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Business and biotechnology: regulation and the politics of influence

Peter Newell and Dominic Glover

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INSTITUTE OF DEVELOPMENT STUDIES
Brighton, Sussex BN1 9RE
ENGLAND

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Summary

The regulation of biotechnology products at the national and international level inevitably involves private sector companies. Biotechnology firms are, in many ways, the "street-level bureaucrats" of biotechnology, those expected to enforce and implement government regulations regarding biotechnology products. Not only are they the front-line producers and distributors of the technology, a fact which places them well to provide insights and channel their experience into the design of regulatory systems, but the in-house scientific expertise they have and the level of capital they own, make them key advisers and powerful political players in the politics of biotechnology regulation. This paper analyses the political role of the firms that are in many ways driving the "gene revolution" which systems of public regulation at the national and international level seek to manage in an orderly and environmentally-responsible fashion.

The first section looks at ways of explaining why firms are such influential players in the debate about the appropriate scale and scope of biotechnology regulation, drawing on the literatures on business influence to account for their structural advantages and bargaining assets. The following sections look firstly, at the ways in which firms have sought to shape public regulations pertaining to biotechnology products in a way which addresses their concerns about "unnecessary" interference in international trade, harmonised approaches to risk assessment, intellectual property protection and the need for commercial confidentiality. Secondly, in sections on the regulation of business, we explore other strategies that have been adopted by NGOs and consumer groups to try and develop their own forms of "governance" of the trade in GMOs as a reaction to the perceived weakness and inadequacy of existing systems of public regulation. In each case, we attempt to tease out possible implications for the strengthening of a policy agenda more firmly grounded in concerns about the food security of the poor.

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Preface

Biotechnology Policy Series

This IDS Working Paper series emerges from a series of three interlinked projects. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy-making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to "democratise" biotechnology?

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This paper is a product of the 'Globalisation and the International Governance of Modern Biotechnology' project. Other papers in the Biotechnology Policy Series are listed inside the back cover.

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1 Introduction

The regulation of biotechnology products at the national and international level inevitably involves private sector companies. Biotechnology firms are, in many ways, the "street-level bureaucrats" of biotechnology, those expected to enforce and implement government regulations regarding biotechnology products. Not only are they the front-line producers and distributors of the technology, a fact which places them well to provide insights and channel their experience into the design of regulatory systems, but the in-house scientific expertise they have and the level of capital they own, make them key advisers and powerful political players in the politics of biotechnology regulation.

A project looking at the factors and actors that shape the international governance of biotechnology would not, therefore, be complete without some analysis of the political role of the firms that are in many ways driving the "gene revolution", which systems of public regulation at the national and international level seek to manage in an orderly and environmentally-responsible fashion. This paper aims to contribute to such an analysis. The first section looks at ways of explaining why firms are such influential players in the debate about the appropriate scale and scope of biotechnology regulation, drawing on literatures on business influence to account for their structural advantages and bargaining assets. The following sections look, firstly, at the ways in which firms have sought to shape public regulations pertaining to biotechnology products in a way which addresses their concerns about "unnecessary" interference in international trade, harmonised approaches to risk assessment, intellectual property protection and the need for commercial confidentiality. Secondly, in sections on the regulation of business, we explore strategies that have been adopted by NGOs and consumer groups to try and develop their own forms of "governance" of the trade in GMOs, as a reaction to the perceived weakness and inadequacy of existing systems of public regulation. In each case, we attempt to tease out possible implications for the strengthening of a policy agenda more firmly grounded in concerns about the food security of the poor.

2 Accounting for influence

Though firms have been active from the very earliest days of the technology's development, it is important to differentiate the strategies firms use at the national level from the international level and to explain why they may be more influential with some governments than others. Work within the business influence literature suggests that although some companies may benefit from international decision-making processes that are distant from publics and the intense scrutiny of civil society groups, firms often prefer to engage with national governments where they are based with whom good relations may have been nurtured, trust built up and where channels of access and representation are familiar and clearly-defined. Many of these advantages do not apply at the international level, where decision-making processes are slow and complex, very legalistic and traditionally not open to extensive inputs from non-state actors. More explicit channels of influence either through legislative hearings or contributions to party funds are also, of course, closed (Egan and Levy 2001). Moreover, it can be difficult to influence a government's agreed negotiating position once multilateral negotiations have begun. Therefore business

lobbyists regard it as more important – and more effective – to influence policy discussions in national capitals governments' national negotiating stances are agreed. They tend to see their participation in multilateral negotiating forums as a secondary tactic, useful for monitoring the negotiating process, distributing information to delegates and dealing with urgent or unexpected situations that may emerge from the deliberations (Newell 2000).

The key strategic difference, from the point of view of industry, is not only between the national and international, however, but the different types of institutional design and organisational culture associated with the US as opposed to the EU, for example. Though there is potential, as Levy and Newell (2000) note, for the transatlantic integration of capital to nurture common approaches to the regulation of GMOs, and there have been industry-led attempts to facilitate transatlantic dialogues between industries and policy-makers in Europe and North America, distinct political cultures and the role of NGOs conspire to create unique challenges which businesses have to comprehend and adapt to in their political strategies.

Before looking further at competing approaches to the regulation of GMOs and the firms driving the "gene revolution" to assess how far, and the ways in which firms have helped to define rules and shape the conduct of the institutions responsible for the international governance of biotechnology, it is worth summarising the key strengths of firms as political actors in general, for it helps to account for their high profile role in public regulation of biotechnology products as well as the attention they have attracted from civil society groups anxious to check the perceived power of biotechnology multinationals. Broadly-speaking, approaches to accounting for business influence can be divided between more pluralist explanations and those which place greater emphasis on the structural power of business actors *vis-à-vis* the state. Below we also discuss those features of the biotechnology issue that are conducive to the influence of business actors in this arena, without overlooking the ways in which some of these advantages can be countered or off-set by the activities of civil society actors which we discuss in the latter sections of the paper.

Pluralist accounts of the role of business in the policy process emphasise the expertise and resources of firms which make them important players, without attributing them structural power in the way Marxist and neo-Marxist accounts do (Holloway and Piccottio 1978). Pluralists emphasise the openness of policy-processes to any actors able to organise themselves and with the resources to represent their concerns (Dahl 1961). Those with access to high-quality sources of information, more resources and that are better organised internally are likely to be more successful at advancing their case with policy-makers. Their starting assumption is that no one actor or group of political players is in a position to ensure systematic and privileged access or to secure outcomes favourable to them on a repeated basis. The bargaining assets emphasised in these accounts are returned to below, in the discussion about how the nature of the sector shapes influence, and come through strongly in the analysis throughout this paper.

Structuralist accounts, on the other hand, suggest that the owners of capital exercise structural power over state managers, in that they are able to shape the context in which states make decisions (Strange 1988). This leverage has been enhanced as a result of changes associated with globalisation such as the

capital mobility that allows firms to relocate and discipline both the state and organised labour. These developments have led some observers to elaborate the concept of the "competition state" to describe a shift of power between firms and states in which national governments perceive as one of their primary responsibilities the maintenance of a favourable policy and regulatory environment to attract and retain private investment (Cerny 1990). But this change aside, the contribution of major firms to the tax base of the state, the growth they generate and the employment they provide, mean that states, for reasons of resources, expediency and legitimacy, in many ways, require the acquiescence of large firms for the success of their political programmes.

The manifestations of these forms of power are many. Predominant in these literatures are concerns about the "mobilisation of bias" (Schattschneider 1960), ideas about "non-decision-making" on issues that are screened out of the policy process by being ignored or not even considered because they may threaten key interests (Bachrach and Baratz 1962) and "anticipated reaction" where state decision-makers refrain from making certain decisions on the basis of how a powerful industry (or other actor) might react. In most such literatures, it is accepted that the idea of what constitutes the interest of capital is not hegemonic as there are of course many fractions of capital each with their own (often competing) interests. What is significant is the extent to which particular sectors that are regarded as having high strategic importance to the success of the economy as a whole, are able to project their interests as those of capital-in-general, for the benefit of industry as a whole (Newell and Paterson 1998). In mediating between the interests and concerns of different fractions of capital, such accounts emphasise the way in which state managers are charged with the responsibility of determining what is in the interest of capital-in-general. The way in which the biotechnology industry has sought to present the sector in these terms is discussed further below.

In addition to these general accounts of the power of business actors, there are some features of the biotechnology issue which dispose it towards business influence. In a situation of uncertainty, those with access to the necessary expertise to comprehend the dimensions of a problem and propose solutions to it become cast as key knowledge brokers. Because of their superior access to scientific expertise and capital, firms are able to nurture their own 'epistemic communities' (Haas 1990) of scientists and experts who take a common view of the risks associated with biotechnologies and the forms of regulation that are most appropriate for addressing these. This makes them indispensable to policy-makers struggling to identify an appropriate response to the new technology, for their expertise can help to identify not only areas of environmental risk but also the political cost and opportunity structure of a problem.

A second key factor is the way in which the biotechnology industry, in many states, is afforded a privileged position in policy debates because of the strategic importance attached to biotechnology by governments as a key component of the high-tech knowledge economy (Levy and Newell 2000). This means that is easier for major firms wanting to gain access to decision-makers to claim that addressing the needs of their sector is a sure way of doing what is best for the economy in general. In theoretical terms, it is a classic case of a particular fraction of capital being able to project its interests as indistinguishable from those of capital in general alluded to above.

Thirdly, we should also note that many of the major commercial players in the biotechnology market are large chemical companies such as Monsanto and Du Pont that have a long and established history of working with regulators in different political jurisdictions. Far from being newcomers to the "game" of regulation, therefore, these firms are strongly embedded in important policy networks within and outside government and are situated within established wider social networks which bring industry and government personnel together (Miliband 1973). The people the firms employ as lobbyists and in their regulatory affairs divisions are therefore known to regulators from frequent interactions across a range of issues facing the chemical industry.

Fourthly, and perhaps most importantly is the fundamentally private-sector driven nature of the "gene" revolution. Whereas the last "green revolution" in agriculture was heavily managed by public sector research institutions, the biotechnology revolution, in terms of scientific discovery, production and distribution, is largely a result of innovation and capital in the private sector. As is often noted in debates about biotechnology, the balance between actors and their authority in the public and private spheres has been significantly reconfigured in favour of the private.

