New Delhi. Text on file with author.

Meyer, Hartmut (1998) *Precise precaution versus sloppy science – a case study* Workign Group on Biodiversity, Forum Environment and Development, Germany. Third World Network Briefing Paper. 5th meeting of the Ad Hoc Working Group on Biosafety, 17-29 August, Montreal. Text on file with author.

Miller, Clark (1998) *Extending Assessment Communities to Developing Countries* (ENRP Discussion Paper E-98-15, Kennedy School of Government, Harvard University, Cambridge, MA).

Mitchell, Ronald B. (1998) "Forms of Discourse, Norms of Sovereignty: Interests, science and morality in the regulation of whaling" in Litfin, K. (ed.) *The Greening of Sovereignty in World Politics* (Cambridge: MIT Press).

Mruthyunjaya and P. Ranjitha (1998) "Indian Agricultural Research System: Structure, Current Policy Issues and Future Orientation" in *World Development* (Vol. 26, No. 6, pp. 1089-1101).

Mubashir, Ellora (1999) "Introducing Transgenic Crops in India: a Joint-Venture Approach" in Joel I. Cohn (ed.) *Managing Agricultural Biotechnology: Addressing Research Program Needs and Policy Implications* (New York: CABI Publishing, in association with International Service for National Agricultural Research [ISNAR], The Hague).

Expert Panel (2000) *Recommendations on the Establishment of Research and Development Facilities for Evaluation of Indian and Imported Transgenic Plant Material in India* : A Panel of Experts Report, coordinated by the University of Delhi. Text on file with author.

Parida, Ajay (1999) "Genetically modified crop plants: issues of food safety and security in Asia" in *Proceedings of the International Conference on Biotechnology for Sustained Productivity in Agriculture* , Hyderabad, India. November 1-2, 1999.

Paroda, R.S. (1996) "Sustaining the Green Revolution: New Paradigms" The Dr. B.P. Pal Commemoration Lecture, Friday November 22, 1996. Delivered to the Special Session at Vigyan Bhawan of the 2nd International Crop Science Congress (New Delhi: Indian Agricultural Research Institute).

Paroda, R.S. (1999) "Keynote address: biotechnology and future Indian agriculture" in TERI (1999: 16-25).

Prakash, C.S. (1999) "Relevance of biotechnology to Indian agriculture" in TERI (1999: 43-48).

Rai, Mangala and B. M. Prasanna (2000) *Transgenics in Agriculture* (New Delhi: Indian Council of Agricultural Research).

Raina, S.K. Dr. (2000) *GM foods: can we afford to ignore?* Indian Institute of Foreign Trade: Workshop on Biotechnology with a special focus on genetically modified foods, 14 July. Text on file with author.

Rao, S.R.,(1999) "Building public acceptance of genetically modified products in India" in TERI (1999: 94-103).

RFSTE [Research Foundation for Science, Technology and Ecology] (1998) *Monsanto: Peddling "Life Sciences" or "Death Sciences"* (New Delhi: RFSTE publications).

RFSTE (1999) Writ Petition (Civil) No. 71 of 1999. In the Matter of Research Foundation for Science, Technology and Ecology (Petitioner) versus Union of India and Others (Respondents). Supreme Court of India, Extraordinary Original Jurisdiction, Filed on 16 January 1999. Text on file with author.

RFSTE (1999b) Common Rejoinder Affidavit to the Counter Affidavits Filed by the Union of India thro ugh Ministry of Science and Technology (Respondent No. 1) Maharashtra Hybrid Seeds Company Ltd (Respondent No. 2) and Monsanto Biotech (India) Private Ltd. (Respondent No. 3). Writ Petition (Civil) No. 71/1999. Supreme Court of India. Extraordinary Original Jurisdiction. Text on file with author.

RFSTE (2000) "US Government dumping genetically engineered corn-soya mix on victims of Orissa super cyclone" *RFSTE Press Release*, dated June 2, 2000. Text on file with author.

Rosenau, James (1995) "Governance in the Twenty-first Century" in *Global Governance* Vol.1, 1:13-44.

Science for People (1999) *Terminator logic: Monsanto, Genetic Engineering and the Future of Agriculture* (New Delhi: RFSTE publications).

Sharma, Manju (1999) "Inaugral Address" in TERI (1999: 11-15).

Shiva, Vandana (1998) *Seeds of Suicide: the ecological and human costs of globalization of agriculture* (RFSTE: New Delhi).

Singhal, N.C., (2000) "Seed Quality Law Enforcement in relation to transgenics" Paper presented at the Biosafety Training Seminar, National Bureau of Plant Genetic Resources, New Delhi, August 14-27, 2000. Text on file with author.

Starr, C., (1969) "Social Benefits versus Technological Risk: what is our society willing to pay for safety?" in *Science* Vol. 165: 1232-1238.

Telils, Olga (1993) "Kissa Kisan Ka (The Farmer's Story)" in *The Sunday Observor* March 14-20, p. 7.

TI [Times of India] (1999) "Transgenic crop varieties spark controversy" in *Times of India* July 2.

TERI [Tata Energy Research Institute] (2000) *Stakeholders' Dialogue on Agricultural Biotechnology: Biosafety and Economic Implications*. Proceedings of a Workshop held on 25 November 1999 at the Tamil Nadu Agricultural University. (New Delhi: TERI publications).

