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**Harmonizing Global Environmental Governance, Exploring
Tensions between Trade and Biodiversity: Assessing the
Environmental Risks of Genetically Modified Organisms**

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Introduction

This paper examines the relationship between the demands of foreign trade and regulatory regimes determining the environmental safety of agricultural biotechnology crops. The enforcement of agricultural biotechnology involves a complex matrix of actors and institutions, locally and globally, who have pushed for the trade liberalization of genetically modified organisms (GMOs). Yet, closer market integration has intensified public and private sector commitments to harmonizing regulations in spite of generalized public skepticism of GM foods (Jasanoff 2002). The focus of this article is the analysis of environmental safety standards for dealing with GMOs in terms of global policy-making and institutional commitments in biotechnology global governance. It is our contention that agricultural biotechnology governance has been largely conceived around the ability to open agricultural export markets and as a consequence, the institutions and principles developed to regulate the commercial release of GM crops apply scientific rules and standards that provide predictable biotechnology governance nationally and internationally (Coleman and Gabler 2002). In particular, the terms of scientific risk assessment for determining the relative environmental safety of GMOs have been largely developed by and can be traced within multilateral policy and standard-setting agencies such as the Organization for Economic Cooperation and Development (OECD), the World Trade Organization (WTO), the Cartagena Protocol on Biosafety (CPB) and the United Nation's *Codex Alimentarius* Commission. However, we believe that the harmonization of biotechnology governance might not be realizable in the short or long-term because of fundamental questions that remain ignored about the desirability of GM agriculture and more specifically, about the soundness of scientific risk assessment procedures. Scientific disputes about the extent to which risk can be evaluated, predicted and managed contribute to ongoing debates regarding our ability to govern GMOs. We examine how the fundamental differences and disagreements between two key agreements, the WTO and CPB, might actually be a useful tool for conceiving of better biotechnology governance instruments. Rather than trying to harmonize, we contend that the contexts out of which these two agreements emerged and the processes which structured them might actually serve as policy learning tools for better management of disputes.

Our interest lies in the potential for global biotechnology governing institutions to act as spaces where the fundamental disagreements can be identified and acted upon in cases where traditional regulatory or dispute settling instruments fail to address non-technical issues. Policy convergence and divergence will be examined in two key international agreements, both committed to the market liberalization of GMOs and sustainable development. On the one hand, the WTO's implementation of Codex standards through the Sanitary and Phytosanitary (SPS) Agreements as the basis for its dispute settlement body relies on a scientific assessment of risk for facilitating decisions about the legitimacy of trade barriers (Harlow 2004). On the other hand, the Cartagena Protocol on Biosafety (CPB) uses the Precautionary Principle as its norm for determining the environmental safety of GMOs, involving a different set of scientific assumptions which consider non-scientific factors in decision-making procedures. This research is premised on the fact that when issues of free trade and environmental protection come into direct

conflict, as is the case of GMOs, deeper questions can be asked about the nature of fundamental disagreements, their origin and their possible resolution at the micro and macro-level. Theoretically, this study will draw on the Science and Technology Studies literature, specifically dealing with social construction of risk and negotiation theory, starting from the premise that both the WTO and CPB are negotiated agreements, in order to frame questions of scientific uncertainty and social indeterminacy within the context of global governance.

This study draws on two types of analysis. First, it seeks to explain the regulatory strategies and the scientific instruments shared by national, regional and international agencies and institutions. Our focus is fundamental disagreements that constrain harmonization efforts as well as the opportunities that promote common regulatory approaches. Global governance is understood as “governing without government” (Reinicke 1998) or an attempt to develop non-interventionist decision-making processes that obey a market model (Bourcier 2002). The theoretical framework used to elucidate the dynamics between the use of science-based risk assessment in the CPB and WTO draws from the Policy Transfer literature. This approach describes the “dynamic whereby knowledge about policies, administrative arrangements or institutions is used across time and space in the development of policies, administrative arrangements and institutions elsewhere” (Stone 1999). The objects of transfer include policies, institutions, ideologies or justifications, shared knowledge and understanding of issues, ideas, negative lessons and regulatory tools (Stone 1999). This framework allows the processes of globalization through policy harmonization, to be revealed. Moreover, this approach identifies domestic circumstances or structures that aid effective policy transfer, such as learned lessons about the management of food crises and the involvement of state regulators and industrial actors. In situations when there is no scientific consensus or a lack of information about a new policy problem or issue, as with biotechnology, uncertainty provides policymakers opportunities for transfer. The dynamics of transfer are not politically neutral, they emanate from market logic which emphasizes harmonization and standardization of rules. In this sense, transfer can be seen as coercive and not democratically legitimated. The regime complex for biotechnology lends itself to this type of analysis because according to Raustiala and Victor (2004), GM food regulation consists of an “array of partially overlapping and non-hierarchical institutions governing a particular issue-area.”