3 Explaining and assessing regulation

In the next sections of the paper, we assess the capacity of different approaches to the regulation of genetically modified (GM) crops to effectively manage the social and environmental risks associated with the technology. We start by examining the mechanisms of public regulation that have evolved to date at the national, regional and international level. We argue that public regulation suffers from a number of flaws and limitations and fails to address key public concerns about modern biotechnology. We argue that these weaknesses may be attributed, in large degree, to the influence of the biotechnology industry over the policy-making and regulatory process. Biotechnology regulations have responded more to commercial and trade concerns than to public anxiety about environmental and social risks. In this sense, much contemporary regulation provides *regulation for* business rather than *regulation of* business.

In the following sections, we argue that the perceived limitations of public regulation have prompted civil society actors to resort to alternative means to contest the commercialisation of GM crops in order to influence debates about the appropriate scope and scale of regulation, and to put pressure directly on biotech firms. These means include the use of civil liability litigation, direct action against GM crops and trial sites, and forms of "civil regulation". We examine what contribution these techniques and strategies make to the overall regulatory environment and argue that they help to plug "governance gaps" in the existing public regulatory system, as well as perform broader political functions. These broader functions include democratising and politicising the biotechnology debate by challenging the hegemony of prevailing scientist and technicist discourses, and drawing companies into a debate about their social responsibilities as well as economic rights. Our aim in these sections is to critically assess the role of these strategies in holding the biotech companies to account for their actions and providing for the more effective regulation of business.

4 Regulation for business

The scope of regulatory activity in relation to crop biotechnology covers areas as diverse as the regulation of laboratory research, intellectual property protection, oversight of field trials, the trade in genetically modified organisms (GMOs), issues of food and feed safety, and product labelling. The structures that exist to regulate genetic technologies include 'a mass of legal regulations, non-legal rules, codes, circulars, practice notes, international conventions and ethical codes' (Black 1998: 621). These are generated and overseen by an enormously complex set of advisory bodies, committees, professional bodies and industry associations operating at the international, national and sub-national level. In 2000, the Cartagena Protocol on Biosafety, the international agreement on the management of international trade in GMOs, gave new impetus to many governments to develop national biosafety laws. However, many had developed their own regulations independently during the 1990s. A key point of contention in the biotech debate is how far existing regulations, for example those relating to chemical pesticides, are sufficient to cover the potential risks arising from GM technologies. In this regard, the United States and the European Union have taken strikingly different approaches to the development of regulatory regimes for GM crops (Cantley 1995; Dunlop 2000; Endres 2000), and these two approaches have emerged as predominant models that frame the global debate on regulating GMOs.

The US adopted a product-oriented system which focuses on the characteristics and intended use of the end product rather than the recombinant technology deployed to create it. The US stance has been to regard GM crops as products that are "substantially equivalent" to their conventional counterparts, and that therefore they pose no special risks, such that regulatory oversight is left to the authority of existing laws and agencies. Under the second broad approach, adopted by the EU, regulatory oversight of a GMO is triggered by the genetic engineering process by which it was created (Cantley 1995; Dunlop 2000). This process-oriented approach regulates all products that have been produced using modern biotechnology techniques. EU regulation implements this approach by requiring prior consent and risk assessment for every proposed release, applying broad ecological criteria on a case-by-case basis both before and after a GM product's release into the environment or a market (Dunlop 2000: 151). This precautionary approach means that controls are put in place even in the absence of definite information about the risks posed (Black 1998: 629).

Despite these differences in approach, broadly speaking, regulation performs three key and closely related functions in the biotechnology context. These are (i) risk management (ii) facilitating commercial transactions and (iii) generating public trust in the new technologies (Newell 2002). While these functions overlap in practice, in this section we argue that the imperative of facilitating the commercialisation of GM products has been allowed to override a fuller consideration of the potential environmental and socio-economic risks associated with GM crops. This has undermined public trust and confidence in the regulation of biotechnology products.

Any public regulatory system designed to establish and enforce environmental safeguards is likely to have weaknesses that undermine its effectiveness or legitimacy. Some may be peculiar to developing

countries, where capacity and resource issues represent serious constraints. Others may be related to the nature of the technology in question, or the strategic importance attached to it by the state or by industry. Collectively, these factors help us to understand the limits of effective public regulation and provide the context for understanding the alternative strategies adopted by opponents of biotechnology, who perceive existing forms of public regulation to be weak, poorly enforced and corrupted by private interests. We discuss these factors in turn below.

4.1 State capacity

Governments and regulatory authorities everywhere struggle to keep up with the pace and fluidity of change in the biotech sector. Regulatory systems are slow to evolve and modify, and governments often react to technological change in the private sector rather than drive it. The practical difficulties of tracking the cross-border trade in GMOs, monitoring where such crops are being grown and enforcing biosafety regulations at farm level presents technical, logistical and administrative challenges to even the most developed countries. Human and financial constraints magnify these problems for developing countries. A related issue is the ability of biotech companies to evade the regulatory authority of governments. NGOs in particular have expressed concern that developing countries, which may lack the resources and capacity to oversee field trials and enforce regulations, may be viewed by biotech firms as attractive regulatory havens (Brac de la Perriere and Seuret 2000). There have already been allegations that GM crops have been grown illegally in parts of sub-Saharan Africa, Latin America and South and East Asia. In India recently, *Bt* [1] cotton was found to have been cultivated without authorisation in the state of Gujarat (Srinivas 2002). The cotton seed in question was supplied by an Indian seed company which appeared to have back-crossed illicitly-obtained GM cotton into Indian cotton varieties. The story highlights the degree to which the capacity to carry out micro-surveillance at farm level is required both for the enforcement of biosafety laws and for the effective protection of private companies' intellectual property.

The issue of capacity building for the effective management and enforcement of a national biosafety system has therefore been a prominent issue in the negotiations for the Biosafety Protocol. Many less-developed countries lack an indigenous capacity in biotechnology, but find that they need to implement a biosafety regime in order to deal with the arrival of GM seeds and foods on the international market. They find that importers are seeking permission to bring GMOs into their countries, while some export markets are demanding supplies of credibly certified non-GM foods and feeds. Many developing-country governments have therefore insisted that they require financial and technical support in order to fulfil their obligations concerning the regulation of this trade. In response, industry groups have offered contributions in the form of workshops, training for developing-country regulators, and pilots of software for the Biosafety Clearing House set up under the Cartagena Protocol. It is difficult for LDC governments to turn down such offers of support from the private sector, even if most are alert to the risk of being influenced by such forms of support. For its part, the industry is cautious about providing direct financial

[1] *Bacillus thuringiensis*, shorthand for an insecticidal toxin.

support for individual countries to conduct their national biosafety policy processes. Although industry executives are concerned about the stigma that may be attached to corporate funding, they are also reluctant to meet developing-country requests for financial support unless they also have some assurance that the industry's views and concerns will also be taken on board. In practice, the decision whether or not to provide financial or other support is generally taken on the basis of a business assessment of the company's interest in the country concerned.

Although corporate representatives and developing country policy-makers are mutually cautious about being seen to engage with one another, the fact remains that LDC negotiators rely heavily on private sector sources for technical information about biosafety procedures and their implications for the trade in GMOs, particularly from grain traders who have accumulated vast experience in this area (Reifschneider 2002). The biotechnology industry therefore uses the opportunity of multilateral summit meetings to circulate briefing notes and press releases and screen audio-visual presentations which LDC representatives are able to collect and review without having to approach an industry representative directly. One industry lobbyist claimed that their materials were generally snapped up by delegates from developing countries but rarely examined by developed country representatives. By contrast, representatives from the countries like the US or member-states of the EU were much more likely to talk directly with industry participants, but clearly did not depend so heavily for information on industry materials.

Biotech firms also question the capacity of some developing countries to manage the demand for approvals of GMOs. Regulators in developing countries, in particular, have been subject to industry pressure to speed up application procedures for biotech developments, to avoid "undue delay". For example, the Indian government has been under pressure to create a "one-stop" approval process, thereby consolidating the existing sequential series of regulatory steps (AIBA Report 2000). Though concerns regarding capacity may be less acute, similar pressures to accelerate the approval process have been applied to countries such as Canada where, 'thorough assessment of environmental hazards and meaningful public dialogue have been sidelined by the imperative to market GE crops quickly and competitively' (Barrett and Abergel 2000: 7). Companies also express frustration at the lack of know-how and experience among government regulators, especially in developing countries, and the delays caused by "excessive" caution of officials responsible for risk assessments and approvals. For example, the company Ciba Geigy expressed their distrust of the competence of the national regulatory authorities in Thailand. Their objection was that the biotech regulations were not understood by all parties, including the public and private sector researchers and government officials controlling and approving experiments. One well-placed observer from an international organisation that we interviewed drew attention to cases from the European experience in which private firms had submitted incomplete, insufficient or erroneous biosafety assessment data to government regulators. In such cases, everything depends on the capacity of the regulatory agency to identify and challenge such flaws and inconsistencies. There is cause for concern about whether regulatory agencies in some developing countries have the capacity to meet this standard.

The biotech industry has also raised concerns over the security and confidentiality of commercially-sensitive data submitted to regulators, especially where decision-making is fragmented across different government departments. In this regard, firms regard with suspicion regulatory scientists who, as fellow biotechnology researchers, are potentially in competition with the private sector. By virtue of being regulators, public sector scientists have access to information and data that may be useful to their own research and would be unavailable by other means (AIBA 2000). In the US and Canada, applicants have made extensive use of exclusions on grounds of commercial confidentiality (Barrett and Abergel 2000; NAS 2002). This is an important barrier to the free sharing of information and, while some information is made public, there remains a tension between transparency on the one hand and protecting the commercial interests of those being regulated on the other (Black 1998: 627). The reluctance of firms to disclose information about their research and development work inhibits a more participatory and deliberative policy process, and therefore forms a barrier to the exercise of broader and more inclusive forms of public scrutiny and control over the direction and applications of the technology.

The question of state capacity also arises in relation to the participation of developing countries in multilateral negotiating forums. It has been observed in relation to WTO decision-making processes in particular that poor countries lack the resources to participate effectively in major negotiations, particularly where a number of sub-committees and working groups, dealing with a variety of specialised technical matters, meet simultaneously in different rooms. The nature of the negotiating process on biosafety issues raises similar concerns. The ICCP (Intergovernmental Committee for the Cartagena Protocol) meetings on the Biosafety Protocol routinely break up into at least two separate working groups to discuss specific issues. A poor country with just one delegate cannot be represented as effectively as a country like the US or a trading bloc like the EU that may have the advantage of a dozen representatives from a variety of government departments, including many experts (scientific and legal) on their delegation.

