

The Biosafety Protocol: Multilateral Agreement on Protecting the Environment or Protectionist Club?

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I. INTRODUCTION

On 11 September 2003, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereafter the Biosafety Protocol (BSP)) entered into force with ratification by the 50th country. It is generally considered to fall into the classification of international arrangement known as multilateral environmental agreements (MEAs). While the BSP was negotiated under a veil of environmental respectability, it is, fundamentally, a trade agreement pertaining to agricultural commodities produced using modern biotechnology that is solely concerned with establishing the rules under which countries can limit imports. Further, these rules are crafted in such a way as to allow unfettered restrictions on imports. This leaves the regulation of imports of these products open to influence by a broad range of protectionist interests that have nothing to do with protection of the environment. The result is that the agreement is losing its multilateral inclusiveness—none of the major producers and exporters of agricultural crops based on biotechnology (e.g., the United States,¹ Canada, Argentina and China) have ratified the Protocol. Hence, there is the possibility that the BSP will become little more than a club of protectionist countries and a failed MEA. This judgment may be too harsh as it is still early days for the BSP but the Protocol and the negotiations leading up to it are a worthy topic for examination given what is at stake.

Multilateral environment agreements represent important international instruments to deal with environmental concerns that cannot be dealt with by nation states acting unilaterally. While MEAs are not new (Kerr and Hall, 2003), their importance and number increased considerably in the final decades of the twentieth century as awareness of environmental issues increased and the need for cooperative international action to deal effectively with them was recognized. Important MEAs negotiated in recent years include the 1987 Montreal Protocol on Substances that

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¹ The United States cannot be a party to the BSP, which is legally under the broad umbrella of the 1992 Convention on Biodiversity (CBD), because the US Congress has not ratified the CBD. Even though it was clear that the United States would not be a party to the BSP, it was allowed to take an active part in the negotiations given the important place it holds in biotechnology development, production and trade.

Deplete the Ozone Layer, the 1989 Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal, the Convention on the International Trade in Endangered Species (CITES) and, if it is successfully ratified, the Kyoto Protocol on greenhouse gas emissions. Both governments and environmental non-government organizations (NGOs) have made considerable investments in time and effort in the MEA system and having one with a high profile, such as the BSP, become an obvious failure could impose a negative externality on both existing and future MEAs through loss of prestige, reputation and credibility. This is particularly important at the current time because the present US administration is less positively disposed to multilateral commitments than those of the recent past.

In the international trade literature, there has been considerable analysis of the incompatibility of the BSP's trade provisions with those of the World Trade Organization (WTO) (Phillips and Kerr, 2000; Isaac *et al.*, 2002), whether the BSP or the WTO will take precedent in a trade dispute (Isaac and Kerr, 2003; Safrin, 2002) and the effect on firms wishing to engage in trade in the products of biotechnology (Perdikis *et al.*, 2003; Gaisford, *et al.*, 2001). This analysis begs the question, however, as to whether the BSP can act as an effective multilateral protector of biodiversity that balances the risks that environmental sustainability may be threatened by the introduction of living modified organisms (LMOs)² with the risks that considerable opportunities for substantial human benefits will be forgone if the use of LMOs is overly restricted. In its Preamble, the BSP explicitly takes account of the latter as part of its responsibilities:

The parties to this Protocol, . . .

Recognize that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health

The risk that opportunities will be forgone may be particularly important for developing countries that have rapid rates of population growth and face severe environmental constraints to expanding agricultural production based on current technologies. Hence, the analysis here differs from that in the trade literature because it focuses on the effect on parties that have agreed to be bound by the BSP rather than issues between countries that want their trade in LMOs governed by the BSP and those that want it governed by the WTO.

This article examines the BSP with its need to balance these two risks in mind. Before examining the provisions of the BSP, it is first necessary to discuss the negotiation process under which it arose because it is only within this context that the BSP can be fully understood.

² This is the term used in the BSP. More common terms are genetically modified organisms (GMOs) or the products of modern biotechnology.

II. THE POLITICAL ECONOMY OF CREATING AN INTERNATIONAL REGULATORY REGIME FOR BIOSAFETY

The stage for the negotiation of an international regulatory agreement on biosafety was set with the signing of the Convention on Biological Diversity (CBD) in 1992. As has become common with international environmental agreements, a broad framework Convention sets out the principles and objectives of the preservation of biodiversity. Being too broad in scope to fully accommodate effective environmental protection provisions, the Convention was to be followed by the negotiation of more specific agreements to provide detailed arrangements for particular aspects of biodiversity preservation. Excellent analysis and summaries of the process of negotiating the BSP have been produced by The Secretariat of the Convention on Biological Diversity (CBD, 2003) and Bail *et al.* (2002) for those interested in blow-by-blow accounts and the insights they provide. The analysis below examines the wider question of regime formation in the international context.