TERI [Tata Energy Research Institute] (1999) *Genetically Modified Plants: Benefits and Risks* . Proceedings of a Workshop held on 24 June, 1999 in New Delhi (New Delhi: TERI publications).

UNEP [United Nations Environment Programme] (2000), *Cartagena Protocol on Biosafety: final draft text submitted by the legal drafting group* UNEP/CBD/ExCOP/1/L.5, 28 January 2000. Available at http://www.biodiv.org.

VanDeveer, Stacy (1998) *European Politics with a Scientific Face: transition countries, international environmental assessment and long-range transboundary air pollution* . (ENRP Discussion Paper E-98-09, Kennedy School of Government, Harvard University, Cambridge, MA).

Van Dusen, Eric (2000) *Challenges for biosafety regulation in developing countries* Biotechnology Viewpoint, posted June 12, 2000 at the Science, Technology and Innovation Program, Center for International Development website. Available at http://www.cid.harvard.edu/cidbiotech/comments/

Victor, David G., Kal Raustiala and Eugene B. Skolnikoff, eds. (1998) *The Implementation and Effectiveness of International Environmental Commitments: theory and practice* (Cambridge, MA: MIT Press).

Weiss, Edith Brown and Harold K. Jacobson, eds. (1998) *Engaging Countries: Strengthening Compliance with International Environmental Accords* (Cambridge: MIT Press).

Wirth, D.A., (1994) "The role of science in the Ur uguay Round and NAFTA trade disciplines" *in Cornell International Law Journal* Vol. 27, no. 3: pp. 817-859.

TABLES

Table I: Scope of "informed consent" and other decision-procedures under the Cartagena Protocol

Category of LMO	Developing country rationale for inclusion	OECD rationale for exclusion	Final outcome
LMOs intended for deliberate release into the environment (e.g. modified corn or soya intended for planting as seed in the environment of the importing country)	Necessary to include in the protocol and the advance informed agreement (AIA) procedure to assess for potential adverse impacts on biodiversity and human health	- None -	Included in the protocol; full AIA procedure to apply
LMOs intended for "food or feed or for processing" i.e., LMO-FFPs or agricultural commodities (e.g., modified corn intended for processing into edible oils; modified fruits intended for human consumption).	Necessary to include in the protocol and the AIA to assess for potential adverse impacts; intended use for food or feed or processing cannot always be guaranteed (thus, modified corn intended for feed could be planted as seed)	Include in protocol but exclude from AIA; LMO-FFPs are not intended for release into the environment and thus do not pose threat to biodiversity; functioning of bulk commodity trade makes AIA procedure impossible to apply	Included in the protocol; a decision process distinct from AIA to apply; it calls for information sharing on domestic approvals of LMOs; countries can notify biosafety clearing house if they do not wish to import LMO-FFPs
LMOs intended for contained use (e.g., in research labs or greenhouses; some definitions of contained use can include field trials)	Necessary to include in the protocol and the AIA to assess for adverse impacts; definition of containment can vary; safety of containment is dependent upon context and capacity	Include in the protocol but exclude from AIA; LMOs for contained use do not pose threat to biodiversity; instead of AIA, documentation on LMOs to be provided with the transfer	Included in the protocol, excluded from AIA; documentation to accompany LMO transfers for contained use. The importing country's definition of containment to apply
LMOs in transit, i.e., LMOs transiting through a country before reaching the final destination	Necessary to include in the protocol and the AIA to allow transit countries to assess for potential adverse impacts	Include in Protocol but exclude from AIA; documentation to accompany LMOs in transit	Included in the protocol; excluded from AIA; documentation to accompany LMOs in transit
Finished products of LMOs, i.e., "products thereof or processed materials that are of LMO origin containing detectable novel combinations of replicable genetic material..." (e.g., oil from modified corn)	Necessary to include in the protocol to assess for potential adverse impacts; it is not certain that processed products of LMOs do not pose risks	Exclude from protocol and AIA. Processed products do not pose risk to biodiversity. It would be a logistical impossibility to include this vast category of products within the protocol	Very circumscribed inclusion in the protocol, excluded from AIA, instead of AIA, limited information sharing requirements specified in Article 20 and in Annex I & II on notification requirements and risk assessment parameters
LMOs that are pharmaceuticals for humans (e.g., genetically engineered insulin, modified live vaccines for humans)	Necessary to include in the protocol to assess for potential adverse impacts; distinction between agricultural and pharmaceutical LMOs can be hazy in the future	Exclude from protocol; the Convention on Biological Diversity is not the appropriate forum to regulate pharmaceuticals, other international fora more suitable	Excluded from the protocol as long as LMO-based pharmaceuticals are being addressed by other international fora

Source: Adapted from Gupta, A. "Governing Trade in Genetically Modified Organisms: the Cartagena Protocol on Biosafety" in *Environment* Vol. 42, Number 4, May 2000, pp 28.