The second type of analysis will draw from Science and Technology Studies (STS) in order to frame issues of risk and uncertainty within scientific discourse. The strength of this approach is that it makes visible the boundaries between science and politics, not only questioning the value-neutrality of science but allowing deeper questions to emerge about intra-disciplinary uncertainties and disputes (Jasanoff 2004). By studying the sub-political system of science and technology, it is possible to analyze the role of scientific expertise in defining the terms of regulations at the international and national levels as well as the function of alternative scientific framings in the GMO debate (Haas 1992). This exposes how scientific discourse is constructed and interpreted within various institutions and how it is mobilized, through science-based regulations, to arbitrate non-scientific matters. There is increasing reliance on science to facilitate decisions regarding

the legitimacy of trade barriers (Harlow 2004). An STS approach also reveals how science is used as a bridge upon which a legitimate international legal process can be built. The basic disagreements between science and the law, in terms of the nature of knowledge, the mutability and certainty of facts, and the types of evidence that serve as a basis for adjudication, raise important questions about harmonizing international trade law using scientific principles. Finally, an STS analysis provides an explanation of the different assumptions about the role of science in environmental protection contained in the Precautionary Principle. These include provisions for local or traditional knowledge in opposition to the “universal” claims of science. Both theoretical approaches provide a complex analysis of GMO governance.

Global Governance of GMOs

The marketplace for science and technology has become global and, in the case of agricultural biotechnology, has posed new economic, social, environmental and political challenges for state policy-makers. Faced with the novel risks posed by biotechnological development, new international regulatory instruments and norms are needed in order to cope with the potentially disruptive consequences of GMOs. At the heart of biotechnological innovation, questions of social and scientific uncertainty and risk have focused the attention of regulatory bodies worldwide. Genetic technologies have been characterized as presenting new and intractable bio-hazards which have been defined by lack of consensus on facts, values and policy principles. The technology is plagued by the uncertainty and disputability of causes and consequences (O’Mahony 1999). Among the most contentious issues facing world trade liberalization concern the detection and management of the risks posed by foods and organisms derived from biotechnology. Globally and locally, the debate has been polarized around the establishment of international food and environmental safety standards to protect against the potential health and ecological risks posed by GMOs while maintaining state and international support for the biotechnology industry. Increasingly, trade regimes carry enormous influence on the determination of environmental and food safety rules. Consequently, harmonization efforts to create global environmental safety regulations for GMOs aim to strike a balance between seemingly contradictory processes, environmental protection and industrial growth through global market liberalization. Issues of food safety and agricultural biotechnology have been addressed in both multilateral trade negotiations included in the WTO and environmental treaties such as the Cartagena Protocol on Biosafety (CPB), which governs the transboundary movement of GMOs and stemmed from the Rio Convention on Biodiversity. However, the rules developed in each of these regimes have not been consistent and have led to conflicts between the norms of “scientific risk assessment” in terms of trade and the use of the Precautionary Principle for environmental purposes (Winham 2003). Thus, conflicts between the principles embodied within free trade and environmental regimes have constrained global efforts to harmonize biotechnology regulations.

Currently, nine international bodies coordinate efforts related to biotechnology governance (CBAC 2002). Market oriented institutions, such as the OECD, have played a

major role in defining the terms of biotechnology governance since the late 1980s (Newell 2003). The pursuit of international biotechnology governance has largely been confined to global institutions where states have set up the legal and institutional infrastructure for globalization and trade liberalization. States have deregulated certain sectors of their economy by defining new types of regulations and legalities which are embedded in global processes and institutions. One consequence of this process is that norm-making capacities in the area of food biotechnology have taken place outside of democratic structures even though enacted in the public domain (Sassen 2003). The demands of citizens to participate in global politics have been severely restricted by the incursion of private interests inside a domain represented as public –the protection of public and environmental health. New patterns of hierarchy and inequality and of inclusion/exclusion are shaped by this worldwide process of “harmonization” which is unlikely to redress existing asymmetrical transnational relations. In addition, the relationship between state regulators, international standard-setting bodies and market actors has played a major role in structuring the governance of biotechnology products and their development (Newell 2003). Since the largest market actors tend to have a transnational focus, domestic biotechnology policy has also had a global focus. Hence, patterns of globalization have influenced the local governance of biotechnology and have revealed how issues such as GMO risks might be dealt with at a policy level. Conversely, domestic and regional structures of governance also determine regulatory approach. In their study, Bernauer and Meins (2003) show how the multilevel system of governance of the EU provided different access points for anti-GMO activists and downstream food producers giving rise to more stringent and comprehensive biotechnology regulations. This type of analysis provides us with a model of democratic governance in which contentious issues are more likely to be addressed in policymaking.

Generally, agricultural biotechnology regulations involve “a complex mix of advisory bodies, committees, professional bodies and industry associations operating at international, national and sub-national levels” (Newell 2003). Despite this institutional confusion, regulatory functions such as risk management, under pressure from industry, have been designed specifically to keep markets open to GMOs and provide regulatory predictability for GM products (Ibid). This has influenced the design and implementation of scientific regimes for evaluating GMOs towards non trade restrictive measures, explaining the rapid expansion of GM foods in the last decade. As a result, fundamental questions about the desirability of GMOs and deep scientific uncertainties surrounding their large-scale release have been left out of harmonization efforts. Generally, domestic regulatory regimes for managing the risks of agricultural biotechnology have attempted to weigh commercial and industrial interests against public safety concerns. While the scope of regulatory approaches varies greatly between countries, reflecting different values, the push towards a harmonized regulatory system for the environmental release and transboundary movement of genetically engineered organisms is being constructed at the same time as untested structures of global governance.