It is possible to distinguish three stages to the process of regime formation. Keohane *et al.* (1993) state that effective environmental institutions influence the policy process through the setting of appropriate agendas, the development of intergovernmental bargaining and, finally, the policy responses made by national governments. It is this sequence of activities that determines the degree and success of a policy change. This framework can clearly be applied to the issue of international biosafety regulation. Indeed, by breaking down the process of regime formation into its component phases, a better understanding of the network of political economy interests involved in the process is provided.

A. AGENDA SETTING

The first stage in the long process of regime formation is to identify the problem(s) that require a collective international response (Keohane *et al.*, 1993). Furthermore, an important part of this agenda-setting phase is to ascertain precisely what focus is needed to understand and deal with the particular problem in the most effective manner. The case of international regulation of biosafety is highly illustrative. The biotechnology issue is essentially identified as an environmental issue, particularly when linked to the problem of global biodiversity loss. However, the negotiators of the BSP chose a trade focus as the means of obtaining a collective response to the problem of the environmental safety of LMOs. By doing so, the discussion of international biosafety regulation is placed within a political economy framework, thus altering the perception of the environmental issue. As a result, there is nothing in the BSP that deals directly with establishing multilateral standards or co-ordinated environmental policy. Hence, it stands in stark contrast to MEAs such as the Kyoto protocol that seek a multilateral consensus on a strategy for greenhouse gas emissions. This highlights the fundamental role of the agenda-setting phase in shaping the entire nature of the regime that is

ultimately formed. The objective of the BSP is to ensure the safe transfer, handling and use of LMOs that may adversely affect biological diversity by “specifically focusing on transboundary movement” ((Article 1) Cartagena Protocol on Biosafety, 2001). The focus on the trading of LMOs and their products thus places the BSP within both the trade and environment arenas. As a supplement to the CBD, the motivation for a separate BSP is ostensibly environmental. Indeed, “as agricultural markets and the transfer of new seed technologies assumed a global scale and as it became clear that the regulation of biotechnology could not be accomplished at a purely national . . . level”, the need for some kind of mechanism to deal with the international implications of GMOs was evident (Vogler and Russell, 2000, p. 2). It is not possible to have complete moratorium on LMOs and new biotechnology processes agreed upon. Instead, the “response of the international community to the manifold and uncertain environmental implications of the new biotechnology” has been to negotiate a regime for biosafety through an agreement to regulate the international trade of LMOs (Vogler and McGraw, 2000, p. 123).

The Biosafety Protocol is therefore a “*de facto* trade agreement” (Phillips and Kerr, 2000, p. 67). The use of trade, a political economy instrument, as a means of regulating the use of biotechnology broadens the focus of the original environmental treaty and involves a large matrix of political, economic and social actors in the negotiation and implementation phases. The explicit linking of trade and the environment in this way was seen by some as necessary to adequately address the issue of the commercialization of biotechnology on an international scale (Falkner, 2002). However, it also opens up a Pandora’s box of problems at the implementation stage when the two contrasting agendas are likely to clash. It is clear that little attempt was made to deal with biotechnology’s environmental aspects in isolation from politics or economics. Indeed, some authors have used terms such as “political ecology” (List and Rittberger, 1992, p. 88) or even “ecolomics” (Thomas, 2000, p. 14) to try to capture the ambiguous and encompassing nature of international environmental regimes.

Multilateral environmental agreements that have included trade elements are not without precedent. Approximately 20 MEAs have trade provisions (Kerr and Hall, 2003). An example of an international environmental regime that has successfully managed to integrate the trade and environment agendas is the 1972 Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). The purpose of this MEA was not to halt the cross-border exchange of animals and plants, but to merely manage trade and reduce the negative effects of trade in endangered species (Princen and Finger, 1994). Since 1973, it has successfully overcome the disparate interests of over 100 countries, thus obtaining near global participation in the regime. By adapting norms and principles from a purely environmental context to include political economy interests arising from international trade, its rules and decision-making procedures reflect a workable compromise between the two agendas. It has therefore been successful in changing international behaviour to further the ultimate goal of limiting environmental degradation. Unlike the case of endangered

species, there is much less consensus regarding the environmental implications of biotechnology. As a result, finding a balance in the negotiations became much more difficult and allowed those who express strong preferences to have considerable influence at the negotiations as well as other non-environmental political economy interests to have their agendas included in the negotiations.

B. NEGOTIATION

The framing of the biosafety environmental issue within the trade arena greatly extends the range of interests affected by the Protocol's rules and regulations. It is inevitable, therefore, that a whole range of actors would wish to have input into the negotiations. In order to fully understand the nature of regime formation, it is helpful to analyse the political economy interests they represented throughout the progress of intergovernmental bargaining from 1996 to 2000. It is clear that non-state actors have been of fundamental importance to the process of regime formation in the case of biosafety. The roles played by civil society, industry and epistemic communities suggest that a political economy approach to regime formation yields a far better analysis than traditional state-centric theory.

