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Biotechnology and the politics of regulation

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Summary

This paper is a contribution to a research project on biotechnology and the policy process in developing countries. It aims to provide an overview of the issues, debates and ways of thinking about the regulation of third generation crop biotechnologies. Firstly, it looks at debates about the role and purpose of regulation. Secondly, it examines the different approaches that have been adopted towards the regulation of the products of modern biotechnology. This means, in addition to looking at the peculiarities of regulation in developing country contexts, also looking at developments in countries of the OECD and at the international level, as these often serve to establish the appropriate boundaries for regulation within which the rest of the world has to operate. Finally, the paper explores some of the ways of understanding the policy processes by which regulations develop and are enforced.

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Preface

Agricultural biotechnology and policy processes in developing countries Working paper series

Policy processes surrounding new agricultural biotechnologies today involve a wide and growing range of actors, including scientists, government officials, international organisations, local and transnational companies, and farmers' organisations among others. Policy processes occur at different scales, ranging from local negotiations around agricultural technology priorities to global debates surrounding property rights, biosafety regulation and biodiversity protection. Given the rapid pace of technological change and the fast-moving international regulatory environment, developing effective national policy processes is a major challenge. Yet relatively little work has been focused on understanding how particular national and local contexts influence policy processes. Similarly, at the international level, the globalisation of the biotechnology industry has not been matched by the internationalisation of effective regulation. Overall, there has been a lack of critical attention to the way in which the policy processes connecting local, national and international levels can be enhanced so that emerging policies and regulations support the livelihood needs of poor people in the developing world.

This Working Paper series emerges from a series of three interlinked projects which together address these issues. 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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IDS WP145, *Agricultural biotechnology and food security: exploring the debate*, Ian Scoones
IDS WP147, *Science, policy and regulation: challenges for agricultural biotechnology in developing countries*, Ian Scoones

More details of these projects and downloadable versions of all papers in this series and other project outputs can be found at: www.ids.ac.uk/ids/env/biotechpubs.html. For further information please contact: k.hawkins@ids.ac.uk

1 The purpose of regulation

The scope of regulatory activity in relation to crop biotechnology is broad and covers areas as diverse as regulation of lab activities, oversight of field trial sites and rules about the legal protection of innovations in crop technologies. 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. The number of regulatory fora in which issues concerning research, development and marketing of GMOs are dealt with, leads to a significant degree of regulation in this area. Amid this institutional messiness, however, I want to argue that there are, broadly speaking, three key and closely related functions that regulation performs in the biotechnology context. These are (i) risk management (ii) facilitating commercial transactions (iii) generating public trust in the new technologies.

1.1 Regulation through risk management

Different issues confront each attempt to control the production and release of GMOs, but it is notable the way risk has come to be the organising principle for regulation (Black 1998: 624). Even if it is contested outside the regulatory circle, there is little debate among regulators about whether risk is the appropriate frame. Rather, the debate centres on which risks should be the focus of attention. This means that broader ethical questions around the desirability of the technology, or of the power relations it implies, are left off the agenda. Instead, scientific disputes become a surrogate for 'unstated ethical or economic conflicts' (Jasanoff 1995: 325). For Levidow *et al.*, risk assessment is the process by which 'the state defines the problems for which it accepts responsibility' (1996: 136). Implied by it is a 'social contract' that specifies the terms under which state and society agree to accept the costs, risks and benefits of a given technological choice (Jasanoff 1995: 311), even if it is unclear how far society is involved in making that choice.

In this sense, risk management and evaluation is both a means and an end of regulation. It implies a process whereby choices can be made and justified about acceptable risks associated with 'new' technologies. It can both minimise side-effects from the production process and overcome the legitimacy problems of an industrial process. The choice of risks and the approach to assessing those risks are of course contested and politicised, as they imply different degrees of regulation and oversight. For example, existing regulation can appear to be adequate and competent for the task of managing risks associated with biotechnology, because only those risks that can be accurately measured or plausibly known are identified as relevant. Not only does a focus on particular risks imply a level of technical competence, but the forms of expertise that are thought to be relevant in formulating assessments help to determine who is in a position to participate in regulatory choices.

Conventionally, many forms of risk assessment do not question the boundaries and assumptions within which technological development takes place or its' appropriate social function. Moser argues that

'Controversies over risk in biotechnology do not allow one to question the strategy, the understanding of knowledge and the values involved in scientific and technological knowledge production' (1995: 17) because they are understood as questions of 'environmental engineering' or 'scientific management'. This is problematic given that what is at stake 'is not simply a choice of administrative procedures, but also the approach to dealing with environmental impacts: what kinds of previous experiences, and therefore what kinds of facts, should be considered most relevant for anticipating the effects of GMO releases? What would count as adequate knowledge for dealing with ecological uncertainties? What would be the most likely, and acceptable, effects on agriculture.' (Levidow and Tait 1995: 121). Risk, in this sense, cannot be isolated from ethical and political questions about socially acceptable levels of risk, how much uncertainty we are willing to live with and socially negotiated trade-offs between the risks and benefits of pursuing particular courses of action.