Another challenge concerns the role of science in global regimes for biotechnology. Regulatory principles developed by the US and Canada have served as the basis for international rules for defining the process of scientific risk assessment during the WTO’s

arbitration of trade disputes. The WTO's Sanitary and Phytosanitary (SPS) Agreement adopted a scientific basis for adjudicating trade disputes based on international standards developed by the *Codex Alimentarius* Commission, a United Nations standard-setting agency concerned with food safety. Codex standards were developed in conjunction with national experts, namely the largest exporters of GMOs.

Trade Disputes, WTO and Risk Science: Framing the need for Harmonized Regulations

WTO membership requires that countries remove “trade barriers” to global commerce. The essence of free trade is deregulation. In practice this means that governments relinquish public protections that may result in an “unfair trade advantage”. The use of different regulatory approaches in the European Union and North America implies that decisions regarding effective application of trade liberalization commitments remain ambiguous. Among some of the most important differences in GM regulations include: Process versus product-based regulations, strict traceability and labeling regimes in the EU versus no identity preservation systems and voluntary labeling rules in North America. In this case, the application of the traditional GATT distinction between legitimate and illegitimate domestic regulations, regarding the potential for regulations to act as disguised protectionism, requires that transparency in the domestic regulatory process be assured. However, in practice, technical rationale, norms and standards governing the relative safety of GMOs are established within a regime complex that includes an array of overlapping institutions governing biotechnology (Raustiala and Victor 2004). These tend to be captive to biotechnology interests, restricting meaningful open debate and/or participation about biosafety. As a result, the lack of transparency in decision-making concerning the safety of GMOs has reinforced public fears and tensions between GM exporting countries and importing countries. Non-discrimination rules mean that science is the authority that decides whether domestic regulations that are stricter than international standards are legitimate. Because it is difficult to determine the extent to which a given regulation is legitimate or illegitimate, due to lack of transparency of regulatory procedures, harmonization through international standards may be justified (Howse 2000). This removes ultimate power of decision from democratic communities that regulations purport to protect placing it instead at the international level. Science lies at the core of trade regimes like NAFTA, GATT and WTO which have enormous clout in determining food safety rules as well as environmental policy. It is therefore incumbent on these bodies to develop the institutional capacity to understand and act within the context of principles and systems of evidence, which is why the use of a risk assessment mechanism is in place that would harmonize trade rules.

According to Harlow (2004), trade law views science as a critical bridge upon which to build a legitimate trade process because it provides the mechanism for distinguishing legitimate regulations from restraints on trade. Science is increasingly facilitating decisions regarding legitimacy of trade barriers and it has thus become the authority the WTO relies on. The use of scientific information is mostly reflected in the (Sanitary Phytosanitary (SPS) Agreement that requires that measures related to food safety, agricultural safety and health be based on risk assessment. Article 715:3(b) of the WTO

states that “with the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each WTO member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.”

However, harmonization of scientific and legal systems of evidence is problematic and integration of scientific and legal evidentiary processes requires interdisciplinary dialogues (Harlow 2004). Harlow, who is approaching the issue from a trade law perspective, suggests that “the scientific community needs to develop better understanding of the emerging legal context of environmental and health-related trade disputes and provide proactive guidance regarding incorporation of science into the emerging body of international trade law while also providing scientific evidence necessary to meet the legal requirements of that law” (Ibid). She also states that the process for incorporating scientific evidence with the dispute settlement process is lacking and that the international community needs to identify specific areas of attention for incorporating science and principles of risk assessment in trade law. One of the main problems is that the WTO does not require or set health and safety standards, and it does not require common international standards *per se*. The only caveat is that the national regulations of each member country must not discriminate against a trading partner under the obligation of non-discrimination or “like” products. Hence, the characterization of products as “like” and “not like” is at issue in most trade disputes. In the case of GMOs, the determination of environmental safety is based on a scientific measure which takes into account non-discrimination as its focus.

One question that is central to this paper is “how can science be invoked to compare the relative approaches to regulation?” The WTO/SPS requirement that regulation governing food safety, agricultural and health safety be based on risk assessment is different and separate from the requirement of non-discrimination (Harlow 2004). Science cannot tell how conservative or protective regulatory measures are. The science of Risk Assessment is used as evidence to prove more than a “theoretical” or “hypothetical” possibility of risk, actual scientific evidence must be produced. However, risk assessments depend upon a set of assumptions about the levels of risk that are considered acceptable or minimal. These assumptions tend to be largely reflective of the particular socio-cultural and political contexts and the constraints out of which they emerge. Hence, risk is contextual and its determination is based on a given level of error or uncertainty in a scientific assessment. According to Rose, “Risk denotes a family of ways of thinking and acting, involving calculations about probable futures in the present followed by interventions into the present in order to control that potential future” (2001). In a democracy, this will depend on citizens’ preferences about risk, which is why scientific risk assessment alone does not provide sufficient guidance for decision-makers.