In an effort to deal with this shortcoming, groups like the G77 or the African Group combine their strength and coordinate their participation in the different negotiations. In doing so, country representatives rely on the ability of delegates from other countries to faithfully represent an agreed negotiating position and provide an accurate report back at the end of a session. Unlike the EU or the Miami Group, which are relatively small and have only to accommodate a narrow range of interests, large developing country groups can struggle to represent a wide diversity of interests, making them unwieldy and difficult to coordinate. One observer of the Biosafety Protocol negotiations pointed out that this tends to mean that the G77 can only agree a very general "lowest common denominator" position. In practice, many delegates who lack expertise or are poorly prepared tend to defer to a handful of delegates who have sufficient experience or knowledge to develop a coherent negotiating position. For these reasons, the Ethiopian delegate Tewolde Berhan Gebre Egziabher is almost universally regarded as the leading representative of the African Group and G77 and frequently attracts criticism for his ability to set agendas for the whole group.

4.2 Public regulation for private interests

Businesses benefit from clear and transparent regulations that help to make their activities more certain, stable and predictable, enabling them to make more informed, confident investment choices. Regulation can bring order to commercial interactions and lower transaction costs, as well as confer legitimacy upon business transactions. Internationally, harmonised regulation can reduce barriers to trade by creating common standards and rules of conduct, and prevent the growth of obstacles to investment. However, firms also want regulatory procedures that are quick, entail low transaction costs and create minimal interference with their commercial goals. For these reasons the private interests that are meant to be the subject of public regulation have been proactively shaping the form and scope of that regulation.

Businesses are often keen to ensure that decision-making is as technical and devoid of political conflict as possible. Therefore industry has expressed concern about widening the regulatory circle too far, both in terms of the actors involved and the range of issues considered. For example, during the negotiation of the Biosafety Protocol, industry sought to resist the attempt by countries such as Ethiopia and Malaysia to insert language that would have allowed states to evaluate the socio-economic impacts of GMOs in their risk assessments (Newell and Mackenzie 2000). While the European Commission conceded that, in special cases, it may consider socio-economic aspects of the technology, the European biotech industry has insisted that product regulation should 'assess only safety, quality and efficacy for man and the environment on the basis of objective scientific criteria' (Levidow and Tait 1995: 134). 'From industry's standpoint social need [for the technology] should be determined by the free choice of consumers in the market' (ibid).

One of the ways in which firms have sought to restrict the scope of systems of public regulation for GM crops, is by invoking international trade rules (Newell 2003). Where GM risk assessments do not conform to industry's preferred standards, and especially if they are considered to include "political" elements, they are prone to be condemned as "illegitimate" trade barriers. For example, US industry spokespeople have attacked the EU's de facto moratorium on GM crops as a WTO-illegal restriction on trade. From industry's perspective, the WTO has the advantage that its dispute settlement mechanism can adjudicate on trade disputes and gives priority to trade considerations in all its deliberations. An essential feature of this approach is that regulation on environmental and food safety risks should be founded on the principles of "sound science". For example, the Technical Barriers to Trade (TBT) and Sanitary and Phyto-Sanitary (SPS) agreements of the WTO stipulate the use of "sound science" criteria as the only legitimate basis on which risks may be invoked as grounds for restricting trade. This narrows the opportunities available to countries to justify restrictions on trade according to other criteria. From an industry point of view, the appeal to science is also key to public credibility. As Roger Krueger of Monsanto also notes 'There was a strong belief within the biotech industry that sound science would drive consumer acceptance of products' (Krueger 2002: 3).

The appeal to trade rules also reinforces the effort to harmonise risk assessment procedures internationally. Increasingly there is a set of global pressures for establishing common means of

identifying and managing the risks associated with GM products, that emanates from the OECD, the "Miami group"[2] and leading companies in the biotech sector. Mansour and Bennett claim;

> Manufacturers are already bedeviled by a maze of conflicting, counter-intuitive and often useless regulatory certification documents in more than 150 jurisdictions around the globe that serve to do little more than . . . that which the worlds' food manufacturers already do on their own initiative-test and self-certify the safety of their products (2000).

As a result, the biotech industry has lent its support to initiatives such as the OECD guidelines, which are aimed at reducing barriers to trade by making regulatory requirements more transparent, predictable and universal, thus helping to reduce transaction costs for business (OECD 1992). As Levidow *et al.* note (1996:140), 'harmonisation efforts gained impetus from many sources: from free-trade imperatives, from applicants operating across national boundaries and ultimately from marketing applications, which stimulated regulators to try to reconcile their data requirements.' The way in which particular approaches to regulation and risk assessment are reified as an appropriate model for the world has important implications for the policy discretion of developing countries that are expected to accept and endorse these standards. Scoones (2002: 17) shows how the 1993 guidelines issues by the State Science and Technology Commission in China followed OECD guidelines and how guidelines produced by India's Department of Biotechnology draw both on OECD guidelines and those of the US Department of Agriculture's, Animal and Plant Health Inspection Service. The issue is not just one of the transferability of regulatory models where, as Jasanoff argues, 'Transplanted to other national decision-making contexts, risky technologies are exposed to different underlying conceptions of causation and control as well as to different cultural attitudes about the trustworthiness of regulatory authorities' (2000: 279). Instead, as Scoones argues 'with the pressures to conform to the emergent globalised market system, science is employed . . . to generate standardised procedures and processes which serve a particular form of global capitalism and particular regional industrial and political interests' (Scoones 2002: 14).

The use of "scientific" principles, which compare the novel aspects of technologies with what we already assume to be safe, has been one device for projecting confidence that any undesirable effects are under control. For example, the principle of "substantial equivalence" (SE) is used to compare the risks associated with products containing GMOs with those produced with traditional plant-breeding techniques. It is designed, not as a substitute for risk assessment, but rather as a means to provide reassurance that a new food product is comparable in terms of its safety to its conventional counterpart (Barrett and Abergel 2000). The OECD has sought to get SE accepted as an international regulatory concept by establishing a programme on the harmonisation of regulatory oversight in biotechnology. The idea is to provide policy-makers with science-based and predictive capacities in any political and ecological setting, thereby encouraging harmonised regulations that facilitate trade. For Michael Osborne of the

[2] The Miami Group was made up of the US, Canada, Australia, Argentina, Uruguay and Chile.

OECD, 'This harmonisation process provides significant savings for countries by avoiding duplication of scientific trials and creating mutually acceptable best practices among regulators' (Scoones 2002: 13).

In the European context too, efforts at achieving a harmonised approach to biosafety regulation are driven by the broader political and commercial objective of creating a single market. The EC Deliberate Release Directive (90/220) explicitly constructs procedures to 'complete the single market', helping also to address industry concerns that divergent regulatory regimes would hamper access to the European market. European regulators were under pressure from industry groups claiming that companies would shift R&D investment to North America if product approvals were unduly delayed (Levidow, Carr and Wield 2000: 192–3). Differences in implementation of the European model of harmonisation by individual member states are thought to produce a 'different harmonisation model' rather than a deviation from harmonisation per se (ibid).

The concept of "familiarity" is also used in many regulatory regimes for the dual purposes of projecting confidence in the regulatory process, as well as facilitating the trade in GM products. It has been incorporated into the regulations of several countries as a "trigger" for risk assessments. Because the only way to gain familiarity with commercial releases is by allowing for commercial releases, 'familiarity closely binds regulatory oversight with industrial interests and market imperatives' (Barrett and Abergel 2000: 10). These authors find that in practice both substantial equivalence and familiarity, 'support decisions to de-regulate genetically engineered crops by promoting biotechnology as an innovative and competitive technology, while simultaneously downplaying concerns for environmental hazards' (ibid: 2). For them, familiarity and SE function as a type of 'international currency that facilitates the trade and exchange of genetically engineered crops' (ibid: 3). The principles act as powerful gate-keeping tools, in so far as risk assessments are only mandatory for GM crops not considered to be familiar or substantially equivalent. Ironically, of course, while trade barriers are to be removed on the grounds that there is essentially nothing new about GM products, for the purpose of protecting intellectual property, they have to seen as novel and innovative.

The high level of start-up capital that is required in crop development drives companies to seek intellectual property protection for their investments from public regulators. This is in order to cover the substantial research and development costs of crop innovation and, for many firms, to satisfy the demands of venture capitalists, on whom they are dependant, for start-up money, for a short-term return on their investments. Biotech firms claim that intellectual property protection is crucial to their business strategies, such that 'Implementation of a regulatory framework and administrative procedures to ensure the protection of intellectual properties, are a vital prerequisite for economic development through innovation' (Aventis 2000). This commercial imperative explains the support biotech companies have lent to the TRIPs[3] agreement of the WTO which requires member countries to put systems of patent protection in place at the national level. Susan Sell (1999) has described how major US-based transnational

[3] Trade-Related Intellectual Property Rights Agreement.

companies stimulated demands for the TRIPs agreement and at the same time mobilised their "home" governments to apply bilateral pressure on "host" countries to tighten and strengthen their national patent regimes.

Regulation for business brings other commercial benefits for firms. For example, Miller (1999) argues forcefully that major biotech companies have lobbied for more restrictive regulation than could be justified on "scientific" grounds, in order to create a market-entry barrier to smaller competitors, that are less able to afford the costs of compliance. Moreover, as Levidow and Tait suggest, 'Even those who downplay the risks favour such regulation, if only in order to establish clear rules for commercial competition and to allay public fears' (Levidow and Tait 1995: 132). In this regard, the biotech firm Aventis[4] notes the potential usefulness of labelling: 'Aventis supports labelling of GMO produced food products, viewing it as a fundamental step in the future acceptance of biotechnology and genetically improved foods' (Aventis 2000a).

4.3 The mutual interests of business and the state

The nature of the relationship between the state and business is crucial to understanding why governments have been so responsive to the pressures and demands made by biotechnology companies of public regulators that we have described above. The relationship is intensified in the case of biotechnology because the interests of industries coincide strongly with governments' own definitions of their national interest, envisaged as generating growth through hi-tech development in the biotech sector (Levy and Newell 2000: 13). The biotech industry has been able to present itself as a key component of the knowledge economy, invoked as a major driver of growth by both European and North American governments, especially the US and UK. To encourage companies to engage in biotechnology R&D, governments have provided a range of financial incentives, soft loans and other subsidies, supportive infrastructure and policy frameworks, as well as sponsoring public-private partnerships.[5] In many countries of the South too, high hopes are invested in biotech to deliver rapid growth. Srinivas notes how in India 'State governments are encouraging biotechnology as an industry and are offering many facilities . . . Karnataka and Andhra Pradesh . . . view biotech as an essential part of the knowledge economy and are all out for promoting biotechnology and genetic engineering' (2002: 156).