1. *Civil Society*

Princen and Finger's (1994) study of environmental NGOs in world politics credits the organizations as being key agents of change, particularly in the formation of environmental regimes. NGOs tend to have considerable bargaining leverage by working as independent actors from states, thus creating a new "diplomatic niche" (Princen and Finger, 1994, p. 33), which allows them to exert a certain influence over the negotiations. Within the intergovernmental bargaining forum there appears to be "political space . . . for those who have expertise, who appeal to higher values, who command the public's attention, and who enjoy legitimacy when governments and traders do not" (Princen and Finger, 1994, p. 143). These findings are indeed borne out by the experiences of the biosafety negotiations. In the BSP case, however, it appears that the role of environmental NGOs reached new levels of influence and in some cases no longer acted independently from states. This influence was manifest through the integral part they played in the development of negotiating positions of some developing countries (Isaac *et al.*, 2002)

In terms of international biosafety regulation, consumer groups have been just as important in their opposition to LMOs as environmental NGOs. The international agendas of four identifiable types of civil society groups that oppose biotechnology have been outlined by Kerr (2001). Together they have proved to be a powerful force throughout the negotiations and indeed the entire policy-making process. There were a large number of environmental NGOs, each voicing slightly different concerns regarding biotechnology and its impact on biological diversity. It is beyond the scope of

this article to detail all these complaints and the interests involved. However, a few examples of campaigns by prominent transnational NGOs highlight the main issues embodied in the dispute over biotechnology. A Greenpeace campaign, “no genetic manipulation of nature”, focuses on the environmental impact on biodiversity associated with the globalization of monoculture farming practices. In its view, the modification of traditional agricultural processes is a “serious threat to our biological heritage, cultural roots, and global food security” (Greenpeace, 2001). The Rural Advancement Foundation International (RAFI) seeks to promote the conservation and sustainable improvement of agricultural biodiversity and is particularly concerned about the potential loss of genetic diversity posed by the development of modern biotechnology (Rural Advancement Foundation International, 2001). The work of both these organizations has been instrumental in highlighting the potential risks associated with genetic engineering and its products, and therefore played an important role in influencing public opinion throughout the negotiating process.

Public opinion has also been shaped by consumer groups such as Action Aid and the European Consumers’ Organisation (BEUC). Their criticisms of genetic modification have a different focus to those of environmental groups. While they may not be against the use of biotechnology *per se*, they do want to highlight potential or suspected risks to human health from genetically modified products. Action Aid has been more vociferous in its criticisms of genetically modified crops; its “Wake up and smell the GM coffee” campaign targets not only the producers of genetically modified coffee beans, but also retailers who may purchase genetically modified coffee (Action Aid, 2001). The BEUC has campaigned for consumers to have the right to decide for themselves whether or not they wish to consume genetically modified products. They would like to see adequate labelling and packaging information, as well as tighter controls on the marketing of LMOs and their products (BEUC, 2001). Such consumer groups have initially had most success in Europe, where concern over food safety is particularly high, and also in developing countries. However, recent transnational initiatives have succeeded in transplanting consumer concerns within North American society as well. A Transatlantic Consumer Dialogue, consisting of 40 European and 24 US consumer groups, is now in operation and is working on both food and trade issues that span the biotechnology arena (BEUC, 2001).

The transnational nature of many civil society groups gives them a unique perspective in the international biosafety debate. They are able to transcend national borders by appealing to basic concerns that it is both inherently wrong and poses too great a risk to artificially mutating nature if modern biotechnology methods are allowed to be used. They therefore function as “definers and purveyors of moral interests” and aid the process of social learning (Princen and Finger, 1994, p. 143). Being independent of national governmental delegations at the negotiations, NGOs are clearly “levers of power that can be used to affect world public affairs” (Wapner, 1996, p. 4) and their efforts have been extremely important in mobilizing citizens’ interests against LMOs across the globe.

In the case of the BSP negotiations, however, the influence of environmental NGOs went further than simply raising awareness and mobilizing public opinion. Input from NGOs came to have a pivotal role in the development of formal negotiating positions. This was to have profound effects on the BSP's final configuration.

It has been a consistent complaint of developing countries, particularly African countries, that they do not have the capacity or resources to fully participate in complex international negotiations. Their delegations, if they have them at all, are often composed of lone individuals with no technical support at the negotiating venue and little analytical back-up in their government ministries back home. Yet, early in the BSP negotiating process at the second meeting of the Ad Hoc Working Group on Biosafety, the African delegation, spearheaded by Ethiopia, produced a draft for the Protocol that was far more detailed and advanced than those of any of the other participants. The report released by the Secretariat of the Convention on Biodiversity chronicling the BSP negotiations is instructive here (CBD, 2003). In its reporting on the inclusion of socio-economic considerations in the decision-making criteria of the BSP, an issue about which NGOs felt very strongly, it states:

The African Group presented the most comprehensive submission on socio-economic factors, incorporated into a number of draft provisions throughout the Protocol: objectives, general obligations, notification procedure, risk assessment and management, liability and compensation. The draft article on socio-economic considerations proposed by the African group included taking into account the length of time before such impacts may be manifest and proposed a seven year notification period prior to export. The African group proposal contained an extensive list of socio-economic considerations to be included in a risk assessment: anticipated changes in existing social and economic patterns; possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture; impacts likely to be proposed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside agroclimatic zones; anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities; disruptions to social and economic welfare and possible effects contrary to the social, cultural, ethical and religious values of communities. It constituted the most detailed list of socio-economic considerations to be taken into account by the Protocol (CBD, 2003, p. 79).