By requiring the application of risk assessment, to regulations, a presumption is established that lack of apparent and explicit reliance on science may be construed as a form of protectionism. This requirement carries enormous implications for many

countries that do not have the capacity to conduct risk assessments as part of their regulatory process. Each country may determine its appropriate level of sanitary and phytosanitary protection which may include non mainstream science. However, the WTO dispute settlement mechanism relies on the authority of science to determine what is scientific or what constitutes conventional or non-conventional science but this can only be done through the lens of mainstream science. This means that in practice there is a built-in mechanism that discriminates against non-conventional science or alternative interpretations of scientific phenomena. Scientific disagreements within the mainstream scientific community are sidelined during trade disputes as are “non-conventional” forms of scientific and/or traditional knowledge. This raises questions about the institutional capacity of the WTO and other similar bodies to adjudicate science-based trade disputes. It must be recognized that science is not unanimous regarding the environmental impacts of GMOs; there is a lot of controversy regarding the “acceptability” of risk and this is negotiated among scientists and policy-makers. The acceptability of risk may not simply be a scientific decision; it may include other factors which are presently excluded from decision-making, such as socio-cultural issues. Trade disputes give technical standards more weight than political and ethical arguments. Science is used and mobilized in different institutional contexts in order to arbitrate non-scientific and conflicting issues.

The rules of the WTO’s dispute resolution mechanism (through Appellate Body adjudication) place constraints on the right of governments to establish their own level of protection against risk. A contentious issue concerns the WTO panel’s treatment of “minority” science. Minority science refers to what we termed non-conventional or alternative science and it is included in the SPS Agreement when the degree of uncertainty is high and when there are conflicting opinions. According to Wagner (2000), the history of science demonstrates that majority does not rule when it comes to the search for truth and so, many truths once considered flawed by the majority scientific community have been incorporated into conventional science. In addition, decision-making procedures must consider that minority scientific opinions may be correct and may be used as the basis for establishing an appropriate level of protection against risk by member states. As a result Wagner concludes that limiting the use of minority science in dispute settlements limit a government’s ability to establish a high level of protection of its population.

It must be recognized that science is not unanimous regarding the environmental impacts of GMOs; the level at which they pose a risk assessment is used in commercial arbitration and risk information/knowledge is regarded as unproblematic when in fact it is not. Regulatory decisions about the acceptability of risks should not simply rely on a scientific assessment. They must include socio-ethical considerations.

Scientific uncertainty is a feature of GM politics. Uncertainty refers to the lack of complete data sets, the existence of competing theories through which data are interpreted and the impossibility to predict phenomena. It remains unclear how uncertainty is addressed under the SPS Agreement. The very existence of divergent scientific views indicates that there is scientific uncertainty. This means that SPS decisions must include not simply mainstream scientific opinion but from scientists

taking divergent views. Similarly, SPS requirements for “sufficient scientific evidence” to prove the relative safety of GMOs do not provide a measure of the scientific threshold of proof or certainty that need to be achieved. Therefore, scientists are also asked to make technical/scientific judgment about the adequacy of risk assessment as a regulatory tool. Unfortunately, the disproportionate influence of organized interests and the relative absence of affected parties from the decision process during trade disputes mean that scientific information may not be sufficient to bring closure to controversial risk issues.

Science is by definition an open-ended process within which knowledge and understanding of phenomena develop over time. In contrast, judicial decisions require final and definitive answers which are best described as the legal principles of rule of evidence and burden of proof (Crawford-Brown et al. 2004). This means that there are areas of contradiction between science and the legal process or trade law which have to be explicitly recognized. In WTO adjudication, this implies that “the equation now made between “science-based” and “absence of trade protectionism” is not watertight” (Ibid). How does the Appellate Body of the WTO deal with conflicting scientific evidence? How can decisions be made in light of scientific uncertainty and indeterminacy of facts?

The Precautionary Principle has been used to deal with uncertainty issues at the policy level. The WTO often attacked by environmentalists who argue that trade takes precedence over environmental protection. But recent Appellate Body decisions regarding Asbestos for instance imply that the protection of human health provision contained in the SPS Agreement may override risk assessment during trade disputes (Goldstein and Carruth 2004). This suggests that the WTO process could in fact support the environment by interpreting SPS Agreement in a manner consistent with the Precautionary Principle. In fact, it is now believed that the PP can play a greater role in justifying trade barriers designed to protect human health and the environment. The challenge presented by the precautionary principle to standard scientific risk analysis will likely become a central focus of WTO dispute resolution, especially concerning the current transatlantic GM dispute.

Trade disputes involving European restrictions of North American GM products highlight the different conceptions of risk assessment, regulatory review and approval processes for determining the environmental safety of GM crops. Canada is the third largest producer of genetically modified (GM) crops and, with the United States and Argentina, generates 99% of global GM crop acreage. Canada’s regulatory framework is promoted for expanding GM exports due to its use of “sound science” and a streamlined process of product approval unsurpassed internationally (CBAC 2002). However, a 2001 Royal Society of Canada report severely criticized the soundness of Canada’s risk-based regulations (RSC 2001). Unresolved scientific and trans-scientific issues such as the desirability of transgenic agriculture and the lack of product traceability have restricted trade of GM products. Japan and the EU have banned imports of transgenic crops. Meanwhile, countries heavily committed to agricultural biotechnology, such as Canada, are relying on the scientific basis of their regulatory systems, insisting on the equivalence status of GM crops and a decade of experience approving GM product, to press for the harmonization of international food and environmental safety standards for GM crops.