Leading individuals within the policy process have also used their positions to support the development of the industry. UK Science Minister Lord Sainsbury, for example, with his own commercial interests in biotechnology companies, produced a report advocating support for the development of "biotechnology clusters".[6] There is also evidence of a "revolving door" between the biotechnology industry and government agencies. In the US, for example, government officials have moved into industry jobs and vice versa (Ferrara 1998). While Val Giddings went from being responsible for biotechnology

4 Now part of Bayer.

5 See Gottweiss (1995) on the extensive efforts made by governments in Europe and the US to promote biotechnology as a technology key to growth.

6 'Biotechnology Clusters' report of a team led by Lord Sainsbury, Minister for Science, August 1999.

regulation within the US department of agriculture and part of the US negotiating team in the biosafety negotiations to become Vice President for Food and Agriculture of the Biotechnology Industry Organisation, Michael Taylor, the FDA's deputy commissioner for policy and responsible for drafting the labelling guidelines on GE cattle drug rBGH, was formerly Monsanto's lawyer for seven years (AgbioIndia 2002). There are important implications here for governments' responsibilities as regulators, when promoting an industry is equated with removing regulations. The Thatcher government in the UK, for example, issued a White Paper stating the government's desire to support the biotech industry by removing 'regulatory constraints inhibiting biotechnology development, such as the burdensome health and safety regulations' (Gottweiss 1995: 205).

The degree of industry mobilisation around the GMO issue also helps to account for the distinct regulatory approaches that have emerged in the US and Europe. While in the US during the 1980s the industry was already pressing government officials on biotechnology regulation, in Europe the biotech lobby came together too late to influence the 1990 European Directive on deliberate release (90/220). 'The very existence of directive 90/220 undoubtedly reflects the absence, for most of the 1980s, of any powerful biotech lobby organisation in Europe' (Dunlop 2000: 152). Consequently the European industry organisation EuropaBio spent most of the 1990s attacking what they refer to as "Catch 220" and its protracted approval processes. By contrast, Dunlop attributes the US regulatory focus on end products to the 'undeviating pro-product pressure from both the scientific lobby and that of the biotech industry' (Dunlop 2000: 151). FDA policy did not require companies to submit their products for review prior to marketing, opting instead for voluntary consultations on safety and regulatory issues. It was not until 2001 that the FDA published a proposed rule to replace the current voluntary consultations with mandatory pre-market consultations and many commentators feel that 'the switch from voluntary to mandatory consultations should not dramatically impact current industry practices' (Belson 2000: 8). The public mood in Europe makes it more likely that a precautionary approach will be retained, however, despite industry claims that wealth creation is being stifled by process-based legislation, putting the EU at a competitive disadvantage in relation to the US and Japan in particular (Levidow *et al.* 1996).

If there is to be any convergence between the two regulatory approaches, the initiative may well come from industry itself. Increasingly, biotech firms on both sides of the Atlantic are organising to press for similar approaches to regulation in Europe and the US with a clear preference for product-oriented rather than process-oriented regulations. As long ago as 1998, AgrEvo's[7] CEO Dr Gerhard Prante urged an audience of 100 high-level politicians and government officials to 'seize the chance to "harmonise" regulatory frameworks internationally (presumably down to the US standard), before differences had time to solidify' (Corporate Watch 2000). Companies are now coordinating their lobbying internationally through transatlantic business dialogues which bring together senior public regulators in Europe and

[7] Later part of Aventis, itself now part of Bayer.

North America and leading industrialists from the biotech sector (Levy and Newell 2000). Their efforts are aided by the increasingly trans-Atlantic integration of biotechnology investment (Levidow *et al.* 1996: 140).

Similar to the story in Europe, industry coordination at the international level was initially poor. One industry lobbyist who has followed the Biosafety Protocol process since 1995 described to us the industry's performance in consultation meetings with policy-makers as "embarrassing". In 1997, industry representatives were invited to a meeting with representatives of the EU, but neither side was well-prepared. The EU bureaucrats had arranged the meeting as an opportunity to the industry to represent their views, but the industry representatives had expected merely to be briefed on the EU's position. There was no coordination among the industry representatives and none of them felt they had a mandate to speak on behalf of the group. The corporate executives left the meeting with the feeling that they had performed badly and needed to be better organised in the future (Reifschneider 2002).

Today, firms are key actors in the international institutions engaged with the biosafety issue. Much of the capital and knowledge about GMOs is tied up in the private sector and so it is unsurprising that those with the expertise and whose products are the subject of regulation, are heavily involved in the international governance of crop biotechnologies. For the purposes of presenting a unified position at the international negotiations on biosafety, national and regional industry bodies formed a Global Industry Coalition in 1998. The coalition brings together groups such as EuropaBio, BIO (Biotechnology Industry Organisation (US)) and the BioIndustry Association (UK) and works closely at national level with organisations such as the 'All India Biotech Association' that have played a prominent part in articulating industry concerns within state level policy processes.[8] As a result of these forms of political mobilisation and the expertise and financial clout of the firms that underpin them, the biotech sector provides further evidence of what has been called the 'privatisation in the United Nations' (Lee, Humphreys and Pugh 1997), where standard-setting is increasingly conducted by corporate representatives, working alongside other governmental and non-governmental specialists. For example, industry groups have played a key role in the work of the Codex Alimentarius Commission and the Intellectual Property Committee of the WTO, where the life science industries are 'hugely influential' (Barrett and Abergel 2000: 10). Multinational corporations and trade associations are aware of the role that Codex has been given by the WTO agreements as the organisation through which disputes over trade in food products may be resolved (Mansour and Bennett 2000). It is notable, however, that the work of Codex on labelling, that has been strongly opposed by many industry groups, has been slow to develop as 'narrow technical issues, once only of interest to specialists, have become public policy issues of huge economic importance' (MacKenzie 2000). 'After eight years of deliberations . . . consensus among members on such standards remains elusive' with basic issues such as what is to be labelled and when a label may be necessary, unresolved (Kalaitzandonakes and Phillips 2000: 1). At the national level too, 'Development of relevant

[8] Interviews in India with AIBA and with industry representatives at ICCP2, Nairobi.

legislation has progressed with glacial speed, standards are often only partial, implementation remains spotty and in most occasions and enforcement is weak if present at all' (ibid: 2).

The prominent role of industry groups in building the capacity of governments to engage in the trade in GMOs, and working with the GEF[9] on pilot biosafety programmes, also indicates a high level of engagement. The Biosafety Protocol itself reads in places rather more like an investment agreement for biotechnology, confirming the entry and exit options of MNCs, than an environmental accord. This is attributed by some observers to the influence of biotech firms on the positions of key players in the negotiations, such as the US and Canada from the Miami group, in ensuring that the agreement was consistent with the free trade principles of the WTO (Stabinsky 2000). Key to performing this role has been a degree of organisation and cohesion among leading firms involved in the process which has grown over the course of the negotiations (Reifschneider 2002). At the first meeting of the Ad Hoc Working Group on Biosafety (BSWG) in Denmark in 1996, private sector participation was extremely limited and companies and associations were unsure about what level of resources to commit to the process. Reifschneider notes that once 'word spread of the protocol and its potential impact on international trade in agricultural, medicinal and other important products of modern biotechnology . . . the private sector contingent grew, became better organised and began to participate more effectively in negotiations' (2002: 274). Though many had to familiarise themselves with the routines and processes of international environmental diplomacy, some such as Tom Jacob of Du Pont, could draw on vast experience of attending similar negotiating processes on behalf of firms in the areas of climate change and persistent organic compounds.

There are issues here, however, of representation relating to priority-setting and decision-making within industry associations. Other work on the role of industry associations in international environmental negotiations has found that "global" coalitions are often better at representing the concerns of European and Northern American firms than of the few firms from developing countries among their membership (Newell 2000a). The case of the biosafety negotiations provides evidence of the same pattern. Though representation from developing countries has increased over time, Reifschneider concedes that the Global Industry Coalition is 'Led by association leaders from Canada, the United States and Europe' (2002: 275). Nationally-based firms and small and medium-sized enterprises are also under-represented in these global coalitions and they often lack the resources to track, much less influence, international decision-making processes in their own right. Industries represented in the coalition are principally drawn from seed and pharmaceutical companies, commodity traders and shippers and food manufacturers (Reifschneider 2002: 275).

It also appears to be the case that Southern-based firms, including those which are subsidiaries of or involved in a joint venture with a more powerful TNC, have little opportunity to get their concerns adopted by industry associations that are dominated by large and powerful TNCs based in North America and Europe. Representatives of southern subsidiaries of biotech multinationals expressed to us their

9 Global Environment Facility.

frustration about how the political priorities and lobbying strategies of their firm, and the industry groups to which they belong, are determined. One industry executive from the South also articulated a scepticism about the way in which individuals from southern firms are put in the spot-light, as "voices of the south", mobilised to support the claims made by the parent company about the appropriateness of biotechnology to developing countries. Interviews suggest that the priority-setting process within industry coalitions does not inherently exclude issues that concern southern members, (which include, for example, the impact of GMOs on food security). However, the priorities chosen tend to reflect both the composition of the membership, skewed as it is towards the North, as well as the superior access which Northern firms have to both strategic information (legal and scientific) and the channels of influence necessary to articulate industry interests effectively.

This balance of power also tends to be reinforced by the role of key individuals within industry organisations, who tend to have a perspective which reflects that of the dominant Northern member-companies. Individual lobbyists (employed by or on behalf of the industry association collectively) or executives (delegated by their companies), are responsible for tracking the negotiations, feeding back and consulting members about developments, coordinating meetings, email discussions and telephone conferences, and elaborating new positions for the coalition. These individuals therefore have a strong influence over the agenda-setting process. Some individual firms seem to be better equipped to engage with this type of process than others. For example, Monsanto South Africa is apparently the only TNC in that country which has a dedicated person dealing with Government Affairs, while DuPont is unique in employing a senior executive whose major function is to monitor and engage with international policy processes on behalf of his company. Because of their depth of experience and acknowledged expertise, these individuals tend to be deferred to by other personnel both within their own firms and by other companies in the sector and, as a result, are able to exercise significant influence over the policy stances taken by, not only their firm, but by the industry as a whole.

4.4 Implications for effective public regulation

The limitations of state capacity, pressure from the private sector and powerful governments, the constraints imposed by international trade rules and demands for harmonisation, and the tendency of many politicians to equate key strategic national interests with the interests of private companies, raise questions about the extent to which public policy-makers can exercise a degree of autonomy to determine what regulations are appropriate and desirable for their own country. Again, because of their economic weakness and dependence on firms for inward investment and aid from donors in GMO-exporting countries, the autonomy of developing countries is likely to be particularly circumscribed.