The list could, for the most part, apply to any modern technology and is a clear attempt to have the BSP deal with much broader issues than biodiversity. According to Isaac *et al.* (2002), the African Group proposal was largely the work of a transnational NGO.

A request for draft protocols resulted in an Ethiopian submission in October 1996 submitted on behalf of the African delegation and written by the Third World Network (TWN).³ This draft protocol, considered representative of the views of many developing countries, used as a framework the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. As a result, the draft protocol treated shipments of LMOs with the

³ Egziabher (2002) from Ethiopia would appear to deny that transnational NGOs had a role in the process but Najir (2002, p. 267) of the TWN reports "the legal implications of a particular proposal were outlined and draft language provided".

same degree of prescriptive regulation as shipments of toxic or nuclear waste. Further, this draft protocol placed an enormous burden upon the Party of export (the exporting country) and the exporter to ensure biosafety and to gain approval before any shipment of LMOs (Isaac *et al.*, 2002, p. 38).

With this draft proposal on the table, much of the subsequent negotiating effort centred on moderating its approach. Having LMOs, where there was no scientific consensus regarding their threat to the environment, treated in a similar fashion to toxic or nuclear waste where a scientific consensus as to the dangers they present exists, can be considered a major coup for non-state actors in the process of regime formation.

2. *Industry*

The biotechnology industry also played an important role in the process of negotiations. In contrast to civil society movements, the biotechnology industry has sought to influence the intergovernmental bargaining process in favour of LMOs and to obtain the least amount of restriction on their trade. Appealing to commercial interests across the globe, multinational biotechnology producers have the potential to exert a powerful presence. Indeed, it has been noted that, "Monsanto, dubbed the Microsoft of biotechnology, has a global vision that embraces all the world's main crops" (The *Guardian*, quoted in Neale, 1999, p. 116). Monsanto had moved to consolidate its presence within the biotechnology industry by expanding to take over other producers and processors of genetically modified material. Indeed, Monsanto represents the "agrobiochemical complex" typical of multinational firms in the biotechnology industry (Neale, 1999, p. 116).

Biotechnology firms have established institutions to represent their interests. One example is the US-based Biotechnology Industry Organization that represents over 850 companies, academic institutions and biotechnology centres in over 25 countries. This organization seeks to promote the interests of the biotechnology industry and maintains strong links with members involved in the research and development of medical, agricultural, industrial and environmental biotechnology products. Their public message focuses on the benefits of pharmaceutical biotechnology through the development of drugs and vaccines for the treatment of cancer, obesity, heart disease and ageing diseases. They seek to disseminate their view that biotechnology is "a big word that means hope" (Biotechnology Industry Organization, 2001) to a somewhat suspicious public.

At first glance, it appears that the major conflict in the biosafety area is between these producers, the majority of whom are based in North America, and European consumers. Closer examination of the political economy interests behind the debate reveal that the situation is far more complicated. Since the main representatives of the biotechnology industry are multinational organizations and transnational industry organizations, it is difficult to segregate the discussion along national lines. While US-based firms are the main developers of agricultural biotechnology, EU-based firms are

the second major group and collectively hold approximately one-third of the patents (Gaisford *et al.*, 2001). It seems, therefore, that the biotechnology industry has itself carved out a diplomatic niche within the intergovernmental bargaining setting similar to that achieved by civil society movements. Industry organizations also claim that they are involved in the process of social learning by providing the public with an alternative perspective on genetic engineering from that disseminated by consumer and environmental organizations. In contrast to the consumer and environmental NGOs, however, the representatives of the biotechnology industry are acting as defenders of commercial interests and the right of companies to develop an enabling technology that could benefit healthcare, the food supply and the environment.

Despite their considerable resources, the efforts of the biotechnology industry appear to have been largely unsuccessful except when “preaching to the converted”. Thus, while they may have been able to effectively put their case to the governments where their industry was relatively well established, they had little success in altering negative perceptions of biotechnology among EU consumers and policy-makers as well as policy-makers in developing countries. Instead, they had to be content with ensuring that segments of the industry, such as pharmaceuticals, were exempt from the provisions of the BSP.