WTO and CPB: reconciling scientific uncertainty through international agreements

The use of the precautionary principle has been central to international biotechnology governance. In particular, its relationship to risk assessment for GM crops has been included in WTO (implicitly) and CPB agreements. The precautionary principle generally provides guidance on decision-making under circumstances of uncertainty. As such it contains “an admonition to prevent damage to public health and the environment under conditions where (i) potential harm has been recognized, and (ii) there remains scientific uncertainty regarding the possible extent and nature of harm that may occur” (Barrett and Abergel 2002). Coleman and Gabler identify several areas of disagreement and incompatibility between the norms and principles included in the WTO and the CBD, which compete in terms of risk assessment regimes for declaring GMOs safe (2002). Disputes include the use of precautionary science or strict science-based risk analysis for establishing food safety and “the relationship between the trading rules and trade measures adopted in pursuit of biodiversity objectives” in various international agreements (Ibid). The CBD questions the use of science-based risk assessment as the only legitimate approach for determining safety, it advocates strong precautionary measures for maintaining biodiversity; while the WTO on the other hand, relies on a restricted definition of sound science which vaguely refers to the precautionary principle (Ibid). In 1998, the WTO Panel explicitly rejected the use of the Precautionary Principle as a basis for trade-restrictive measures in its beef hormone decision (Goldstein and Carruth 2004). Whereas under the CBD, biodiversity overrides trade in terms of its guiding norms and principles, the opposite is true for the WTO. The latter is consistent the Canadian approach while the European system of risk assessment is closer to the biodiversity view “that sees scientific determinations of risk thresholds and related assumptions about what constitutes harm as highly subjective” (Coleman and Gabler 2002). The CBD places the burden of proof on the exporters of biotechnology products, who tend to be the strongest supporters of liberalized trade and the largest producers of GM products. The WTO places the onus on those wishing to restrict entry of GMOs in their jurisdiction to prove the safety of GM products, based upon the specific scientific criteria outlined for determining their relative safety.

This paper is informed by the development of guiding scientific principles and norms and their implementation in different institutional contexts as a way of asking deeper questions about the role of scientific expertise in deliberative democracies and global governance. According to Luke (2003) asymmetrical relations that operate within global governance institutions currently escape the analytical frameworks of both International Relations and Environmental Studies theorizing. This study attempts to reveal the processes by which the ‘greening of the economy’ becomes the foundation for ‘commodifying Nature’ and for establishing rules that legitimize undemocratic decision-making. Specific to GMO regulation, global harmonization efforts act as grounds for excluding non-market issues from regulatory regimes, thus restricting the scope of potential regulatory regimes for transgenic agriculture and more generally, narrowing food security options.

Cartagena Protocol and Biosafety: Tensions and Harmony

The Cartagena Protocol on Biosafety (CPB) continues along the course of international cooperation in recognizing environmental concerns as a component of international economic development. The regime places biosafety – safety in the use of biotechnology – as its mandate. Thus biosafety develops further “environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and human health” (CPB introduction notes). The CPB unlike the Convention on Biological Diversity (CBD) recognizes transgenic technology as risky products; therefore biosafety departs from the depiction that GE biotechnology and transgene organisms (referred to as LMO – living modified organisms in the regime text) are beneficial and without danger (Agenda 21: 16.1). Thus biosafety is not only safety in the use of biotechnology, it is also about preventing harm to the earth’s natural diversity, specifically the diversity which provides the sources of life and its continuation.

For the purposes of challenging the assumption that biotechnology can be managed, controlled and used appropriately, the CPB regulatory formula will be examined. This section examines whether the CPB is able to accomplish the safe use of transgenic technologies. This question begins with a suspicious view, to allow examination of the regulatory formulae which also promises to protect biodiversity. The mandate of biodiversity protection was brought forward by the Like Minded Group, which opposed the development of biotechnology, in particular the unregulated importation of LMOs into its territories.

Cartagena Protocol on Biosafety (CPB) has been hailed as the first international regime that regulates the transboundary movement of modern biotechnology. Since coming into force on September 11, 2003 the CPB continues to garner much speculation about its potential to mitigate the dangers of biotechnology while also preserving the world’s biological diversity (hereafter biodiversity). Despite an ‘agreement’ the debate continues regarding genetic transfer technologies and its products to preserve biodiversity as it is used to privatize the delivery of everyday material goods through intellectual property rights (IPR) or patents. Within the literature on the CPB, this speculation is twofold; one avenue pertains to the compatibility with WTO agreements, in particular the Sanitary and Phytosanitary (SPS) agreement and the other avenue concerns the regulatory formula, in particular the compatibility of scientific risk assessment and precaution. An assumption of incompatibility brings with it a desire to harmonize thus any discrepancy is met with pejorative dismissal of ecological considerations giving privileged status to economic (materialist) analysis.

The following explores CPB in respect to its regulatory formula in the CPB and its linkages with the WTO. Many connections to WTO remain speculative; however, the CPB was negotiated while the WTO deliberated on the subject of agricultural biotechnology.