Table II: Developments in transgenic research and applications in India (as of early 1999)

Institute	Transgenic crop	Transgene inserted	Aim of project and progress made
Central Tobacco Research Institute, Rajahmundri	Tobacco	Bt toxin gene	To confer crop resistance to lepidopteran pests. One round of contained field trials completed
Bose Institute, Calcutta	Rice	Bt toxin gene	To confer crop resistance to lepidopteran pests. Ready for greenhouse testing
Tamil Nadu Agricultural University, Coimbatore	Rice	Reporter gene	To study extent of transformation frequency.
University of Delhi, South Campus, New Delhi	Mustard	Bar, Barnase, Barstar	To develop better hybrid cultivars suitable for local conditions. Ready for greenhouse trials
	Rice	Selectable marker genes	To undertake gene regulation studies. Transformations completed
National Botanical Research Institute, Lucknow	Cotton	Bt toxin gene	To confer crop resistance to lepidopteran pests. Transformation in progress
Indian Agricultural Research Institute, Shillong substation	Rice	Bt toxin gene	To confer crop resistance to lepidopteran pests. Transformation in progress.
Central Potato Research Institute, Simla	Potato	Bt toxin gene	To confer crop resistance to lepidopteran pests. Ready for greenhouse trials
ProAgro-PGS India Ltd. New Delhi	Brassica (mustard), cauliflower	Bar, Barnase, Barstar	To develop better hybrid cultivars suitable for local conditions. Glasshouse experiments underway for cauliflower. Contained field trials in over 15 locations completed for mustard. Further contained open-field research trials in progress at many locations
	Tomato, Brinjal, Cauliflower, Cabbage	Bt toxin gene	To confer crop resistance to lepidopteran pests. Glasshouse experiments in progress. One season contained field trials completed for tomato.
Mayhco, Mumbai	Cotton	Bt toxin gene	To confer crop resistance to lepidopteran pests. Multicentric field trials in over 40 locations completed and further contained field trials in progress
Rallis India Ltd. Bangalore	Chilli, Bell pepper, Tomato	Snowdrop Lectin gene	To confer crop resistance to pests. Transformation experiments in progress.
Jawaharlal Nehru University, New Delhi	Potato	Gene expressing for protein with lysine	To increase nutrient value. Transformation complete, under evaluation.
Indian Agricultural Research Institute, New Delhi	Brinjal, Tomato, Cauliflower, Mustard	Bt toxin gene	To confer crop resistance to lepidopteran pests. Transformation and greenhouse trials completed. One season field trial completed for brinjal and potato

Source: Adapted from Ghosh and Ramanaiah (2000)

Table III: Composition and Functions of Indian Competent Authorities (as of September 1999)

Competent Authority	Composition	Functions
Recombinant DNA Advisory Committee (RDAC)	As determined by the Department of Biotechnology—to consist of experts in their individual capacity	To review biotechnology developments at national and international levels; to recommend suitable biosafety regulations for India.
Review Committee on Genetic Manipulation (RCGM)	Member Secretary, Department of Biotechnology; Indian Council of Medical Research; Indian Council of Agricultural Research; Council of Scientific and Industrial Research; other experts in their individual capacity	To issue guidelines for GMO research; to authorize rDNA projects in high risk category III; to authorize controlled field experiments; to permit imports of GMOs for research
Genetic Engineering Approval Committee (GEAC)	Chair: Additional Secretary, Ministry of Environment and Forests; Co-Chair: Dept. of Biotechnology representative; Representatives from Ministry of Industrial Development, Departments of Biotechnology and Atomic Energy; Indian Council of Agricultural Research; Indian Council of Medical Research; Council of Scientific and Industrial Research; Directorate of Plant Protection; Central Pollution Control Board; others in individual capacity.	To authorize commercial use (including import) of GMOs or their products; to authorize large scale production and release of GMOs and their products into the environment; to mandate restrictions or prohibitions on production, sale, import or use of GMOs, if necessary.
Institutional Biosafety Committees (IBSC)	Head of the Organization; scientists engaged in rDNA work; Biosafety or Medical Officer; Nominee, Department of Biotechnology	To oversee rDNA research activities; to seek RCGM approval for category III risk; to ensure adherence with biosafety guidelines; to prepare an emergency plan; to inform DLC, SBCC & GEAC about relevant experiments.
State Biotechnology Coordination Committee (SBCC)	Chief Secretary, State Government; Secretaries, Department of Environment, Health, Agriculture, Commerce, Forests, Public Works, Public Health; Chairman, State Pollution Control Board; State microbiologists and pathologists; Other experts in individual capacity	To periodically review safety and control measures in institutions handling GMOs; to inspect and take punitive action in case of violations through the State Pollution Control Board or the Directorate of Health; to act as nodal agency at the state level to assess damage, if any, from release of GMOs, and to take on site control measures.
District-Level Committee (DLC)	District Collector; Factory Inspector; Pollution Control Board Representative; Chief Medical Officer; District Agricultural Officer; Public Health Department Representative; District microbiologists/pathologists; Municipal Corporation Commissioner; Other experts in individual capacity	To monitor safety regulations in installations; to investigate compliance with rDNA guidelines and report violations to SBCC or GEAC; to act as nodal agency as district level to assess damage, if any, from release of GMOs and to take on site control measures

Source: Compiled by author from: GEAC (1989), Ghosh and Ramanaiah (1999).