3. *Epistemic Communities*

Given that biotechnology is a sector at the forefront of scientific discovery, epistemic communities have also had a potentially important role in the formation of international biosafety policy. Transnational networks of experts and specialists have provided an interface between science and politics (Vogler and Russell, 2000) and, thus, can be highly influential in determining the progress of intergovernmental bargaining. However, studies of international bargaining processes rarely pay sufficient attention to this fact. Adler and Haas (1992, p. 367) criticize traditional international relations theory for its lack of “a credible . . . set of explanations for the sources of international institutions, state interests, and state behaviour under conditions of uncertainty” and claim that an acknowledgement of the importance of ideas and knowledge would fill this void. The work of epistemic communities is important for facilitating a degree of understanding between the actors in the policy-making process and thus for creating order based upon collective meaning (Adler and Haas, 1992). This role was clearly applicable to the controversial issue of biotechnology and the potential risks associated with its usage.

In terms of biotechnology, two distinct groups of epistemic communities can be identified. The academic community of molecular biologists have contrasting views of the benefits and likelihood of risks of modern biotechnology to those of ecologists. As Vogler and Russell (2000, p. 6) point out, “their competing paradigms may be described in terms of atomism and holism”. The views of the ecologists have been largely taken up by the environmental civil society groups, as described above.

Likewise, the work of molecular biologists has been at the forefront of the development of genetic engineering processes used by large biotechnology firms. This clash of expertise serves to further complicate the political economy issues surrounding the application of modern biotechnology. The vital influence of epistemic communities upon policy formation in this international setting is demonstrated by the huge divergences between sceptical European and pro-biotechnology North American governmental positions. The fundamentally different views of science, particularly regarding its reliability and desirability, broadly reflect the conflict between the two main sets of experts within the biotechnology arena.

There are numerous academic and research institutions dedicated to biotechnology around the world and the number of undergraduate and postgraduate degrees available in the subject is rapidly increasing. In addition, there are several networks of scientists and other experts in the field that seek to disseminate information on biotechnology by maintaining close links with industry. For example, the Life Sciences Knowledge Center, sponsored by Monsanto, works to promote understanding of the processes and benefits of agricultural biotechnology (Life Sciences Knowledge Center, 2001). A US-based Council for Biotechnology Information also aims to deploy scientific research in order to better understand and appreciate the benefits of the technology (Council for Biotechnology Information, 2001). Its members include major biotechnology producers such as Monsanto, Aventis and DuPont as well as the Biotechnology Industry Organization itself. Such networks have a shared set of principled beliefs in the benefits of biotechnology and thus provide a consensual knowledge base upon which policy can be formed. By guiding the behaviour of international policy-makers with their possession of knowledge and information, epistemic communities associated with biotechnology could occupy a very powerful position. Indeed, Haas' (1989) identification of power and knowledge as explanatory variables for state behaviour in the formation of international environmental regimes could be a possible model for the Biosafety Protocol negotiations. It is through the work of epistemic communities that ideas become disseminated internationally and eventually embedded in institutional structures, such as the regulatory systems. They can, therefore, be key to understanding how an international regime is arrived at.

In the case of biotechnology, however, the influence of the scientific community in the process of formulating an international regime was considerably muted. In part, this was the result of the split between the ecologists and molecular biologists noted above. It was also the result of the significant change taking place in the funding of genetic research in agriculture (Klein and Kerr, 1995) whereby, due to the fiscal difficulties of many developed country governments combined with the increased likelihood of private interests being able to appropriate the rents available from technological improvement (Boyd *et al.*, 2003), research has been moving from the public to the private sector. As a result, as many in the scientific community who had applicable knowledge now were employed by biotechnology firms, their independence

could be questioned and their credibility diminished. As pointed out above, some of the major sources of scientific information were funded by the biotechnology industry. Further, biotechnology represents a transformative technological change (Gaisford *et al.*, 2001) meaning that many scientific questions cannot be answered with a high degree of confidence. Thus, there was less scientific consensus than there would be with a more iterative technological change. The net result was that the scientific community's role in the shaping of the BSP was less than might have been expected. The absence of consensus meant that, in effect, scientists were enlisted by civil society NGOs and industry groups as their advocates, something that was not lost on policy-makers. According to Helmut Gaugitsch, a scientist and member of the Austrian delegation negotiating the BSP:

Although science did therefore to a certain extent directly influence the negotiations of the protocol, scientists themselves did not play a major role. Despite a few side events and oral presentations—e.g. in a two-day workshop just before the first round of negotiations in Aarhus in summer 1996—scientists did not have a strong presence at the negotiations. However, through the active participation of interest groups, such as environmental and other NGOs as well as industry, scientific developments and discussions had substantial indirect influence ... (Gaugitsch, 2002, p. 83).

The increasing importance of the variety of non-state actors in intergovernmental processes has been documented in the international relations literature. Rosenau and Czempiel's influential work on *Governance Without Government* (1992, p. 2) claims that authority is being relocated "both outward toward supranational entities and inward toward subnational groups". They claim that governance, a broader and more encompassing concept than formal government, is a more accurate depiction of international political processes. Governance, like an international regime, depends upon intersubjective meanings shared by actors that help to facilitate order in world affairs. Wapner (1996) has applied ideas of governance involving non-state actors to world environmental politics and describes supra- and sub-state elements as being vital to effective environmental action. He claims that the state alone cannot solve international environmental problems and that its efforts must be supplemented with the work of civil society and NGOs. In the international governance of biosafety, civil society, industry and epistemic community groups can be identified as comprising such a system of governance. Their presence and influence in the agenda setting and negotiating forums was important although civil society influence received greater weight in the BSP negotiations.