One key challenge is the apparent tension in the politics of regulation, between the potentially conflicting goals of promoting a strategic industry and, at the same time, regulating the ecological and social impacts of that industry. This tension between governments' role as *promoter* of biotech and *protector* of the public interest is manifested in competing bureaucratic mandates. In Germany, for example, these functions are also combined in a single law, affirming 'the state's presumed capacity to undertake these

potentially conflicting tasks without compromising the rights or values of its citizens' (Jasanoff 1995: 323). As states have sought to reconcile these tasks, Gottweiss argues that '[r]ather than inhibiting genetic engineering, the emergence of risk and its regulation turned out to be critical for the diffusion of the new technology into research and industry' (Gottweiss 1995: 153), driven, in the European case, by a fear that the US was stealing a commercial lead.

The extent to which this tension will impact upon the effectiveness of public biotechnology regulation will depend partly on the extent to which a government has sufficient capacity for autonomous action. It will also depend on the extent to which there is an active civil society contesting the predominant framings of regulation for business. Nevertheless, the European and Indian experiences suggest that vocal protest movements may be more effective at engaging with consumer concern than they are at re-orienting regulatory systems towards meeting broader notions of the public interest. Concessions may be made, decisions delayed and outcomes contested, but as Levy and Newell show (2000), most regulators have been successful at accommodating dissent and modifying aspects of policy without fundamentally altering systems geared towards meeting the needs of producers rather than consumers of biotechnology products. Those governments that have sought to take a more restrictive stance on the trade in GMOs, such as Croatia and Sri Lanka, have encountered intense opposition from GMO exporters and in many cases have been forced to back down following intense bilateral pressure from the US government, including the threat of a case being brought at the WTO (Newell 2003c). For example, in 1998 Egypt announced its intention to ban the import of GM foods from the United States unless they were properly labelled. Madeley comments, 'The US responded to Egypt's move by threatening to ban all trade between the two countries in soya beans and maize. Egypt reversed its decision' (Madeley 2000: 113). Where countries maintain a unified stance, they are perhaps better placed to resist such pressure. The solidarity of the African Group in the face of an alleged attempt by the US to use the threat of withdrawal of USAID funding to exert pressure on member-countries of the group at a key stage of the Biosafety Protocol negotiations, suggests that this is the case. Nevertheless, the increasing influence of the WTO on the GMO debate may create a degree of lock-in for developing countries that are unwilling to conform to international standards. In the case of Codex, for example, national measures that conform to international standards set by the body are exempt from change while those that deviate from the standard may be challenged and required to change (Kalaitzandonakes and Phillips 2000). According to Mansour and Bennett (2000), developing countries will also rely increasingly on Codex activities and the deliberations of delegates from more industrialised nations for the necessary guidance and information to fill regulatory gaps which derive from their own lack of expertise and financial resources.

For the various reasons discussed here, public regulation is in many respects, at this stage, a blunt and ineffective instrument for managing the social and environmental impacts of biotechnology that reflects the privileging of trade and commercial concerns. We have also seen how the scope and nature of regulations adopted by international organisations are often shaped by market needs and the pressures exerted by market actors. The emphasis of bodies such as the OECD on harmonisation of risk

assessments, as a means to facilitate trade, and the preference of UNIDO for a code of conduct on biotechnology[10] (as opposed to more restrictive and binding regulations), both indicate the ways in which the policy preferences of international organisations and their autonomy of operation are conditioned and affected by prevailing ideologies about what constitutes an acceptable form of regulation, which accord with the preferences of leading market actors (Newell 2003).

5 Regulation of business

Partly in response to the limited scope and effectiveness of public regulation, opponents of GM crops and actors whose interests are threatened by biotechnology have resorted to alternative strategies to contest the policy process and make their voices heard. In the following sections we examine the role and effectiveness of these approaches to regulation that are based on civil society action. These include the tactical use of litigation as well as the various techniques of "civil regulation" which have been used to scrutinise and discipline the conduct of firms (Bendell 2000; Newell 2000, 2001). The key questions here are: What political functions do they serve in the debate? What extra checks and balances do they introduce as mechanisms of accountability on the activities of biotechnology companies, in particular? Through engagement, exposure and surveillance, what extra forms of pressure for compliance do they succeed in generating?

5.1 Liability and redress as elements of a regulatory framework

There is a substantial degree of scientific uncertainty over the magnitude of risks associated with GM crops, and the probability that they will materialise. Given that the theoretical risks have a reasonable foundation, questions arise about what mechanisms may be used to manage these risks and how society should insure itself against possible harm. Equally, the widespread introduction of transgenic crops to agriculture entails a likely redistribution of costs and benefits among the actors in the sector. If transgenic technology is seen to conflict directly with the legitimate and lawful interests of other existing agricultural producers, such as organic farmers, this raises questions about how the state should arbitrate between the players. Who (if anyone) should be held responsible for causing the redistribution of resources and power? Should there be a duty on those responsible (or third parties, or the state) to smooth the transition, mitigate the losses or protect those whose interests are being undermined?

The legal concept of liability provides one way of addressing both of these issues. A liability regime gives rights to injured parties to sue those responsible for causing the harm, and imposes obligations on others to limit the risk, mitigate the harm and provide redress. Liability law is often considered to be merely a mechanism for resolving disputes "*ex post*" and obtaining compensation after damage has already occurred (Wilde 1998). However, it can also help to prevent harm from occurring in the first place, because it creates incentives for both potential plaintiffs and defendants to keep hazardous activities under control. A system of civil liability can therefore contribute to the effectiveness of a regulatory regime by

[10] Voluntary Code for the Release of Organisms into the Environment, 1991.

providing 'an additional sanction for infractions, thus ensuring stronger compliance incentives' (EU Commission Working Paper on Environmental Liability, quoted in Wilde 1998: fn.47). From a public policy perspective, liability rules can also be used as a tool to help strike a balance between competing collective and individual social interests. By allocating responsibility for managing risks and insuring or indemnifying against potential harms, liability rules can alter the distribution of benefits and risks between different actors or groups.

It is because the allocation of legal responsibility entails such important – and potentially costly – consequences that liability is such a critical strategic node in the struggle between the competing interests that are ranged around the application of modern biotechnology in agriculture. The potential legal liabilities for harm caused by GMOs have attracted strategic attention from both proponents and opponents of the technology. For example, the anti-GM organisations, The Institute for Agriculture and Trade Policy (IATP) and Genetically Engineered Food Alert (GE Food Alert), recently issued a report warning US farmers about the risks of being sued by their neighbours for genetic contamination (Moeller 2001). Meanwhile, the US law firm Faegre & Benson has prepared legal briefings to alert American seed companies to the range of possible claims that might arise out of genetic drift, and defences that might be used to resist them (Mandler and Eads 2000).

There are two dimensions to the confrontation over liability. On the one hand, anti-GM NGOs such as Friends of the Earth and Third World Network and organic farmers' organisations such as the UK's Soil Association, are campaigning at national and international levels for the elaboration of a new, special liability regime for GM crops. The fiercely contested struggle over the liability issue has meant that the elaboration of a settled liability regime for GM crops, especially the harmonisation of norms internationally, is proving difficult. In the absence of such a regime, liability claims under existing legal frameworks, such as torts in the United States, are being used instrumentally as a tool for direct resistance against the introduction of GMOs in agriculture.

5.2 Formal public regimes for liability and redress

In accordance with the product-oriented approach adopted in the US, no special provision has been made for civil liability for harm caused by GM crops. 'Neither the regulatory agencies nor citizens may use the various federal laws regulating biotechnology to recover for GMO-caused damage' (Endres 2000: 481). Consequently, those wishing to sue for GMO-caused damage must fall back on existing areas of the law, notably product liability regulation, contract law, and the common law of torts (specifically trespass, nuisance, negligence, and potentially also claims under the theory of "strict liability") (Endres 2000; Moeller 2001). The process-oriented approach in the EU is much more open to the development of a special liability regime. Inevitably, however, the design of such a regime has been controversial and time-consuming. As Wilde has noted: 'It is likely to be some years before any EC environmental liability regime is actually implemented. In the meantime it would be necessary for an aggrieved conventional or organic

farmer [in Britain] to rely on existing common law torts' (Wilde 1998: 167). We discuss the implications of this conclusion in the next section.

At the international level, a liability framework for GMOs is envisaged under Article 27 of the Cartagena Protocol on Biosafety (CPB) (CBD Secretariat 2000) which oversees the "transboundary movement" of GMOs.[11] One of the major struggles over the proposed liability regime is between those countries and interest groups that favour a narrow interpretation of its scope, and those who would prefer a broader construction. A narrow interpretation might limit the application of its liability rules strictly to harm caused to biodiversity and only to GMOs in transit across borders. On the other hand, many developing countries and environmental NGOs are pressing for a more liberal interpretation of the Protocol's ambit that would include a broader range of activities and harms including "socio-economic" impacts (Stabinsky 2000).

The focal points of this struggle can be seen in the discussions that took place during a facilitated "dialogue workshop" that was convened in September 2001, in advance of the second meeting of the Intergovernmental Committee on the Cartagena Protocol (ICCP-2), to discuss the key issues relating to the implementation of the Article 27 liability and redress regime (Meridian Institute 2001). Discussion centred on the question of whether the definition of "damage" under the Protocol would have to be restricted only to damage to biodiversity, or could be expanded to include 'damage to human health, property, other economic losses resulting from [GMOs], and harm to the environment' (ibid: 6). Similarly, participants were divided on the question of imposing liability for legal deliberate releases of GMOs to the environment (as opposed to accidental or unintentional releases), and whether states or civil actors should be held liable for the resulting harm. A related issue was whether the Protocol calls for the elaboration of a new international GMO liability regime, or existing national laws on civil product liability could suffice (ibid: 5, 8). Also controversial was the discussion of the appropriate grounds for liability, with some participants arguing for a "strict liability" regime (ibid: 8, 9).

The principle of "strict" or "no-fault" liability is an area where the stakes are particularly high for the opposing sides in the GMO debate. This principle exists in common-law jurisdictions like the United States and the United Kingdom, and may also be imposed by statute or treaty. Strict liability may be applied to activities that are judged to be inherently hazardous, so that it is not necessary for an injured party to prove fault (e.g. negligence) by the party in control of the activity. It is only necessary to show that damage has occurred and to establish a causal link between the harm and the hazardous activity (see Repp 2000: 616–20). If the Parties to the CPB were to adopt a strict, civil liability regime this could have a serious disincentive effect on firms contemplating commercialising or trading in GMOs. Anti-GMO campaigners may feel that in strict liability they have identified a powerful tool for resisting the commercialisation of GMOs. However, the burden of proof may be prohibitive because of the degree and extent of uncertainty in knowledge about genetic modification, the mechanisms of gene transfer in the

[11] In the Biosafety Protocol, GMOs are referred to as 'Living Modified Organisms' or 'LMOs'.

environment and the complexity of ecological processes in general, as well as the time it may take for damage to manifest itself or be noticed and quantified (Meridian Institute 2001: 8, 9; Endres 2000: 486–91).