ENDNOTES

[1] One influential study which has examined the role of ambiguity in international regimes is Chayes and Chayes (1993), who suggest that ambiguity of agreement is one reason why states may not be complying with their international obligations. However, my argument precedes the issue of compliance by suggesting that one way in which a regime might be "effective" - if effectiveness is equated with cross-cultural credibility - is through the ambiguity of its obligations, because such ambiguity allows distinct national approaches to persist unchanged in realms where the nature of the probiem remains contested.

[2] For detailed discussion of this change in terminology and its implications, see Gupta 1999: 4-6.

[3] Council Directive of 23 April 1990 on the contained use of genetically modified microorganisms (90/219/EEC) and Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC). *Official Journal of the European Communities* , no. L117/1-27.

[4] The text of the finalized Cartagena Protocol on Biosafety is available at: http://www.biodiv.org.

[5] The developing country rationale for inclusion of commodities within informed consent was that intended use of LMOs for "food, feed or processing" could not be guaranteed, since the same LMO intended for feed could also be planted as seed, and thus constitute a deliberate release. The agricultural exporting countries of the Miami Group argued that LMO commodities were not intended for release and that the structure and functioning of the bulk agricultural commodity trade precluded inclusion of commodities within an informed consent procedure. They argued, instead, that information sharing rather than solicitation of consent should suffice for countries to take safety precautions, if needed (Gupta 1999).

[6] The protocol's definition of contained use (UNEP 2000: Article 3b) negotiated by a group of scientific and technical experts came under sustained criticism by developing countries and green groups for being too open-ended. As phrased, contained use for the purpose of the protocol could include field trials or even biological containment through "terminator" technology or "gene protection systems". This technology is designed to render seed sterile as a form of intellectual property protection, yet it can also serve as a form of biological containment in preventing spead of novel genes into the receiving environment. Developing countries argued that excluding such LMOs from informed consent by characterizing them "LMOs for contained use" would negate the purpose of negotiating a protocol on biosafety (Gupta 1999).

[7] The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) completed during the Uruguay Round of multilateral trade negotiations, which also culminated in the establishment of the World Trade Organization, is an explicitly science-based agreement designed to ensure that differential national sanitary and phytosanitary standards (relating to human, animal and plant health) do not become nontariff barriers to trade. For a detailed discussion of the SPS Agreement and its science-based provisions, see Wirth (1994).

[8] See Meyer (1998) for an argument that there is no inherent dichotomy between sound science and precaution, if only sound science is conceptualized as science that is cognizant of uncertainties and advocates caution where necessary.

[9] Articles 10.6 and Articles 10.6 and 11.8 of the Cartagena Protocol on Biosafety (2000) state that "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism..., in order to avoid or minimize such potential adverse effects" (UNEP 2000, p.6).

[10] Principle 15 of the Rio Declaration on Environment and Development (1992), perhaps the most widely known formulation, states that "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". Article 5.7 of the World Trade Organization 1993 Agreement on Application of Sanitary and

Phytosanitary Measures (SPS) states that "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt...measures on the basis of available pertinent information...in such circumstances, Members will seek to oBtain the additional information necessary for a more objective assessment of risk and review the ...measure accordingly within a reasonable period of time" (Rio Declaration text available at http://www.igc.apc.org/habitat/agenda21/riodec/html and Ur uguay Round Agreements, Final Act, SPS Agreement text available at http://www.wto.org/legal/finalact.htm).

[11] Thus, Paragraph 9(1) of the Rules states that "Deliberate or unintentional release of genetically modified organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment, shall not be allowed". Paragraph 9 (2) states, however, that "the Genetic Engineering Approval Committee may in special cases give approval for deliberate release" [1989 Rules, para 9 (1) (2).] Text on file with author.

[12] For example, in detailing the procedure to be followed for subchronic oral toxicity studies in goats, the 1998 Revised Guidelines note that "the methods, species of animals and routes of administration described in this protocol are based on the standard OECD Guidelines No. 408 (1993)".

[13] Addendum to the "Revised Guidelines—August 1998" issued on 24 September 1999. Text on file with author.

[14] Documentation requirements to accompany LMO commodity shipments were extremely contentious during negotiation of the protocol. The dispute centered around the European Union proposal that documentation accompanying commodity shipments should specify the identity and unique characteristics of each LMO present in a shipment. This was rejected by the Miami Group since it would have mandated segregation and tracking through the commodity chain of different LMOs, currently not the norm, although market forces could be moving the agricultural commodity trade in that direction. The compromise in the finalized protocol calls commodity shipments to state that they "may contain" LMOs rather than specifying which ones. In addition, parties to the protocol are to determine, over a period of two years following its entry into force, any further information to be provided (UNEP 2000, Gupta 2000b).

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS

BCSIA is a vibrant and productive research community at Harvard's John F. Kennedy School of Government. Emphasizing the role of science and technology in the analysis of international affairs and in the shaping of foreign policy, it is the axis of work on international relations at Harvard University's John F. Kennedy School of Government. BCSIA has three fundamental issues: to anticipate emerging international problems, to identify practical solutions, and to galvanize policy-makers into action. These goals animate the work of all the Center's major programs.

The Center's Director is Graham Allison, former Dean of the Kennedy School. Stephen Nicoloro is Director of Finance and Operations.

BCSIA's International Security Program (ISP) is the home of the Center's core concern with security issues. It is directed by Steven E. Miller, who is also Editor-in-Chief of the journal, *International Security*.

