FOREWORD

THE INTERNATIONAL CHALLENGE OF GENETICALLY MODIFIED ORGANISM REGULATION

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In October 1999, the Center on Environmental and Land Use Law at New York University School of Law convened a Colloquium on the Risks and Regulations of Genetically Modified Organism (GMO) Food Products. Scientists, academics, and representatives of industry, environmental and consumer groups, and governments from Europe, the United States, and developing countries participated in a frank exchange of views on this highly controversial topic. This Foreword to a collection of the papers presented at the Colloquium outlines the important legal, policy, and institutional issues presented by the growing international conflicts over GMO regulation.

GMO products—the crops and other organisms that have been genetically modified by use of recombinant DNA technologies and food and other products containing such organisms—are a growing part of global commerce. The risks and appropriate regulation of GMO food products are currently a matter of intense domestic and international controversy. Proponents of the new agricultural biotechnologies argue that they will provide significant consumer, economic, and environmental benefits. Wide use of GMOs will, it is claimed, expand food production, enhance the quality and nutritional value of foods, reduce biodiversity loss caused by deforestation to increase farmland, and reduce use of harmful chemical pesticides and herbicides. Critics point to the uncertainties surrounding the impacts of the new technolo-

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gies, maintaining that they present potentially serious health and environmental risks. Opponents also assert that global marketing of GMO crops by multinational businesses threatens traditional agriculture and the interests of developing countries, including local producers. Many consumers demand meaningful choices and mandatory labeling of products containing genetically modified ingredients.

The conflicts over GMOs have increasingly assumed a transnational character. In Europe, strong opposition to imports of GMO crops and foods poses the threat of trade wars with the United States and other exporting nations. Many developing countries, which often lack well-developed regulatory capacities, are profoundly uneasy about the new technologies and their social, economic, and environmental impacts. These countries also are concerned about reinforcing dependence on "Northern" technologies at a cost to indigenous techniques. At the same time, there has been a tremendous loss of confidence in the ability of existing political and legal institutions at both the domestic and international levels to resolve these controversies and address the underlying risk uncertainties in an effective and credible fashion. There is also increased skepticism about the role of science in resolving regulatory controversies. The recent protests regarding GMO technologies at the World Trade Organization (WTO) Ministerial meeting in Seattle and before the International Monetary Fund (IMF) in Washington, D.C. are manifestations of a growing sense of institutional failure on the part of many stakeholder constituencies.

Because of their different traditions and circumstances, regions and countries vary widely in their attitudes toward GMO risks and in regulatory responses. Until recently, the WTO was the only global institution with authority to address conflicts generated by differences among nations in regulatory approaches. Many believe, however, that the WTO is insufficiently concerned with environmental and health risks. The European Union (E.U.) is currently developing new Community laws and institutions to address GMO risks at a regional level. Individual governments around the world are undertaking or contemplating a variety of independent and potentially inconsistent domestic regulatory initiatives. In all of these settings there is widespread debate over the precautionary principle (or approach) and how it should be defined and applied to GMO agricultural technologies.

This year, the Parties to the 1992 Convention on Biodiversity adopted a first Protocol to that Convention to address the international movement of certain GMOs. Once the Cartagena Protocol comes into force, it will require, *inter alia*, prior notification to importing countries of international movements of GMO crops and other living organisms and prior risk assessment. The Protocol recognizes the right of importing countries to bar the importation of such organisms or to regulate them, consistent with international law. The agreement explicitly endorses the precautionary approach. While not directly regulating the movement of food products containing or derived from GMOs, the Protocol provides that they must be identified: "may contain living modified organisms." The Protocol regime will clearly emerge as a central forum for addressing the international regulatory debates over GMOs. Of particular interest will be the relationship of the Protocol to the WTO regime and national regulatory arrangements.

Questions about the governance of risk are critical to the disputes over GMOs, and these issues are compounded by the international character of the disputes, which include questions about:

- The authority, role, and credibility of national and international regulatory authorities;
- The reconciliation of divergent national views of GMO technologies and international free trade;
- The special circumstances and needs of developing countries in relation to GMO technologies;
- The social, cultural, and economic dimensions of GMO agricultural technologies, as well as health and safety risks in the context of an emerging precautionary approach;
- The influence of non-governmental organizations (NGOs) in global GMO politics and legal regimes;
- The role and influence of consumers;
- The role of scientists and the acceptability of technical expertise;
- The authority and credibility of international organizations in addressing GMO regulatory controversies.

A number of developments compound the difficulties of developing a system for governance of GMO risks that is both effective and enjoys widespread public confidence in the international context. First, the agricultural biotechnologies are

new. While their proponents present substantial arguments in favor of the safety and benefits of GMOs, opponents claim that products have not been adequately tested and present many uncertainties and potential risks. At the same time, there are no well-developed or widely accepted regulatory principles or strategies for addressing the uncertainties posed by the new agricultural biotechnologies. The precautionary principle invoked to address uncertainty has so many different formulations and interpretations that its practical utility is uncertain, and will remain so until its meaning has been clarified by authoritative international interpretation, whether legislative or, more likely, judicial.