The disagreements rehearsed by the participants in the dialogue workshop were reflected in the negotiating positions adopted by the Parties during the ICCP-2 meeting, and also in the positions of lobbyists from NGOs and the biotechnology and seed industries who attended the meeting. For example, WWF circulated a document urging the Parties to develop 'effective provisions on liability and redress as a high priority for the Protocol' (WWF 2001: 4). In particular, WWF called for the provisions on liability and redress to apply the principle of strict liability, to be based on civil liability, and to channel liability to private actors: 'There is no justification for leaving states to assume liability concerning the activities of private parties' (ibid). The Global Industry Coalition, a lobby group representing biotech and seed firms, intervened during one of the sessions on liability to argue that, since the CBD and the CPB are agreements between states, the responsibility for liability and redress ought to rest with states. In the event, the Parties were unable to agree on the substantive issues during ICCP-2, and instead worked to develop a process for elaborating a liability regime (CBD Secretariat 2001: 10–12, 27–9). The debate on the possible contents of a transnational liability regime, therefore, continues to unfold.

5.3 Liability as a tool of resistance: litigation in North America

In the absence of a statutory liability regime that addresses public concerns, private actors are resorting to existing regimes of civil liability law and public law as alternative methods for raising their objections to GM crops and defending their interests. These private actors include those campaigning against GM technology on principle, as well as interested parties such as organic or conventional farmers who claim their rights or interests have been damaged by GM crops. For example, at the time of writing, several private liability (tort) cases have been brought or are being considered in the US and Canadian courts, by producers of organic or "conventional" crops who have been affected by "genetic drift".[12] Tort is a branch of law that provides redress for wrongs or injuries caused by a breach of legal duty to do or refrain from doing something. It derives from the English common law, a body of traditional law developed by the courts, consisting of principles which are embodied in precedents set by previously decided cases. Duties and liabilities under tort law therefore exist independently of statutory provisions that provide for civil liability.

The North American tort cases include class action cases against Monsanto and others in North Dakota, Minnesota, Iowa and Illinois in the USA and Saskatchewan in Canada (Agence France Presse 2002; Cropchoice.com 2001, 2001a; Knight 2000; Kossick 2002; Shadid 2001), as well as a counter-suit filed by the Canadian farmer Percy Schmeiser in his defence in a patent-infringement case brought against him by Monsanto (Mandler and Eads 2000: 8). These cases are worth examining for a number of reasons.

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12 The term genetic drift is used to describe the contamination of one crop by seeds or pollen from another, related crop.

Firstly, although the specific provisions of civil liability law differ from one jurisdiction to another, these North American cases serve to illustrate the types of conflict that can occur between interest groups over the introduction of biotech crops. Secondly, they demonstrate how recourse to law is sometimes used as a form of strategic political intervention by civil society groups. Thirdly, they serve as an example that enables us to critically assess the additional forms of regulatory control and restraint that private actors are able to exercise in the North American context. Finally, the global importance of North America as a seed market and as a grain-exporting region, combined with the geo-political weight of the United States in the global biotechnology debate, means that the eventual outcomes of these ongoing legal struggles may have impacts world-wide. Their example cannot simply be extrapolated across other jurisdictions, however. In particular it should be remembered that citizens' ability to resort to the civil law depends on having access to an effective justice system. In developing countries, this factor may be missing or compromised by a lack of resources, corruption, intimidation or a lack of legal literacy.

Suits for torts like trespass and nuisance have certain limitations, including a heavy burden of proof, and are best suited to resolving disputes between farmers and landowners in cases where property rights have been infringed and economic losses incurred. For example, a tort suit may be a suitable vehicle for an organic farmer to seek redress if it can be shown show that the farmer has lost the market for her crops because of genetic drift from a neighbouring GM farm (although if the financial losses are construed to be a "pure economic loss", damages cannot be recovered (Endres 2000: 502–3; Wilde 1998: 169)). But torts are not ideally suited to claims relating to general environmental harm or general public interest claims (see Endres 2000; Mandler and Eads 2000), or for deciding matters of general principle about the environmental release of GMOs. On a procedural level, environmental pressure groups will find it difficult to establish standing in such cases, although instead they may try to catalyse suits by potential plaintiffs and link up with class actions (Mandler and Eads 2000: 15). Class-action cases in North America suggest that this strategy is indeed being adopted.

The tort of "public nuisance" may offer some scope for public-interest groups to challenge GMO releases to the environment. A "public nuisance" may be found where an activity 'unreasonably interferes with the public use of land or . . . unreasonably endangers the health, safety and welfare of the public as a whole' (Mandler and Eads 2000: 13; see also Endres 2000: 491–2). A class action suit alleging a public nuisance, as well as claims under anti-trust law and international customary law, was filed in December 1999 against Monsanto, by the Foundation on Economic Trends (FET) and the National Family Farm Coalition (NFFC) (FET 1999). The suit seeks damages from Monsanto for failing to adequately test GM crops for human health and environmental safety before releasing them onto the market.

The cases mentioned above suggest that tort claimants are targeting the biotech and seed companies rather than the individual farmers who grow the GM crops or the government agencies that are responsible for regulating them. This may be because of the difficulties of proving causation against an individual farmer (Endres 2000: 486–7; Repp 2000: 604), the deeper pockets of major transnational companies as compared with farmers, the lack of insurance cover against genetic drift claims (Gaia Trust 2000; Minnesota Planning 2001; Shadid 2001), or perhaps an unwillingness on principle to hold individual

farmers responsible for the environmental release of GMOs. The latter concern helps to explain the actions of Terra Prima, a Wisconsin-based organic food processor and wholesaler which decided to recall and destroy 87,000 bags of tortilla chips when they were found to contain GM corn. The company sustained a substantial loss including the cost of destroying the affected bags, damaged consumer confidence and ongoing costs involved in instituting new testing procedures intended to avoid similar incidents in the future. However, the affected corn had come from a long-standing organic supplier to the company whom Terra Prima declined to hold responsible. The farmer believes the contamination resulted from cross-pollination from neighbouring farms. Instead of suing their own supplier, his neighbours, or the firms responsible for developing and marketing the GM corn, the company joined environmental and consumer groups, organic farmers, processors and certifiers in a public interest lawsuit against the US EPA claiming that the Agency had violated the law in giving its approval to the release of GM crops (Center for Food Safety 1999; Chase 1999; Cropchoice.com 2001a; Repp 2000: 591).

None of the cases discussed here has yet reached a final resolution and therefore it is impossible to draw definite conclusions about their likely implications. It remains to be seen whether the tensions and stresses exposed by the GMO liability cases may build pressure for the development of more comprehensive and effective forms of public regulation. One possibility is that, by giving the appearance that these new issues can be managed effectively within existing legal frameworks, pressure for reform may be muted, allowing regulators and policy-makers to justify inaction and shelter from controversy. It is clear from the above examples that, in the absence of a comprehensive liability and redress regime for agricultural biotechnology, tort law provides at least a partial and incomplete avenue for those seeking redress. It may also appear to be a relatively efficient mode of regulation because it adapts an existing regime of civil liability, which already provides a framework for settlement of disputes and redress between citizens. However, tort law provides an unsatisfactory framework for determining whether and under what conditions genetically-modified crops may be cultivated. In particular, by framing the potential problems arising from the environmental release of GMOs as essentially disputes between property-owners and market actors, tort rules out a wider consideration of the ethics or ecological risks involved.

The effectiveness of tort as a means of restraining the uncontrolled environmental release of GM crops is very limited. For example, proof of causation is extremely difficult in genetic drift cases. The doctrine of strict liability may help to address this problem, but it will only apply if the courts judge cultivation of GMOs to be an inherently hazardous activity. In addition, it may prove to be relatively easy to mount a legal defence against a genetic drift claim. For example, the farmer may escape liability if he can show that he followed all the relevant agronomic guidelines and took the recommended precautions, such as notifying his neighbours and planting a buffer zone of conventional crops between his GM plants and his neighbours' fields.[13] Similarly, if statutory regulations stipulated what precautions were legally required, a defendant GM farmer would be able to avoid liability if they had followed them, even if the mandated precautions were not actually sufficient to prevent the harm (Wilde 1998). These examples

[13] See Mandler and Eads (2000) for a discussion of possible defences.

illustrate the reliance that courts or legislators must place on scientific expertise to help determine the probability and magnitude of risks and what precautions are reasonable (see Repp 2000: 615). The premises and evidence on which this scientific advice is based must therefore be regarded as critically important. Equally, however, it is questionable whether lawyers and judges are well-equipped to evaluate scientific evidence about risks, or whether a court is the most desirable forum for determining what level of risk society should be willing to accept. The judicial system is insulated from democratic accountability and there is no scope for public consultation regarding the wider implications of a judgement in a specific tort suit.

The decision by some plaintiffs to target the biotech firms instead of farmers or regulators needs to be understood in the context of their broader strategy and goals. If improved enforcement were the main priority, a legal challenge against government regulatory authorities, as in the Terra Prima case, makes better sense. If it were a question of targeting the party with the best ability to pay, then the corporations might be a good bet, except that torts like nuisance and trespass are likely to be easier to bring against neighbouring farmers than the companies that sold them the seed they planted on their land. The decision to go after the biotech corporations makes sense as part of a wider strategy for delaying GM commercialisation, by adding costs, creating uncertainty and generating adverse publicity that frustrates the plans of the biotech firms. Seen in this light, even failed cases matter to the anti-GM campaigners, provided they succeed in causing delay and drawing attention to inadequacies in the current system of public regulation by highlighting issues that have been overlooked or not fully addressed. Complainants also tend to be animated by a strong sense that, regardless of what the law may judge, the biotech corporations ought to accept the moral responsibility for the risks involved in releasing novel varieties into the environment.