In terms of the BSP, the agenda setting and negotiation phases can be understood using Krasner's (1983) description of principles, norms, rules and decision-making procedures. The agenda-setting phase was dominated by political economy concerns over the interaction between trade and the environment, particularly regarding how an impending Protocol could adequately promote the safe transboundary transfer of LMOs. This process fixed the fundamental principles and norms of the biosafety regime—an environmental agreement with a remit to protect and preserve biodiversity

through the regulation and restriction of international trade. Following this, the negotiation phase formalized the rules and decision-making procedures by which these principles and norms could be achieved. The input of non-state actors was crucial to the outcome of the negotiations; the inclusion of elements such as the precautionary principle, the distinction between LMOs for direct release into the environment and those to be used for food, feed and processing, and the stated relationship between the Protocol and other international agreements was clearly influenced by their involvement. These rules and procedures operate in conjunction with the agreed norms and principles to facilitate a regime that should provide order to the otherwise complex and contradictory issue of transboundary transfer of biotechnology.

However, a regime is not actually created with the simple signing of an agreement between national governments. The endurance of principles and norms and the operation of rules and decision-making procedures are key. Therefore, the implementation phase constitutes a necessary part of the entire regime formation process. The context within which implementation takes place is extremely important and, in this case, the broad framework of trade and the environment that set the agenda of the regime should be recognized. Although the norms and principles of the regime were formalized with the agreement of rules and procedures through the BSP, it remains to be seen whether the parties to the CBD will adhere to them in the long run. As suggested above, much of the existing discussion of the BSP's implementation has centred on its relationship to other trade regimes, particularly the WTO, and how countries that do not ratify the BSP can be made to conform to its rules under international law. There is still the question, however, about the implementation of the BSP among those countries that have or will ratify it. If the BSP is flawed, problems in its implementation may well lead to a failed international regime.

C. IMPLEMENTATION

One of the major concerns of civil society groups with the WTO is with the loss of local sovereignty that its agreed rules imply. Environmental NGOs have been particularly exercised with the willingness of WTO Panels to strike down domestic environmental initiatives on the basis of existing trade commitments. This was the heart of the controversies over dolphin-friendly tuna fishing methods and turtle-friendly shrimp harvesting. The theme of loss of local control is ongoing in the broader debate over globalization. Hence, return of local control of trade rules was a central issue for the anti-biotechnology civil society groups that, as we have seen above, had considerable influence in the negotiations. Further, many developing country governments chafe under the disciplines of their WTO commitments and their limited ability to influence that organization's negotiations—which finally came to a head in the failed WTO Ministerial Meeting in Seattle in 1999 (Kerr, 2002). Latterly, governments of some developed countries, particularly those in the EU, also began to see their WTO commitments as too restrictive when faced with strong opposition to

biotechnology from civil society groups. As conceived, the WTO does not have any mechanism to allow governments to respond to groups other than producers who are asking for protection (Perdikis *et al.*, 2001). This was at the heart of the North American–EU dispute over the importation of beef produced using growth hormones and why, ultimately, the EU chose not to abide by the WTO Panel’s ruling against it (Kerr and Hobbs, 2002). Thus there was a convergence of interests in having trade arrangements for the products of biotechnology that allowed a greater degree of national control. Hence, for an agreement ostensibly about international cooperation on the management of biotechnology, it is difficult to find any references to multilateral cooperation.

The only firm commitment to multilateral cooperation in the BSP is in Article 22 that establishes the Biosafety Clearing House and in which the parties commit to sharing information. The Biosafety Clearing House will keep records of how parties dealt with individual LMOs and the information used in its decisions. This will reduce transaction costs by removing the need for each importer to assess each new LMO if they are willing to be guided by the example of others. Article 22 provides a commitment for cooperation in capacity building for developing countries. Article 26 “encourages” parties to cooperate on research into socio-economic impacts and to share information on these effects. If requested by the importing party, there is a commitment to capacity building in the area of LMOs destined for food or animal feed in Article 11. In Article 18, parties have agreed to “consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant bodies”. This latter weak commitment is particularly disappointing because it leaves this area entirely in the hands of individual importing states. This will mean a multitude of standards that can only serve to make international transfers of LMOs unnecessarily complicated and open to protectionist influences.