Regulatory Formula in the CPB – regulating categories not effect

The CPB accommodates three regulatory formulas. Each formula specifies a particular category of LMO, which is defined according to its initial transboundary movement. The three main categories are: 1) intentional release: LMOs intended to be released directly into the environment; 2) direct use of LMO-FFPs, destined for the marketplace as food, feed or further processing; and 3) contained use: LMOs contained within an enclosed space, understood at the time of negotiation as laboratory containment, thus release was understood as accidental. Scientific research and pharmaceuticals are not covered in the regime. Each category specifies a different procedure, although risk is evaluated according to scientific assessments, carrying with it guidance on precaution in cases of scientific uncertainty. Article 10 and 15 provide decision making and assessment procedures respectively; however it remains open to speculation how this process will operate given the different categories of LMOs.

Direct Release – AIA

Direct release of LMOs is covered in Article 7, Application of the Advance Informed Agreement Procedure. The Advance Informed Agreement (AIA) was to be the main regulatory formula and thus provides the strictest criteria of the three regulatory devices specified in the CPB.

LMOs in Article 7 are explicitly and implicitly referenced. The explicit reference, 7.1 and 7.2 defines which LMOs are not covered in AIA formula, thus LMOs “intended for direct use as food or feed, or for processin (-FFP) are dealt with in Article 11. Furthermore, 7.4 notes only LMOs that have adverse effects on the biological diversity of its intended environment are covered in the AIA arrangement. Implied herein is an understanding that the effects are known, despite the understanding that the consequences of LMO use are not fully known. Thus both claims of benefits and problems are unverified. If effects remain unknown, the onus is on the user to provide scientific evidence that the LMO is the cause of harm to surrounding biological organisms. As to LMOs intended for direct release into the environment, these are noted implicitly. In the absence of specific intentions one can guess that these are genetically modified organisms designed for use in farming (such as seeds or seedlings); mining and forestry operations and other economic sectors that operate in non-urban environments. The term ‘environment’ is not defined explicitly in the protocol, yet an inference can be made that it refers to the outdoors, as in cultivated and wild spaces. This suggests that LMOs will not be used in combination with other processes or transfer points. The inference also carries a simplistic meaning of the environment, as areas not specified as production or laboratory facilities, thus it could mean anyplace out of doors from these sites.

AIA criteria is developed further through Articles 8, 9, 10 and 12 which specify notification and its receipt, import decision procedures and review of decisions – understood as an appeals to the import decision making process. Determination of importation also follows a procedure outlined in Annex I, in which exporters must provide regarding specific information about genetic and taxonomic characteristics of LMOs, identifying importer and exporter as well as documentation referring to use and

validity of information provided. The burden of responsibility is placed on the exporter, to provide importer nation/states complete and accurate information. The importing country uses this information, along with scientific assessments to determine whether to accept or reject the deliver of LMOs.

Direct Use – LMO-FFPs

Article 11 provides guidance on the direct use of LMOs. This category specifies LMOs as food, feed and processing (LMO-FFPs). Although these will be released eventually into environment, the designation of direct use pertains to initial release into market sectors, namely agricultural related production and consumer markets. The implication of this category has been to organize a different regulatory procedure for LMOs based on use in economic sectors. During negotiation of the CPB the conflict about LMO-FFP was over the appropriate forum that would regulate commodities, which were on the verge of entering international markets. Argentina, Australia, Canada, Chile, the United States and Uruguay, calling themselves, ‘The Miami Group’ argued against regulating LMO-FFPs as these commodities should be covered under WTO stipulations. The Miami Group’s negotiating position was based on harmonizing regulatory formula, which was initially an attempt to mold the AIA formula to WTO/SPS requirements and exclude LMO-FFPs from regulation. After intense debate, LMO-FFPs were included in the draft version of biosafety protocol, but under a less restrictive arrangement than the AIA.

This compromise acknowledged positions from both European and Like Minded Group that commodities ought to also be regulated under the CPB. Although some of the AIA criteria remains, such as scientific assessment and precaution, LMO-FFPs place the burden of responsibility on importer countries to address risk. This separate procedure that deals with the transboundary exchange of food, animal feed and products that could have been genetically modified in other countries. Of importance here is that Article 11 can be invoked when LMO-FFPs travel across international borders for the purpose of its intended use rather than its direct release into the environment. Its effect is to bypass regulation criteria on that pertains to release, while maintaining entry into economic markets. Direct use becomes the operative category, thus LMOs intended for use directly as whole or processed foods (human and animal consumption) are subject to the notification, assessment and decision making formula, noted in Article 11 and Annex II and III (risk assessment criteria).