The FET/NFFC antitrust case against Monsanto provides a striking illustration of the way that anti-GM activists are using lawsuits tactically as one element in a broader strategy of resistance to GM crops. The press-release announcing the lawsuit makes this connection explicit:

> FET and NFFC are launching a parallel public campaign to accompany this litigation and are quickly reaching out to Civil Society Organisations (CSOs) – farm, environmental, trade, animal protection, health, consumer, and social justice organisations – as well as political parties and government and business leaders to mobilise world wide support. Our aim is both to use the litigation to raise the critical environmental, health and economic issues surrounding GMO food and to secure a court ordered injunction prohibiting Monsanto from marketing its corn and soy.
>
> (FET 1999)

Similarly, the Center for Food Safety uses litigation alongside a range of other activities and campaigns, as part of a wider strategy aimed at securing a strict testing and labelling regime for GMOs, as well as ensuring that rigorous organic standards are maintained (Center for Food Safety 2002). Recourse to litigation should therefore be seen as a useful weapon in the armoury of those resisting the

commercialisation of GMOs, but one which is deployed alongside other methods and tactics of influence and resistance. These are discussed in the next section.

6 NGOs and civil regulation

The last section looked at the extent to which civil litigation strategies can either improve compliance with existing systems of public regulation or generate new mechanisms of regulation. In this section, we consider a range of other strategies that have been adopted by civil society actors, in order to assess the extent to which they can help address the weaknesses we identified with systems of public regulation in section 1. The desirability of such groups performing these "soft" regulatory functions, in terms of their implications for democratic politics, is beyond the scope of this paper and has been dealt with more fully elsewhere (Newell 2000). Our focus here is upon what they contribute to the strengthening of existing systems of regulation or the creation of new forms of "civil regulation".

The term "civil regulation" provides one way of describing the purpose and means of these strategies (Bendell 2000; Newell 2000). It denotes actions taken by civil society actors that have the intention or effect of restraining, regulating or resisting the actions of private actors that are thought to be beyond state control. The boundaries of the concept are loose, but we use the term here to capture pressures and expectations upon firms that force them to act in new ways which go beyond the requirements of compliance with state-based regulation. Other civil society actions of direct resistance to the technology, mentioned below, may express dissatisfaction with the regulatory process but do not necessarily contribute new mechanisms of governance as such. Indeed the intention is often to ensure that the technology is not used at all, rather than better regulated.

6.1 Resistance

Public opposition to GM crops and the regulatory processes by which they have been approved has been expressed in the form of media-friendly spectacles in which activists uproot the crops in full view of watching journalists. In 1999, 28 British Greenpeace activists were arrested and later acquitted for pulling up GM maize plants being tested at a site in Norfolk, UK on behalf of AgrEvo (Greenpeace UK 2002). Activists invoked the notion of "civil responsibility" to justify their efforts to "decontaminate" field sites by removing GM crops (Levidow and Carr 2000: 262). The combined effect of public protests, according to Levidow and Carr was that the two ministers responsible for safety regulation 'sought to accommodate public protest through more stringent regulation' (ibid: 264). Similar actions have taken place in Australia, France, Germany, Ireland, the Netherlands, New Zealand and the Philippines, among others (Goldsmith 1998; MASIPAG 2001; Robson 2002). In India in 1998, the Karnataka Rajya Rysta Sangha (KRRS) initiated 'Operation Cremate Monsanto', in which grassroots activists including farmers, landless peoples and members of "untouchable" castes tore up and burned test plots of Monsanto GM crops (Kingsnorth 1999).

A second, less prominent approach has been to try and undermine the market for GM crops by encouraging farmers to conclude that the benefits are too slight or the risks too severe to justify their use. Good examples are reports by Moeller (2001), which warn farmers about the legal liability risks they assume by planting GM crops, and Benbrook (2001, 2001a), who undermines the claims of the biotech firms about the cost savings, yield increases and environmental benefits associated with their transgenic *Bt* products. By seeking to undermine the demand for GMOs in this way, they aim to impose additional risks, delays and costs on the biotech companies. In doing so, they are taking advantage of the technical, financial and competitive pressures under which the major biotech TNCs are operating. For example, during the late 1990s, adverse publicity and consumer reaction had a damaging impact on the share prices of major biotech firms like Monsanto, AstraZeneca and Novartis. In response to this pressure, company managers instigated a series of divestments and mergers that were designed to insulate their profitable pharmaceuticals and chemicals divisions from their struggling agricultural businesses.

6.2 Confronting public regulation, constructing civil regulation

Some groups have sought to confront the elite and technicist nature of policy discourses around biotechnology by subjecting expert claims to public scrutiny. Groups such as ActionAid have used "participatory" methods to enable poor farmers to assess the professed benefits of GM crops for themselves by cross-examining "experts" from the scientific, corporate and government community. These methods include "citizens' juries" and "scenario workshops", facilitated and organised by NGOs, academic institutions, and involving associations of farmers and landless peoples in Karnataka and Andhra Pradesh (India), Brazil and Zimbabwe (Glover *et al.* 2003). These events have raised issues of power around access, control and affordability of the crops, as well as the provision of compensation if the crop fails to deliver the claimed benefits (Pimbert *et al.* 2001). In doing so they have helped to highlight issues of concern to the ultimate users of GM seeds and contributed to a more inclusive public dialogue about the appropriate social control of the technology. In India, members of the government's Department of Biotechnology attended the meeting to provide an account of government actions and hear the concerns expressed by the jurors. Even if such events do not result in an immediate change in public regulation, they help to create a bridge between the formal and informal regulatory arenas, as well as drawing these broader issues into the public debate through the media coverage they attract.

In addition to engaging with corporations directly and facilitating alternative policy processes, civil society groups have also played an important role as watchdogs for the effective monitoring and enforcement of public biotechnology regulations. In August 2000, Friends of the Earth US was instrumental in identifying the contamination of the human food chain by StarLink, an Aventis variety of *Bt* maize that was not approved for human consumption. The contamination turned out to be pervasive throughout the US food supply. Hundreds of food products had to be recalled, and USDA was forced to institute a massive buy-back programme in an effort to prevent the contaminated seed from being planted (Dawkins 2001; Greenpeace International 2001; Villar 2001). Environmental NGOs claimed the StarLink affair

> . . . showed a major regulatory failure. The tests that detected [StarLink's] presence were administered not by any biotech company, nor by government inspectors, but by a non-governmental organisation.
>
> (Villar 2001: 11)

In December 2001, the British environmental groups the Gaia Trust and Friends of the Earth UK (FOE) demanded action from government regulators when volunteer oil-seed rape plants on a former Aventis test-plot unexpectedly came into flower during mild winter weather, thus breaching the terms of the field-test consent. When the Department of Environment, Farming and Rural Affairs (DEFRA) ordered Aventis to remove the plants, NGOs claimed the credit for having effectively monitored the company's compliance with its permit. Pete Riley of FOE said:

> Quite obviously these sites have not been properly monitored by Aventis, even though it is legally responsible. If it hadn't been for the alert behaviour of a local farmer and Friends of the Earth these GM weeds would still be polluting the local environment.
>
> (Friends of the Earth UK 2001)

An example from India illustrates both the potential weakness of formal public regulation in developing countries, as well as the role of NGOs in demanding enforcement action from public authorities. In November 2001, the Indian NGO Gene Campaign asked the Delhi High Court to order a criminal investigation into the illegal selling of an unauthorised *Bt* cotton variety, "Navbharat 151", in Gujarat. The illegal plantings had been discovered in October, but despite orders from the Government of India that the crop should be destroyed, it was known to have been harvested and sold on the open market. It was feared that the GM seeds had also been marketed in three other Indian states (*The Hindu* 2001; *Times of India* 2001). The cotton seed in the Gujarat case appears to have been obtained illegally by a seed firm. However, the fact that it was possible for the planting to go unnoticed for up to two seasons gives credence to the concerns of environmentalists, consumer groups and farmers, who fear that the whole apparatus of biosafety regulation may be irrelevant if enforcement is practically impossible and GM "contamination" becomes a widespread fact.

Civil regulation should be seen to be as much about contesting the rights and responsibilities of firms as it is about disciplining their activities through legal means, however. NGOs have succeeded in generating a climate of scepticism about the safety of GMOs. Through consumer boycotts, shareholder activism,[14] alliances with supermarkets willing to declare their food-stuffs GM-free and media battles with biotech companies, they have succeeded in drawing companies into a public debate about the environmental and human safety of GMOs and their ability to address the food insecurity of the poor. This has created new demands of the companies and expectations regarding their conduct. Consequently,

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[14] Krueger (2000) notes that while most food making companies received shareholder resolutions calling for a ban on GM ingredients in 2000, all failed to get passed.

many of the companies find that even where they are in compliance with statutory biosafety regulations, they cannot afford to ignore the extra-governmental demands being articulated by media-savvy and politically-influential NGO groups.

Levidow and Carr (2000: 261) show how 'Political protest has led to strategies of precautionary commercialisation' and prompted industry to devise voluntary guidelines to ensure segregation of GM crops and to limit the spread of GM herbicide-tolerance. The voluntary guidelines were developed by the Supply Chain Initiative for Modified Agricultural Crops, a group representing biotech companies, agricultural suppliers and farmers. Toft also shows how in Denmark public concerns regarding risk, sustainability and ethics, issues which 'lay beyond the regulatory expertise [of government]' encouraged industry to accept begrudgingly a voluntary agreement that only GM fodder beet would be grown on a large scale in Denmark in 1999 (2000: 227). Similarly in the case of Germany, Dreyer and Gill argue that while public regulators advocate precautionary measures including market-stage monitoring, these measures do not address the primary demands of critics. NGOs, it is alleged, 'bring up issues of democracy, transparency and precaution through public mobilisation. This strategy results in an anticipated consumer boycott and thereby a commercial blockage of GM products' (2000: 219). In response to public criticism, Monsanto announced its own pledge comprising five elements; dialogue, transparency, respect, sharing and delivering benefits (Krueger 2002).

The media has been a key battleground for the biotech debate, from Monsanto's full-page newspaper advertisements claiming to offer "food, health and hope" to NGOs' success in stigmatising "Frankenstein foods" and "terminator" seeds. The history of the terminator technology is a good illustration of the ways in which NGOs have succeeded in holding companies publicly to account for their actions, where public regulation has failed to. "Terminator" is the label originally used by activists at the Rural Advancement Foundation International (RAFI)[15] to describe a genetically-engineered trait in which a plant is designed to produce sterile seeds. RAFI and other NGOs launched a high-profile international campaign challenging the morality of sterile-seed technology, focusing in particular on its likely impact on poor farmers, who would normally save seed for replanting. The NGOs were able to stimulate a bruising public backlash against companies promoting the technology (Charles 2001), but despite calls for public authorities to ban its use, governments did not act. Instead, various firms publicly and unilaterally declared their intention not to commercialise terminator. They appeared to do so out of fear of the damaging public relations consequences of being associated with a technology that had been so roundly condemned.