The Strengthening Democratic Institutions (SDI) project works to catalyze international support for political and economic transformation in the former Soviet Union. SDI's Director is Graham Allison.

The Science, Technology, and Public Policy (STPP) program emphasizes public policy issues in which understanding of science, technology and systems of innovation is crucial. John Holdren, the STPP Director, is an expert in plasma physics, fusion energy technology, energy and resource options, global environmental problems, impacts of population growth, and international security and arms control.

The Environment and Natural Resources Program (ENRP) is the locus of interdisciplinary research on environmental policy issues. It is directed by Henry Lee, expert in energy and environment. Robert Stavins, expert in economics and environmental and resource policy issues, serves as ENRP's faculty chair.

The heart of the Center is its resident research staff: scholars and public policy practitioners, Kennedy School faculty members, and a multi-national and inter-disciplinary group of some two dozen pre-doctoral and post-doctoral research fellows. Their work is enriched by frequent seminars, workshops, conferences, speeches by international leaders and experts, and discussions with their colleagues from other Boston-area universities and research institutions and the Center's Harvard faculty affiliates. Alumni include many past and current government policy-makers

The Center has an active publication program including the quarterly journal *International Security*, book and monograph series, and Discussion Papers. Members of the research staff also contribute frequently to other leading publications, advise the government, participate in special commissions, brief journalists, and share research results with both specialists and the public in a wide variety of ways.

The Center's web address, through which all its research programs web sites can be reached, is: http://ksgnotes1.harvard.edu/bcsia/bcsia.nsf/www/Home. The Kennedy School web address is: www.ksg.harvard.edu.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

2000-25 Jaffe, Adam B., Richard G. Newell, and Robert N. Stavins. "Technological Change and The Environment."

2000-24 Gupta, Aarti. "Governing Biosafety in India: The Relevance of The Cartagena Protocol."

2000-23 Eckley, Noelle. "From Regional to Global Assessment: Learning from Persistent Organic Pollutants."

2000-22 Keykhah, Modjeh. "Global Hazards and Catastrophic Risk: Assessments, Practitioners and Decision Making in Reinsurance."

2000-21 Ogunseitan, Oladele. "Framing Vulnerability: Global Environmental Assessments and the African Burden of Disease."

2000-20 Betsill, Michele M. "Localizing Global Climate Change: Controlling Greenhouse Gas Emissions in U.S. Cities."

2000-19 Patt, Anthony. "Communicating Probabilistic Forecasts to Decision Makers: A Case Study Of Zimbabwe."

2000-18 Lund, David C. "Regional Abrupt Climate Change Assessment in the U.S.: Comparing the Colorado and Columbia River Basins."

2000-17 Biermann, Frank. "Science as Power in International Environmental Negotiations: Global Environmental Assessments Between North and South."

2000-16 Krueger, Jonathan. "Information in International Environmental Governance: The Prior Informed Consent Procedure for Trade in Hazardous Chemicals and Pesticides."

2000-15 Stavins, Robert N. "Economic Analysis of Global Climate Change Policy: A Primer."

2000-14 Weeks, Jennifer. "Advice – and Consent? The Department of Energy's Site-Specific Advisory Boards."

2000-13 Yereskovsky, Alexander. "The Global Security Environment and U.S.-Russian Strategic Relations in the 21st Century: Partners or Rivals?"

2000-12 Clark, William et. Al. "Assessing Vulnerability to Global Environmental Risk."

2000-11 Foster, Charles, H.W. and William B. Meyer, "The Harvard Environmental Regionalism Project."

2000-10 Cash, David. "'In Order to Aid in Diffusing Useful and Practical Information': Cross-scale Boundary Organizations and Agricultural Extension."

2000-09 Foster, Charles, H.W. et al., "Colloquium on Environmental Regionalism."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

2000-08	Lee, Henry and Shashi Kant Verma, "Coal or Gas: The Cost of Cleaner Power in the Midwest."
2000-07	Fischer, Markus, "The Liberal Peace: Ethical, Historical and Philosophical Aspects."
2000-06	Cash, David, "Distributed Assessment Systems: An Emerging Paradigm of Research, Assessment and Decision-making for Environmental Change."
2000-05	Donohue, Laura K., "Civil Liberties, Terrorism, and Liberal Democracy: Lessons from the United Kingdom."
2000-04	Golub, Alexander, "Russian Forests for Climate Change Mitigation: An Economic Analysis."
2000-03	Coglianese, Cary, "Policy Implications of Environmental Management Systems."
2000-02	Meyer, William B. and Charles H.W. Foster, "New Deal Regionalism: A Critical Review."
2000-01	Newell, Richard and Robert Stavins, "Abatement-Cost Heterogeneity and Anticipated Savings from Market-Based Environmental Policies."
R-99-01	Rapporteur's Report. "Workshop on Research and Policy Directions for Carbon Management."
99-20	Rufin, Carlos, "Institutional Change in the Electricity Industry: A Comparison of Four Latin American Cases."
99-19	Rothenberg, Sandra and David Levy, "Corporate Responses to Climate Change: The Institutional Dynamics of the Automobile Industry and Climate Change."
99-18	Stavins, Robert, "Experience with Market-Based Environmental Policy Instruments."
99-17	Jaffe, Adam, Richard Newell and Robert Stavins, "Energy-Efficient Technologies and Climate Change Policies: Issues and Evidence."
99-14	Jung, Wolfgang. "Expert Advice in Global Environmental Decision Making: How Close Should Science and Policy Get?"
99-13	Levy, David L. and Sandra Rothenberg, "Corporate Strategy and Climate Change: Heterogeneity and Change in the Global Automobile Industry."
99-12	Biermann, Frank, "Big Science, Small Impacts -- in the South? The Influence of International Environmental Information Institutions on Policy-Making in India."
99-11	Eckley, Noelle, "Drawing Lessons About Science-Policy Instruments: Persistent Organic Pollutants (POPs) under the LRTAP Convention."
99-10	Gupta, Aarti. "Framing 'Biosafety' in an International Context: The Biosafety Protocol Negotiations."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