The remainder of the BSP’s substantive articles all deal with the conditions under which individual parties can restrict imports. Detailed analysis of the BSP’s trade clauses can be found in Bail *et al.* (2002) and Isaac *et al.* (2002); only the BSP’s central trade restricting aspects will be highlighted here. There is virtually no protection or recourse for exporters if the importer turns down an application. There are a number of features of the BSP that bias it in favour of importers. Without a reasonable balance between the rights and obligations of importers and exporters, countries, particularly developing countries, that might wish to domestically license an LMO may find its existing export markets at risk, and may be deterred from adopting the LMO. Hence, a developing country may have to forgo the “great potential for human well-being” that the BSP recognizes can arise from the use of biotechnology due to the provisions of the agreement itself. Further, given that there are to be no multilateral standards, importers can put in place standards that are sufficiently strict that it may not be possible for developing countries that have not licensed an LMO to prove that its exports do not contain them. Hence, while developing countries were insistent on “local control” of

imports during the negotiations, they now risk those same provisions being used against their exports to some developed countries, and the EU in particular.

Paramount among the provisions of the BSP that allow unfettered protectionism is the “precautionary principle”. The inclusion of the precautionary principle was one of the most hotly debated issues in the negotiations. The precautionary principle deals with situations of scientific uncertainty. All countries recognize the need for precaution when uncertainty exists. The problem is that scientific certainty can never exist. As a result, the precautionary principle can always be invoked to bar imports. This means that it can be used for political responses to protectionist influences that have nothing to do with the particular issue of scientific uncertainty. To balance the rights of exporters and importers there needs to be an international agreement on how to operationalize the precautionary principle. This means that there has to be some agreement on what would constitute sufficient scientific consensus for uncertainty to be removed and on who should provide that consensus (Kerr, 2003). More and costly scientific information can always be asked for under the guise of the precautionary principle. This makes the adoption of any LMO by a developing country very risky, particularly if a large existing developed country market for its exports can be closed off by simply invoking the precautionary principle. Given the protectionist pressure that can be faced by governments in developed countries over the issue of agricultural imports, there is no reason to believe that politicians would be reticent to invoke the precautionary principle for nefarious purposes.

The BSP also allows importers to take socio-economic considerations into account when determining whether or not to allow the import of an LMO. The connection between socio-economic factors and the maintenance of biodiversity is tenuous at best.⁴ Socio-economic considerations, however, have everything to do with economic protectionism. Any technological change, and particularly a transformative technology such as biotechnology, will lead to both economic winners and losers. Potential losers have a vested interest in asking for protection from technologically competitive imports. Given that a new technology will cause economic harm to some groups, allowing countries to impose trade restrictions for socio-economic reasons gives them a virtual *carte blanche* to exclude imports. Developing countries already face significant barriers to their agricultural exports as a result of being able to provide their products at a lower cost than farmers in developed countries. The BSP simply gives developed countries another weapon in their protectionist arsenal against agricultural exports from developing countries—one that allows them to deny more efficient technology to farmers in developing countries because it is the use of the technology not its relative efficiency that provides the justification for the imposition of trade barriers.

⁴ For example, the use of biotechnology may alter economic incentives to favour monoculture production which could, as a consequence, reduce biodiversity. However, this “threat” to biodiversity could be eliminated by the establishment of gene banks.

It was, however, developing countries (not the EU) that proposed and pushed for the use of socio-economic considerations as justification for the imposition of trade barriers—they worried about competition from farmers in North America who have the technological lead in the use of biotechnology, and hence enjoy the benefits of increased international competitiveness. This form of protectionism has nothing to do with maintaining biodiversity in those developing countries.

The BSP requires a risk assessment to be undertaken when an exporter makes a request to ship a new LMO into an importer's market. The Protocol, however, allows the importing country to establish the parameters that underlie the risk assessment. The importing country can reject the request for import on the basis of its risk assessment. There is no mechanism in the BSP to allow the exporter to appeal the decision arising from the importing country's risk assessment.⁵ Thus, the importing country is not accountable for its risk assessment. Again, this leaves the risk assessment process open to protectionist influence. The framers of the BSP show a consistent naivety (or cynicism) regarding the willingness of protectionist influences to exploit opportunities to have protection extended. It is almost as if they believe those charged with implementing the BSP will be solely interested in protecting biodiversity and not open to other influences. According to Isaac *et al.* (2002, p. 107):

From the BSP perspective, governments are seen as guardians of the natural environment (and according to some have a responsibility to err on the side of caution). No consideration is given to the possibility that governments may be motivated not only by the wish to prevent potential market failure from an unanticipated environmental risk, but also by a desire to extend protection to vested domestic commercial interests.

The absence of a binding dispute settlement mechanism, which was debated in the negotiations, is a major victory for those wishing to have a return to more local control. In essence, it means that an importer can ignore even the minimal commitments in the BSP with impunity. There will be no adverse “tuna-dolphin” or “shrimp-turtle” rulings from the BSP. Of course, that leaves potential exporters totally at the whim of importers.

III. CONCLUSIONS

On the whole, the BSP is a disappointing multilateral agreement. It is not an agreement that will foster international cooperation in the management of biotechnology for the maintenance of biodiversity. Instead, it allows its parties to take unilateral action to exclude or limit imports of LMOs. There is no commitment to cooperate to develop harmonized international standards for the use of LMOs that will

⁵ In fact, it appears that if a potential importing country simply fails to respond to the request by an exporter to have an LMO assessed for import the exporter has no recourse, meaning that, *de facto*, imports are denied market access.

maintain biodiversity or even a commitment to develop a common risk assessment process for LMOs.