The decision-making criteria, as noted earlier, places the burden on importing nation/state to develop and notify its policy regarding LMO-FFPs. Representing the majority of G77 and China countries, minus Argentina, Chile, and Uruguay of the Miami Group, the Like Minded Group argued that several countries did not have the capacity to develop national procedures and respond to the provisions in a timely and cost-effective manner. In response the Biosafety Clearing House (BCH) was developed in order to assist G77 countries in its decision-making and sharing of information. A fully realized and operable BCH would be a shared responsibility of the Members of the Protocol (MoP) and the CBD Secretariat in Montreal, Canada. Of concern to G77 and China/Like Minded Group was whether LMO-FFPs, as commodities would be subject to similar

decision making guidelines since its tracking procedures as were less restrictive than the AIA. Labeling information of LMO-FFPs, for example, accepts ‘may contain’ language, thus the possibility that genetically modified goods could slip through, unable to track and monitor for the possibility of harming the food supply and farmlands. Agricultural production systems in these countries do not necessarily distinguish between urban and rural environments, nor are these areas subject to segregating domesticated farm breeds from their ‘wild’ cousins. The effect of this less restrictive formula may result in unnecessary changes to the environment instead of reducing risks of genetic contamination as a result of direct use of LMO-FFPs.

Contained Use – Accidental Release

Genetic contamination was one of the concerns regarding risk/hazard of LMO use. Laboratory containment protocols emerged from early policy formation, as noted in the case of the Alisomar Conference and other scientific and government conferences that instituted procedural guidelines in the early years of biotechnology development. The notion of containment stipulated in the CPB continues along these policy directives (Articles 5 and 6). While pharmaceuticals and scientific research and development (R&D) of LMOs are excluded from the CPB, the notion of contained use is brought into its regulatory directives, by reference to what is excluded. As long as genetic transfer technologies and its byproduct, LMO are contained within laboratories these will not subject to regulatory oversight in the CPB. However, as the CPB is an untested regime, it remains an open question how other containment strategies, such as genetic use restriction technology, or GURTs, will be brought into regulation. This speculation persists if GURT technology is used for restricting seed production of plants destined for direct release into the environment as opposed to its category of direct use in cases of LMO-FFPs.

Furthermore, the issue of breached containment highlights several gaps within the CPB. Situations of accidental release, mis-use and failed segregation remain open to future deliberations. Given the present circumstances of the MOP in its negotiations on liability and redress, the accidental or unintended releases of genetic material remain a contested issue without a resolution.

Regulation serves to organize multi-national experience under a system of laws and procedures. This examination of the CPB points to three regulating categories, namely intended introduction, direct use and containment. While the presumption of regulation considers uniformity of responsibility and obligation among parties, the three categories operate differently, excluding and bypassing oversight of untested technologies. The process of harmonization (towards uniformity of scientific risk assessment) obscures exploration of different arrangements within regulatory categories and assumes that a one size fits all approach to assessment will take care of future problems. Negating diverse approaches can prevent us from exposing problems and challenges brought on with the use of genetic transfer technologies. While we, as academics and policy-makers acknowledge diversity in nature and in social relations, we ignore the potential of diversity in approaches, especially when the challenges are multi-national and multi-dimensional.

Relationship between CPB and WTO

The CPB is linked by a 'savings clause' to the WTO. This connection assumes parity between the two regimes, but can also be linked to other agreements, whether trade or other sectors. During negotiation of the CPB, the Miami and European Groups clashed over the question of regulatory power, presuming that a hierarchical authority exists among international regimes, thus more recently negotiated agreements can over-ride the authority of a prior negotiated regime. Again the issue of parity, and even, hierarchal authority is untested yet, the CPB explicitly links into WTO determination by way of risk assessment and precaution. Careful not to restrict the burgeoning biotechnology industry, the Miami Group argued for regulatory parity to the WTO formula of risk assessment. The European Group, along with northern environmental NGOs concerned with human health and environmental genetic contamination sought to restrict WTO influence. During biosafety negotiations, the WTO adjudication board decided a GMO case, the bovine growth hormone, which rejected the EU's arguments of precaution, while accepting the American position that trade was unduly hindered.

The concern here had to do with the WTO in how it used the precautionary principle to decide the merits of trade disputes. The WTO had not rejected the precautionary principle per se rather the decision about the bovine growth hormone concerned the use of precaution, exclusive to scientific risk assessment. Precaution, alone could not be invoked to reject trade of GMOs, that is rejection had to be based on scientific evidence, in which precaution would be a factor if the knowledge was uncertain. Precautionary approach is a feature of both SPS and CPB agreements. While the Like Minded Group asserted the value of precaution, given the untested claims of biotechnology proponents, its use of precaution was to broaden the range of factors that entered into decisions whether to accept or reject importation of GMOs. This use of precaution has been co-opted to safeguard the claims of scientific uncertainty rather than bringing to the fore multi-dimensional approaches in the use and protection of diverse eco-systems. The CPB connection to the WTO comes in two ways – the savings clause and matching risk assessment and precaution to WTO language.

Discussion

Generally, we have identified several important themes: 1) the local and global framing of biotechnology risk: the extent of policy convergence and policy transfer between national regulatory agencies and international organizations involved in biotechnology governance during the development of functional regulations. 2) The mediation between local knowledge and global governance of biotechnological risk: How different scientific conceptions of GMO environmental "safety" are shaped by various contexts - international institutions, private and public, state and non-state actors- and how these may lead to inconsistencies and conflicts that challenge harmonization efforts. 3) The contested use of science in mediating normative conflicts, referring more specifically to the trade dispute between Canada, Argentina and the US against the European Union's imposed GMO moratorium based on the WTO's Panel final decision.