99-09 Seng, Jordan. "If Iraq Gets the Bomb: Zealous Rogues, Old-Fashioned Tyrants, and Nuclear Deterrence."

99-08 Konoplyov, Sergei. "Analytical Centers in Ukraine."

99-07 Foster, Charles, H.W. and David Foster. "Thinking in Forest Time: A Strategy for the Massachusetts Forest."

99-06 Pfaff, Alexander S. and Stavins, Robert N. "Readings in the Field of Natural Resource & Environmental Economics."

99-05 Johnsen, Tor Arnt, Shashi Kant Verma and Catherine Wolfram. "Zonal Pricing and Demand-Side Bidding in the Norwegian Electricity Market."

99-04 Dietrich, William F. "Guide to Research Databases of Acid Rain Assessment and Policy Literatures."

99-03 Grant, Richard. "Power and Prosperity: Challenges and Opportunities for Small States."

99-02 Hahn, Robert W. and Robert N. Stavins. "What has Kyoto Wrought? The Real Architecture of International Tradeable Permit Markets."

99-01 Hahn, Robert W. "The Impact of Economics on Environmental Policy."

98-27 Parris, Thomas and Charles Zracket and William Clark. "Usable Knowledge for Managing Responses to Global Climate Change: Recommendations to promote collaborative assessments and information systems."

98-26 Fisher-Vanden, Karen. "Technological Diffusion in China's Iron and Steel Industry."

98-25 Bunn, Matthew, Neil J. Numark and Tatsujiro Suzuki. "A Japanese-Russian Agreement to Establish a Nuclear Facility for MOX Fabrication and Spent Fuel Storage in the Russian Far East."

98-24 Holdren, John P. "Getting to Zero: Is Pursuing a Nuclear-Weapon-Free World Too Difficult? Too Dangerous? Too Distracting?"

98-23 Stavins, Robert N. and Richard Newell. "Climate Change and Forest Sinks: Factors Affecting the Costs of Carbon Sequestration."

98-22 O'Neill, Kate. "(Not) Getting to 'Go': Recent Experience in International Cooperation over the Management of Spent Nuclear Reactor Fuel."

98-21 Lee, Henry. "Designing Domestic Carbon Trading Systems: Key Considerations."

98-20 Patt, Anthony. "Analytic Frameworks and Politics: The Case of Acid Rain in Europe."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

98-19 Iles, Alastair. "The Evolution of Acidification Impact Frames in Europe: Interactions Between Regional and National Assessment of Forest Conditions."

98-18 Franz, Wendy E. "Science, Skeptics and Non-State Actors in the Greenhouse."

98-17 Cash, David. "Assessing and Addressing Cross-Scale Environmental Risks: Information and Decision Systems for the Management of the High Plains Aquifer."

98-16 Moser, Susanne. "Talk Globally, Walk Locally: The Cross-Scale Influence of Global Change Information on Coastal Zone Management in Maine and Hawai'i."

98-15 Miller, Clark. "Extending Assessment Communities to Developing Countries."

98-14 Bader, Pascal. "Targets and Strategies: The Role of Economic Assessments in European Climate Policy."

98-13 Botcheva, Liliana. "Doing is Believing: Participation and Use of Economic Assessments in the Approximation of EU Environmental Legislation in Eastern Europe."

98-12 Farrell, Alex and Terry J. Keating. "Multi-Jurisdictional Air Pollution Assessment: A Comparison of the Eastern United States and Western Europe."

98-11 Keating, Terry J. and Alex Farrell. "Problem Framing and Model Formulation: The Regionality of Tropospheric Ozone in the U.S. and Europe."

98-10 Samson, Paul. "Non-State Actors and Environmental Assessment: A Look at Acid Rain and Global Climate Change."

98-09 VanDeveer, Stacy D. "European Politics with a Scientific Face: Transition Countries, International Environmental Assessment, and Long Range Transboundary Air Pollution."

98-08 Chayes, Abram. "A Suggested Model for Implementing the Clean Development Mechanism."

98-07 Lynn-Jones, Sean M. "Why the United States Should Spread Democracy."

98-06 Mitchell, Ronald and Ted Parson. "Implementing Joint Implementation: Developing a Management and Performance System for the Kyoto Protocol's 'Clean Development Mechanism.'"

98-05 Hahn, Robert. "An Analysis of the First Government Report on the Benefits and Costs of Regulation."

98-04 Stavins, Robert N. "How do Economists Really Think about the Environment?"