Further, the risks (as well as the benefits) of technologies have many dimensions: they include not only specific environmental and health effects, but broader cultural, economic, and social consequences. Domestic GMO regulatory authorities have a limited mandate focused on environmental and health risks. They tend to ignore the broader cultural, social, and economic dimensions that are of wide concern to the public and many NGOs. Internationally, the WTO has followed a similar, rather restricted focus. The implementation of the Biosafety Protocol remains an open issue. Appropriate institutional and legal arrangements for governance of NGOs must also address the concerns and interests of the many non-governmental constituencies that have developed positions regarding the governance of GMO agricultural technologies. These include industry and a great variety of NGOs from both developed and developing countries concerned with environmental, consumer, agricultural, economic, and other issues.

The Colloquium represented an initial effort to advance understanding of the key legal and institutional issues presented by the current and emerging international conflicts over GMO regulation. Participants sought to assess the role and performance of existing institutions, to lay out options for creating better strategies for regulatory governance, and to explore the possibility of a neutral non-governmental forum in which different stakeholders could participate in a process for designing and shaping potential solutions. The papers presented called for research on the following questions:

- What are the existing regulatory approaches in Europe, the United States, other Organization for Economic Cooperation

and Development (OECD) countries, and developing countries, and the most important differences among them?
- What are the existing international fora for addressing and resolving disputes over GMOs, including the WTO, the E.U., the Biodiversity Convention, and the North American Free Trade Agreement (NAFTA)?
- What are the social, cultural, and economic dimensions of GMO risks and regulation as well as the scientific dimensions of environmental health and safety effects?
- What are the different views, interests, and roles played by different non-governmental institutions (including business firms) regarding GMO risks and regulations, and their implications for governance?
- What are the implications of the expanded conception of risk for governance arrangements, including the issues of trust in science, industry, and regulatory institutions raised by increased NGO advocacy?
- What are the key analytic and normative principles, such as the precautionary principle and environmental impact assessment, and what is their relevance for governance?
- What role do consumers play in decisions about access to public information and the use and labeling of genetically modified products?
- What are alternative governance options for addressing GMO regulatory issues and mechanisms for harmonizing or resolving differences in existing approaches and methods?

These inquiries might conveniently be organized around three related clusters of issues. One cluster concerns the increased activity of NGOs over the role and regulation of GMOs, reflected in demonstrations and consumer actions such as boycotts of genetically modified food products. Although these organizations have been most active in European countries, groups are mobilizing within the United States as well; the events at the WTO meeting in Seattle and before the IMF in Washington, D.C. were but two of many incidents that suggest the growing public concerns about risk.

When grassroots organizations debate the question of risk, the concern is often a proxy for social, economic, and moral issues. These include misgivings about trade imbalance and multinational corporate (and often American) dominance, fears that the corporate quest for profit will override health considerations,

the plight of small farmers, a mistrust of science, the erosion of trust in regulatory authorities, the desire for consumer choice and greater participation in decisions, and moral reservations about the meaning of manipulating living things. In other words, public concerns, as expressed through NGOs, extend well beyond environmental and health hazards. Yet, policies intended to allay public concern through technical studies of risk often fail to resolve these complex multi-faceted disputes. This suggests the need for a broader and more inclusive conversation.

If they are to be credible and effective, international arrangements for the governance of GMOs must be mindful of the cultural, economic, and social bases of public concerns in different countries, which clearly affect attitudes towards new technologies. Who are the activist groups? How do they define risk? What concerns do they express? What are their strategies and demands? And what is their effect on media coverage, regulatory policies, industry groups, and markets in different countries? How have regulatory authorities and industry groups responded? And finally, what could be the role of NGOs and consumers in improved systems of governance?

A second cluster of issues to be addressed relates to the regulatory treatment, at both the domestic and international levels, of scientific uncertainty regarding the environmental, health, and safety effects of GMO technologies and products, and their economic, social, and cultural impacts. These aspects of the GMO debate pose a profound challenge for traditional approaches to regulatory decision-making. Among the issues to be explored in this cluster are the treatment of scientific uncertainty by existing regulatory institutions and, more broadly, the use of science in regulatory decision-making, as well as the treatment of social, economic, and cultural effects in policy decisions. Problems have resulted from institutional failures to adequately address these dimensions of the GMO debate. They call for analytical and procedural methods for addressing the broader dimensions of GMO conflicts, the content and role of the precautionary principle, and the role of civil society in the decision-making process.

A third set of issues relates to the international, legal, and institutional structure of GMO governance. At present, international regulation of GMO risks is decentralized and fragmented. The United Nations Food and Agriculture Organization (FAO) has responsibility for agricultural and nutritional aspects; the

United Nations Environment Programme (UNEP) and the WTO address impacts on the environment and human health; and the WTO has responsibility for international trade aspects. Now the Biodiversity Convention and the Cartagena Protocol have been charged with running a system of prior informed consent for international trade in GMOs, and for labeling GMO food products. Questions therefore arise concerning the global governance and regulatory aspects of GMOs. These questions include the relationships among different governing institutions, the implications to states remaining outside the system, the ways in which these institutions can be made more transparent and accountable to NGOs and civil society, the means of conflict resolution within (or among) these regimes, and the relationship of international institutions to national regulatory authorities.

As the papers in this collection suggest, the governance of GMOs presents a series of significant challenges. These challenges—intellectual, legal, institutional, political, and cultural—must be resolved in an international context. GMO regulation presents an important test case in the globalization of risk assessment and risk management, and the capacities of the international regulatory order. Regulation must take into account potentially competitive societal interests, including free trade and environmental protection; the divergent views of different nations, interests, and groups; the array of existing domestic and international institutions with competence over some aspect of the new techniques and their applications; and the most promising opportunities to develop new international mechanisms for accommodation and cooperation.