Hence, while their behaviour was legitimate in a narrow legal and regulatory sense, company strategy was altered by public protest that was ignited and fanned by media-savvy NGOs. Indeed, from the quiet beginnings of biotechnology regulation, when the regulatory process was essentially an elite, technical and collaborative process that took place out of the public eye (Cantley 1995), NGOs have succeeded in opening it up to the scrutiny of much wider publics. This informal regulation by civil society actors has served to articulate a set of social demands and create normative boundaries within which corporations

[15] Now the Action Group on Erosion, Technology and Concentration (ETC).

are expected to act, providing an extra set of non-legal checks and balances on the activities of companies. In so far as firms internalise the expectations and anticipate the reactions of NGOs and consumers, then a degree of social control over the development of GM technologies can be said to have been exercised, that goes beyond the requirements of formal legal compliance. However, as with civil regulation in general, it fails to meet the tests of predictability and enforceability, operating instead at the level of socially-constructed expectations which companies will find it hard to anticipate and pre-empt (Newell 2000).

In so far as micro-surveillance of GMO testing grounds and exposure of illegal growing by NGOs helps to compensate for the state's own lack of capacity to monitor the trade in and trials of GMOs, civil regulation may be said to lend support to the infrastructure of public governance. Where informal regulatory arenas are created through citizen juries and the like, the basis for new social contracts between firms and publics is created. In so far as firms change their behaviour in light of these encounters, a form of civil regulation can be said to have been exercised that extends control beyond what the public system provides. We may find in the future, however, that firms develop further their own forms of direct engagement with resource-poor groups, rather than have to react to the agendas of those NGOs that claim to be the mouthpiece of the concerns and needs of poorer farmers. Bypassing the role of NGOs as mediators between firms and poorer groups, may allow companies to outmanoeuvre some of the types of "civil regulation" we have described in this paper. There is some evidence that the biotech companies are developing such a strategy of direct engagement. For example, Monsanto has set up a Smallholder Program while Syngenta's Foundation for Sustainable Agriculture is engaging directly with poorer farmers in several developing countries.

7 Conclusion

This paper has explored the ways in which the biotechnology industry has interacted with and been affected by a diverse range of international efforts aimed at "governing" the impact of GMOs on the environment. Drawing on existing work on the role of firms in environmental decision-making in other issue-areas, as well as broader literatures on business influence, we have suggested analytical tools for thinking about the political assets and structural advantages that make companies such key players in the global politics of biotechnology.

We have seen from the above discussion that many of the key international legal instruments and systems of national regulation that have evolved thus far have sought to enhance the competitiveness of the industry, secure intellectual property rights for the innovations undertaken by firms and circumscribe the extent to which the socio-economic impacts of GMOs can be legitimately taken into account. This has certainly made it difficult for developing country governments, in particular, to advance an approach to the management and regulation of GMOs which emphasises food-security concerns, despite attempts by countries such as Ethiopia and Malaysia to do this in the biosafety negotiations. Opposition to the more

extensive treatment of socio-economic concerns in the Cartagena Protocol was led by the Miami group of GMO-exporting countries on behalf of their domestic biotechnology industries.

Developing countries that have sought to adopt a more comprehensive approach to the regulation of GMOs, such as Bolivia, Sri Lanka and Croatia, including proposed moratoriums in some cases, have met with aggressive resistance and sustained lobbying from trade officials from exporting countries, backed with the threat of a case being bought before the WTO. As the preceeding discussion makes clear, the potential for food security concerns to be used as a justification for erecting barriers to trade, is of enormous concern to producers of GMOs and grain traders. The WTO's own bias against the concept is clear in its dismissive definition of the term as a 'concept which discourages opening up the domestic market to foreign agricultural produce on the principle that a country must be as self-sufficient as possible for its basic dietary needs' (quoted in Madeley 2000: 61). It has been shown elsewhere that international bodies that have been vocal on these issues, such as IFAD (International Fund for Agricultural Development), have come under attack from GMO-exporting countries such as the US that have cut their funding (Goodman and Watts 1997). Combined, these practices serve to constrain the scope that developing countries have for autonomous action in this area supportive of national priorities.

To construct a different set of controls on the development and release of GMOs, ones which respond to a different set of priorities, driven by other policy goals, and which potentially place more centrally the food security of the poor, means contesting the current way in which policy is being made and implemented. In an area of high technology, where elite expertise dominates and considerations of commercial confidentiality often make decision-making closed and unrepresentative, opening up the process to broader forms of social control represents a key challenge for civil society. We have shown how civil society actors are responding to that challenge, but it is becoming clear that regulators and enlightened industry players are also having to recognise the importance of greater inclusion and transparency in the policy process as key to the effectiveness and legitimacy of biotechnology regulation. Carr and Levidow (2000) have described how progress towards agreeing and implementing an approval regime for commercialisation of GMOs within the European Union was disrupted because regulations which appeared to have been agreed, did not address key public concerns about biotechnology and therefore failed to resolve controversial disagreements. 'Old controversies . . . resurfaced in new forms. The intractability of the issues suggests that the regulatory procedure . . . had too narrow a focus, leaving outside its boundary many of the more fundamental aspects that cause people in the European Union most concern' (Carr and Levidow 2000: 29).

Similarly, our discussion suggests that the key factor that drives actors to resort to tort litigation, public law challenges, strategies of civil regulation and even civil disobedience, is disaffection with the prevailing modes by which environmental and social risks are identified and managed. This disaffection undermines the effectiveness and legitimacy of public regulation. It contests not only the technical aspects of the process, such as the range of scientific tests and field trials employed to gauge crop and food safety. Much more fundamentally, it raises questions about who gets to make decisions about the future of agriculture, and the appropriate role of new technologies in addressing complex social problems that may

not be amenable to technological fixes. As we saw above, strategies of civil regulation help to place questions of responsibility and liability, access and control and the power to determine levels of acceptable risk, at centre stage.

Civil society demands for a more open and responsive regulatory process pose important questions about the way in which commercial interests and scientific experts are charged with the responsibility for tackling issues that are, in essence, moral and ethical (Levidow and Tait 1995). Underpinning this concern is a breakdown of public trust in the ability of regulatory bodies to adjudicate on the merits of new technologies in the public interest, especially when the boundaries between the scientific community, industries and regulators appear porous at best. This challenge is clearly not exclusive to biotechnology, though in the case of agricultural biotechnology the potential for elite control of the debate about the technology and its implications for society is perhaps heightened. The extent to which there is a crisis of public confidence in regulators of biotechnology depends, however, on whether a country has experienced a crisis in food and agricultural policy, such as the UK, with the BSE and foot and mouth scandals attracting critical scrutiny to the links between government and agribusiness in general. Frequent exposure of the "revolving door" that exists between government regulators and the biotech companies also raises questions about the independence of governments and their ability to simultaneously promote and regulate a business as we saw above. The extent to which governments have their own, clearly-defined agenda on biotechnology and an independent public sector capacity to pursue it, such as China, as well as the extent to which there is democratic space for civil society groups to pursue their own strategies of socially-negotiated forms of regulation, will determine whether civil regulation is able to fulfil the expectations made of it as a mechanism of democratic oversight and accountability.

We also need to be sensitive to the limits of strategies of civil regulation as a vehicle by which to advance a food security agenda in the biotechnology debate, when many of the activities we have described are currently associated with legal battles in the North and the campaigning activities of Northern based civil society groups, that are not in a position to credibly represent southern perspectives in this debate and are, in many cases, not active on issues of food security per se. Development NGOs such as Christian Aid, ActionAid, Oxfam and the World Development Movement (WDM) have drawn attention to the inadequacies of existing systems of regulation, questioned the alleged benefits of GMOs for the poor and raised concerns about concentration in the sector and the patterns of control exercised by biotech multinationals over the farming practices of poorer farmers (through terminator technologies, contract farming and patenting practices) (Christian Aid 2000). Indeed, some groups such as ActionAid have launched campaigns on "food rights" to counter the access and control over genetic resources that they feel biotechnology companies are requiring (ActionAid 2001). ActionAid, as we have already noted, has also been active in constructing alternative political spaces aimed at bringing in the voices of the poor to the debate about the future of biotechnology through their citizen juries. But many of the strategies we have discussed above are currently being undertaken by environmental NGOs, mainly based in the North, and without an active history on food security issues. We should remain sceptical, therefore, about

expecting too much from civil regulation, as a set of strategies for advancing a food security agenda in the international governance of biotechnology.

A key issue is also the interaction between systems of civil and public regulation. From the perspective of many companies, public regulation protects them from the pressure of civil regulation, and certainly provides a more comfortable and predictable arena for companies to negotiate the terms of regulation because of the high levels of access and influence that firms enjoy. Nevertheless, broader public engagement appears both inevitable and desirable, even from the perspective of corporate strategy. Rather than pulling in different directions, civil and public regulation may interact in a mutually supportive way with each approach building on the limitations of the other. While civil regulation constructs new normative frameworks, generates fresh expectations and brings into the regulatory process a wider circle of stakeholders, it can never replace the authority, legitimacy and enforceability of public regulation. In many ways, the regulatory functions that we attribute to public and civil regulation aim to achieve different things. Both can be argued to have the effect of distributing costs and allocating responsibility. Some are clearly meant to encourage or deter particular types of investment, whereas others aim to manage the existing trade and development of GMOs in a balanced and responsible manner. Resort to litigation under the civil law may seek only compensation for victims of harm, that some attribute to a "failure" of public regulation: 'An aggrieved individual may overcome administrative inactivity by taking matters into his own hands and pursuing the polluter in a civil suit' (Wilde 1998: 173). More broadly, civil litigation can be seen to fulfil an intermediate role between the public and private spheres that, when it functions well, can bolster the effectiveness of public regulation while simultaneously providing an avenue for the expression of particular civic interests or concerns.

The future regulation of biotechnology products is likely to be characterised by a complex and increasingly dense and inter-related set of competing pressures to bring the biotech industry into conformity with a broad range of both social expectations and formal regulatory requirements. Firms that perceive themselves to be immune from various forms of civil regulation may find that their intransigence to social pressure harms their public credibility and leads to calls for more burdensome public regulation to discipline their conduct. Even where social expectations eventually translate into state-based regulation, it seems to be the case that pressures on companies to take on a broader range of ethical responsibilities will continue to outstrip those obligations enshrined in law. Hence while civil regulation may have the effect of "ratcheting up" public regulation, the process is an iterative one in which the boundaries of rights, duties and entitlements are always being contested in the courts, in the boardroom and in the media.

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