98-03 Coglianese, Cary. "Getting the Message Out: Regulatory Policy and the Press."

98-02 Stavins, Robert. "Market-Based Environmental Policies."

98-01 Newell, Richard, Adam Jaffe and Robert Stavins. "The Induced Innovation Hypothesis and Energy-Saving Technological Change."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

97-15 Foster, Charles, H.W. "Managing Resources as Whole Systems: A Primer for Managers."

97-14 Anderson, Steven. "U.S. Electricity Restructuring and Environmental Policy: A Survey of Opinions in the Environmental Community."

97-13 Verma, Shashi. "Getting Privatization Right: Establishing a Competitive Market for Electricity Generation in Brazil."

97-12 Hahn, Robert. "Climate Change: Economics, Politics, and Policy."

97-11 Keohane, Nathaniel, Richard Revesz and Robert Stavins. "The Positive Political Economy of Instrument Choice in Environmental Policy."

97-10 Patt, Anthony. "Assessing Extreme Outcomes: The Strategic Treatment of Low Probability Impacts of Climate Change."

97-09 Long, Marybeth and Alastair Iles. "Assessing Climate Change Impacts: Co-Evolution of Knowledge, Communities and Methodologies."

97-08 Kandlikar, Milind and Ambuj Sagar. "Climate Science and Policy in India: Learning Some Lessons."

97-07 Franz, Wendy E. "The Development of an International Agenda for Climate Change."

97-06 Fisher-Vanden, Karen. "International Policy Instrument Prominence in the Climate Change Debate: A Case Study of the United States."

97-05 Agrawala, Shardul. "Explaining the Evolution of the IPCC Structure and Process."

97-04 Wright, Jan C. "'Bright Lines' and the Value of Life: Resolving the Dispute over the Regulation of Carcinogens."

97-03 Parson, Edward A. and Karen Fisher-Vanden. "Joint Implementation and its Alternatives."

97-02 Stavins, Robert N. "Economic Incentives for Environmental Regulation."

97-01 Arbatov, Alexei G. "Military Reform in Russia: Dilemmas, Obstacles, and Prospects."

96-03 de Nevers, Renee. "Sustaining the Transition? Western Efforts to Support Democracy and Prevent Conflict in Russia."

96-02 Rogers, Elizabeth S. "Using Economic Sanctions to Prevent Deadly Conflict."

96-01 Meade, Andre and Sydney Rosen. "The Mixed-Grass Prairie Reserve: Managing the Greater Badlands Region as a Whole System."

95-14 Schatzki, Todd. "The Effects of Uncertainty on Landowner Conversion Decisions."

95-13 Lee, Henry and Negeen Darani. "Electricity Restructuring and the Environment."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

95-12	Clark, William C. and Nancy M. Dickson eds. "The Press and Global Environmental Change: An International Comparison of Elite Newspaper Reporting on the Acid Rain Issue from 1972 to 1992."
95-11	Zaborsky, Victor. "Crimea and the Black Sea Fleet in Russian-Ukrainian Relations."
95-10	Stavins, Robert, Adam Jaffe, Steve Peterson, and Paul Portney. "Environment Regulation and the Competitiveness of U.S. Manufacturing: What does the Evidence Tell Us?"
95-09	Haran, Olexity. "Disintegration of the Soviet Union and the US Position on the Independence of Ukraine."
95-08	Allison, Graham T., Owen R. Coté, Jr., Richard A. Falkenrath and Steven E. Miller. "Avoiding Nuclear Anarchy: Containing the Threat of Loose Russian Nuclear Weapons and Fissile Material."
95-07	Falkenrath, Richard A. "The U.S.-Russian HEU Purchase Agreement: Achievements, Problems, Prospects."
95-06	Stavins, Robert N. "The Costs of Carbon Sequestrian: A Revealed Preference Approach."
95-05	Dietrich, William. "The Challenge of Selecting Goals: Case Studies Regarding the Use of Critical Levels."
95-04	Ferenz, Michele N. and Stephan D. Sylvan. "The Design of a Palestinian-Israeli Water Commission: A Best Practices Approach."
95-03	Stavins, Robert N. and Tomasz Zylicz. "Environmental Policy in a Transition Economy: Designing Tradable Permits for Poland."
95-02	Not available.
95-01	Perlman, Brett A. "Pricing the Internet: How to Pay the Toll for the Electronic SuperHighway."
94-10	Stavins, Robert N. "Correlated Environmental Uncertainty and Policy Instrument Choice."
94-09	Falkenrath, Richard A. "The United States and Ballistic Missile Defense after the Cold War."
94-08	Falkenrath, Richard A. "The United States, the Former Soviet Republics, and Nuclear Weapons: Problems and Policies of Denuclearization."
94-07	Stavins, Robert N. and Adam Jaffee. "Environmental Regulation and Technology Diffusion: The Effects of Alternative Policy Instruments."
94-06	Not Available.
94-05	Zaborsky, Victor. "Nuclear Disarmament and Nonproliferation: The Evolution of the Ukrainian Case."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