Much of the controversy surrounding the governance of GMOs internationally has to do with how Nature is represented in international organizations. The design of negotiations of GE issues is dependent on the interactions between non-state actors and state actors within IOs. Different conceptions of nature and GMOs clash when trade and environmental protection intersect. Nature tends to be viewed solely in terms of its instrumentalization, and so it fails to be recognized within the complex arena of human-nature relationships, evading the scope of most IOs. Some questions remain such as: How flexible are IOs to articulating these thoughts? What is the potential for alternative framings of Nature that do not conform to the demands of policy frameworks within IOs committed to dealing with GMOs and trade? How can environmental principles seen as barrier to market principles be reconciled in the GMO debate?

In the case of the WTO, although not an institution directly involved in Environmental Policy, its decisions, through the dispute settlement tribunal, have important ecological repercussions. In essence, the relationship between trade and environment at the WTO is created through the dispute settlement mechanism, as exemplified in the current GM trade war between the US, Canada, Argentina versus the EU. Implications are that environmental concerns are not dealt with systematically and are not fully accounted for in the multilateral trading system (Shaw and Schwartz 2002). Similarly, food safety issues and public health concerns may be excluded from trade rules.

Integration and harmonization are key principles of global governance that may not apply to environmental issues because "...the increased international competitiveness favoured by a neoliberalized WTO trading system reduces the political and economic ability of member countries to environmentally regulate production" (Hartwick and Peet 2003). Furthermore, according to Hartwick and Peet, increased international trade allows governments to implement effective environmental regulations through multilateral agreements thus shunting "responsibility for environmental destruction away from liberalized trade and plac[ing] the onus squarely on governmental and intergovernmental policy" (ibid). The basic premise of agreements such as WTO and CPB is that trade benefits the environment and specifically, trade of biotechnology products is presented as the solution to some of the world's most pressing environmental problems.

International agreements can act as institutional means for reconciling seemingly contradictory and divisive processes. Multilateral negotiations attempt to bridge fundamental disagreements by encouraging cooperation among nation-states to adhere to international norms and rules. The "displacement of political power upward away from elected national governments and toward international agreements and non-elected global governance institutions" (Ibid) exacerbates the dysfunctional nature of markets and states which contribute to the environmental crisis (Luke 2003).

It is generally assumed that good governance involves transnational players that mediate between grassroots civil society and the Nation-state within an accepted model of international negotiations. In fact, environmental negotiations tend to mostly focus on economic development leaving out philosophical perspectives about nature and broader social issues. These perspectives and social issues underpin environmental governance,

yet they are systematically ignored or are relegated as alternatives or non-conventional in international agreements dealing with GMOs. The approach adopted by international organizations regarding biotechnology is to promote GMOs rather than serving as a forum for asking serious questions about their global application. Global governance of biotechnology becomes the means through which transgenic products are globalized and science is used to legitimize their use. According to Beck (1992) economic growth through industrial development structures society away from political systems into what he calls “sub-political” systems of scientific, technological and economic modernization whereby “ [A] precarious reversal occurs. The political becomes non-political and the non-political political.” Scientific knowledge enables the shift from democratic political decision-making to elite supranational non-politics where the rules of science are used to rationalize non-scientific agendas.

Non-market issues become closed-off if uniformity of standards and risk norms are adopted. Whereas the Precautionary Principle includes provisions for indigenous and “other” forms of knowledge, harmonized trade rules restrict human-environmental interactions to a scientific understanding of environmental change. Consequently, environmental change is framed through multilateral negotiation processes only. This implies a materialistic understanding of nature, biology and human relations with the environment.

Conclusion

Genetic engineering is sanctioned by international organizations such as the FAO and WHO as the only way of resolving world hunger, improving agricultural practice and advancing human health. By framing biotechnology in this fashion, it becomes a prescription for a particular kind of society to the exclusion and termination of all others (Anderson 2004). In other words, good biotechnology policy requires more than sound science, it needs to include socio-ethical issues. Competing regulatory approaches (mainly US and EU regimes) raise questions about the potential role of biotechnology in world agriculture and society and about those deciding its course.

Regulatory harmonization attempts to make all approaches coincide with: a) uniformity in international regulatory formula; b) science as primary source of knowledge and analysis, vis à vis a materialistic understanding of human/nature relationships; c) standardization of approach using free market analysis as benchmark and ideal type.

The prediction that the CPB and WTO are incompatible or pose contradictory mechanisms suggests that uniformity must occur by which to reconcile disharmony among trade and environmental regimes. Harmonization governance assumes then that *a priori* conflicts can be dealt with through unifying regulatory formulas. However, the opportunity to delve deeper into long standing disputes is overlooked. Compatibility of both trade and environmental regimes, in its conformity of rules and concepts, assumes that the problems of GMOs and other transgenic technologies are predictable, manageable and controllable.

In this paper we attempted to problematize the need for regulatory harmonization of risk assessment procedures for the environmental release of GMOs in global governance. Based on the two regimes, CPB and WTO, it is our contention that basic debates about GM agriculture have yet to be addressed by multilateral agreements dealing with biotechnology. It is therefore unlikely that regulatory harmonization will resolve tensions which emerge from the high level of uncertainty surrounding the use of biotechnology at the domestic and global levels.

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