While some who have an interest in the question of biotechnology may believe that the only way to manage LMOs in an environmentally friendly manner is to ban them, the stated objectives of the BSP is to allow their benefits to be reaped while safeguarding biodiversity. If the effect of a country banning imports were simply that its producers and citizens were denied the benefits of a particular LMO, then there would be less cause for complaint—the costs would be borne by the country that imposed them. The banning of imports, however, has considerable externalities associated with it. In particular, it may deny developing countries the benefits of the technology because their existing exports will be threatened if they adopt the technology. They will face the choice of risking their existing export markets if they adopt the use of an LMO or forgoing the domestic benefits that would arise from using the technology. They will not know if the LMO will be rejected by their existing trading partners until after they have licensed and put the LMO into production and want to make the first export shipment. Even if the importing country may have previously allowed the import of a particular LMO from another country, due to the importer's ability to deny market access on the basis of socio-economic factors, which will vary for each potential exporter, the new exporter can have no *a priori* expectation that its exports would be accepted. Hence, the process has no transparency. Once the LMO is adopted in the exporting country, it may be extremely difficult, if not impossible, to return to conventional production. Given the risk of loss of export markets, a prudent country is unlikely to opt for adoption and, hence, will forgo the benefits of the technology. If the BSP were, alternatively, charged with cooperatively developing international standards based on the maintenance of biodiversity, then the lack of transparency would be largely eliminated. While some LMOs could still be denied market access, a country considering the domestic licensing of a LMO would have much better information upon which to make its decision.

The absence of a commitment in the BSP to harmonize international standards for the labelling of imports of the products of biotechnology not destined for release into the environment also leaves potential developing country exporters open to the protectionist whims of importers. This is particularly the case for tolerance levels for contamination. A number of studies suggest that the cost of ensuring purity rises in a non-linear fashion as tolerances for adulteration decline (Smyth and Phillips, 2002; Perdakis *et al.*, 2003, Phillips and McNeill, 2002). Given the limited technical capacity of many developing countries, it may not be possible for them to segregate to a sufficient degree non-biotechnology based crops from biotechnology based crops once they have chosen to adopt the use of, for example, a LMO-based variety of soy. As importing countries individually establish tolerances, tolerances can be set arbitrarily low to limit imports. Hence, the only way a developing country can ensure that it maintains market access for its non-biotechnology based crops is not to license the

LMO variety.⁶ Again, it will be denied the benefits that can be provided by biotechnology. Internationally established tolerances based on ensuring biodiversity would allow market access when the risk of biodiversity loss is low.

Further, without international standards for labelling tolerances, given the low technical capacity of some developing countries, it may be difficult to establish that exports are not tainted by LMO varieties even if the country does not have them. The tests and certification procedures established by importers may simply be too onerous for developing countries to comply with. Thus, it may be the least developed countries that suffer disproportionately from the failure to mandate cooperative multilateral solutions to the management of biotechnology in the BSP.

The emphasis on national (local) control of rules of trade as opposed to multilateral cooperation for preservation of biodiversity in the BSP would seem to be the antithesis of what an MEA should embody. It may well lead to a failed MEA. Much has been made of the BSP's incompatibility with the WTO and how trade with non-parties to the BSP will be dealt with in international law but it would appear that the BSP may well prove unworkable for countries that were willing to voluntarily agree to abide by the rules of the BSP. Parties to the BSP that may wish to avail themselves of the benefits of agricultural biotechnology may have to choose between domestically licensing the technology and withdrawing from trade with other BSP parties or forgoing the benefits of the technology so that they can continue to trade.

Local control, in essence, means that trade policy is open to exploitation by protectionist interests that have nothing to do with the maintenance of biodiversity. This is particularly true because socio-economic considerations have been explicitly allowed as a justification for restricting imports. Agricultural exporting developing countries have been trying to remove barriers to market access for their products for decades in the face of fierce protectionism in both developed and developing countries. The BSP represents a step backward in the battle for better market access and economic development. While it is early days in the implementation of the BSP, it will be a major feat if the Protocol becomes a positive force for the cooperative management of biotechnology for the preservation of biodiversity rather than simply a club for agricultural protectionists.

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⁶ Of course, the BSP will assist in developing countries being able to deny official market access to LMOs, thereby preventing the production of biotechnology-based crops—at least in theory. The experience to date, however, suggests that if the crop gives a competitive advantage to farmers that can adopt it, illegal imports will take place (Gaisford and Kerr, 2002). Given the limited capacity of developing countries to police their borders, production based on unlicensed LMOs is likely to take place. It will then be hard, if not impossible, for many developing countries to comply with the standards of proof imposed by developed countries regarding the LMO status of their exports.

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