94-04	Lachow, Irving. "The Global Positioning System and Cruise Missile Proliferation: Assessing the Threat."
94-03	Fairman, David, and Michael Ross. "International Aid for the Environment: Lessons from Economic Development Assistance."
94-02	Hahn, Robert W. and Carol A. May. "The Behavior of the Allowance Market: Theory and Evidence."
94-01	Bender, Rodd, Wyman Briggs, and Diane DeWitt. "Toward Statewide Unit Pricing in Massachusetts: Influencing the Policy Cycle."
93-06	Hahn, Robert W. "An Economic Analysis of Scrappage."
93-05	Hancke, Bob. "Technological Change and Its Institutional Constraints."
93-04	Portney Paul R. and Robert N. Stavins. "Regulatory Review of Environmental Policy: The Potential Role of Health-Health Analysis"
93-03	Parson, Edward A. and Richard J. Zeckhauser. "Equal measures and Fair Burdens: negotiating environmental treaties in an unequal world."
93-02	Stavins, Robert N. "Transaction Costs and the Performance of Markets for Pollution Control."
93-01	Holla, Rogier A.H.G. "Cultural Attitudes and Institutional Forces: Explaining National Differences in Biotechnology Policy."
92-13	Foster, Charles H.W. "Of Vert and Vision: Ensuring the Legacy of the Northern Forest of New England and New York."
92-12	Hane, Gerald Jiro. "Research and Development Consortia in Innovation in Japan: Case Studies in Superconductivity and Engineering Ceramics."
92-11	Vernon, Raymond. "The Triad as Policymakers."
92-10	Jorgenson, Dale W. and Peter J. Wilcoxen. "Energy, the Environment and Economic Growth."
92-09	Norberg-Bohm, Vicki and William C. Clark, et al. "International Comparisons of Environmental Hazards: Development and evaluation of a method for linking environmental data with the strategic debate management priorities for risk management."
92-08	Hart, David. "Strategies of Research Policy Advocacy: Anthropogenic Climatic Change Research, 1957-1974."
92-07	Dembinski, Matthias. "Ballistic Missile Proliferation and the New World Order: A Critical Survey of the Literature."
92-06	Shlyakhter, Alexander I. and Daniel M. Kammen. "Estimating the Range of Uncertainty in Future Development from Trends in Physical Constraints and Predictions of Global Change."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

92-05	Eaton, Susan C. "Union Leadership Development in the 1990s and Beyond: A Report with Recommendations."
92-04	Hahn, Robert W. and Robert L. Axtell. "Reevaluating the Relationship between Transferable Property Rights and Command-and-Control Regulation."
92-03	Stavins, Robert N. and Bradley W. Whitehead. "The Greening of America's Taxes: Pollution Charges and Environmental Protection."
92-02	Parson, Edward A. "Protecting the Ozone Layer: The Evolution and Impact of International Institutions."
92-01	Branscomb, Lewis M. "S & T Information Policy in the Context of a Diffusion Oriented National Technology Policy."
91-15	Hahn, Robert W. and Robert N. Stavins. "Economic Incentives for Environmental Protection: Integrating Theory and Practice."
91-14	Hahn, Robert W. "Government Markets and the Theory of the *N* th Best."
91-13	Parson, Edward A. and William C. Clark. "Learning to Manage Global Environmental Change: A Review of Relevant Theory."
91-12	Branscomb, Lewis M. "America's Emerging Technology Policy."
91-11	Lynn-Jones, Sean M. "International Security Studies after the Cold War: An Agenda for the Future."
91-10	Rapporteur's Report of the Executive Session: "Negotiating a Global Climate Change Agreement." March 14-15, 1991.
91-09	Jorgenson, Dale W. and Peter J. Wilcoxen. "Reducing U.S. Carbon Dioxide Emissions: The Cost of Different Goals."
91-08	Montgomery, John D., et al. "Values in Conflict: Policy Interactions in the Pacific Basin."
91-07	Summary of Project 88/Round II Workshop Proceedings. "Incentive-Based Policies for Municipal Solid Waste Management." May 16, 1991.
91-06	Proceedings of Project 88/Round II Forum. "Market-Based Strategies for Environmental Protection: A Tribute to Senator John Heinz of Pennsylvania." May 16, 1991.
91-05	Foster, Charles H.W. and Peter P. Rogers. "Rebuilding the Nation's Wetland Heritage: A Challenge for the 1990s."
91-04	Lerner, Joshua. "The Impact of Patent Scope: An Empirical Examination of New Biotechnology Firms."
91-03	Gaskins, Darius and Bruce Stram. "A Meta Plan: A Policy Response to Global Warming."
91-02	Merchant, Gery E. "Freezing CO_2 Emissions: An Offset Policy for Slowing Global Warming."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.

BELFER CENTER FOR SCIENCE AND INTERNATIONAL AFFAIRS
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD UNIVERSITY

Discussion Paper Series

91-01 Jaffee, Adam and Robert N. Stavins. "Evaluating the Relative Effectiveness of Economic Incentives and Direct Regulation for Environmental Protection: Impacts on the Diffusion of Technology."

The Belfer Center for Science and International Affairs (BCSIA) Discussion Papers, established in 1991, will be issued on an irregular basis with three programmatic subseries: International Security; Science, Technology, and Public Policy; and Environment and Natural Resources. Inquiries and orders may be directed to: Belfer Center for Science and International Affairs, Publications, Harvard University, 79 JFK Street, Cambridge, MA, 02138.