Despite this, many regulatory processed are designed in such a way that these broader questions cannot be posed, let alone addressed. Instead regulations often reinforce a division of responsibility whereby environmental risk assessments are determined by 'objective' science, socio-economic effects are decided by consumer choice and bioethics are provided by professional experts (Black 1998). Analyses of regulatory policy processes shows that they are often consciously designed to exclude the possibility of such debates and to contain resistance to the promotion of controversial technologies (Jasanoff 1995). Studying GMO regulation in the UK, Germany and the U.S Jasanoff concludes 'In each country the dominant political framing appeared to rule out one or more of the expected forms of public resistance, thereby ensuring that scientific uncertainty would not spill over into social and political unrest' (1995: 328).

This is, in many ways, how regulation makes a problem treatable and manageable, reinforcing the competence of the regulatory authority to contain risks. Politically and strategically, therefore, regulation can serve to reduce a complex and multifaceted problem to a technical issue subject to expertise and state control. This process has the effect of depoliticising questions about the purpose and social implications of the technology. By rendering the problem a technical one subject to elite expertise, it also takes the problem away from the public.

1.2 Regulation to facilitate commercial transactions

From an industry perspective, in particular, regulation serves the purpose of creating predictability. By providing procedures for approval, articulating expectations and providing time-frames, regulations help firms to anticipate changes and make informed investment choices. Regulation can bring order to commercial interactions and lower transaction costs by creating rules of engagement. This can both stabilise expectations for those engaged in the activity, and confer legitimacy upon commercial transactions. Regulation can reduce barriers to trade by creating rules of conduct and prevent the growth of obstacles to commercial development. The Technical Barriers to Trade (TBT) and SPS (Sanitary and Phyto-Sanitary) agreements of the WTO, for example, call for the use of 'sound science' criteria as a basis for evaluating risks that may legitimate trade restrictions. This narrows the opportunities available to

countries to justify restrictions on trade by other means. This may conflict, however, with the use of the precautionary principle in the Biosafety Protocol, which employs broader notions of risk that do not rely exclusively on recourse to 'sound science'. Differences of opinion on this issue fall broadly along a Europe-North America fault line and reflect both distinct commercial imperatives and competing regulatory ideologies. Reducing the scope for political differences in the way the rules of trade are set is an important aim for the biotechnology industry, in particular. They have leant their support to initiatives, such as the guidelines of the OECD, aimed at developing a harmonised approach to risk assessment which creates a common regulatory environment and reduces the transaction costs of having to meet different standards in different countries (OECD 1992; 1986).

While facilitating trade and supporting infant industries, regulation is also meant to create checks and balances on technological and commercial developments, to ensure that they are not likely to have detrimental impacts on society. Here we encounter an important potential for 'schizophrenia' in the politics of regulation whereby state regulators are expected to promote an industry and, at the same time regulate, the ecological and social impacts of that industry. This schizophrenia is produced by the competing economic roles and public-political duties that states perform. There is a tension between governments' role as promoter of biotech, as a sector with enormous strategic potential, on the one hand, and as protector, adopting regulatory frameworks that accord with broader notions of the public interest, on the other. Jasanoff describes how the functions of protection and production are combined in a single law in Germany, affirming 'the state's presumed capacity to undertake these potentially conflicting tasks without compromising the rights or values of its citizens' (1995: 323). Gottweiss argues on balance, however, that 'Rather 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). In the European context, regulation was driven by a perception that the U.S was stealing a commercial lead. Gottweiss notes that 'developments in US biotechnology were soon to attain a mythical status in the European policy discourse' (1995: 159).

The nature of the relationship between the state and business is crucial here. The relationship is intensified in the case of biotechnology because the interests of industry 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). It is unsurprising then that there is evidence of a 'revolving door' operating between business and government (Ferrara 1998), suggesting a state-capital nexus, albeit one that is continually contested as different fractions of capital compete to present their interests as those of capital-in-general.[1]

Where governments are involved in the development of biotechnology products, they are expected, in effect, to regulate themselves. For example, although companies are key to the development and diffusion of biotechnologies, governments retain a key role in these areas when it comes to public good

[1] Newell and Paterson (1998) make this argument in relation to the influence of the fossil fuel lobbies within national governments on the climate change issue.

technologies, for which there is no short-term or viable commercial market.[2] At the same time, governments are also clearly providing incentives for companies to get involved in research and development of GM crops. Financial support such as tax incentives for research, soft loans and duty-free imports of vital equipment are among the tools used in this way.[3] In addition, tax credits and other incentives are provided for companies to engage in joint ventures and start up local firms, and public procurement and government guarantees of purchase of a given market share can be used a mechanism for stimulating market demand. Effectively, therefore, governments are creating markets for biotechnology products by supporting public-private partnerships and creating the right conditions for GM technologies through policy and infrastructure.[4] 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: 202).

The question then becomes whose interests are being served when regulation is used to create and support industry? In such circumstances, who is regulation for? Using biotech to deliver industrial development and using it address the poverty needs of smaller farmers are two very different goals. The key is how governments attempt to reconcile these two goals or how those goals are prioritised.[5] The outcome, in part, will depend on which part of government is most influential in making policy. For example, Singapore's biotech policy is under the Economic Development Board that has established a special office for biotechnology. The government gives priority to funding the Institute for Molecular and Cell Biology to carry out internationally competitive research and development on biotechnology products. Tensions emerge because different parts of government are interested in different types of biotech research and application. The balance of emphasis on social development, as opposed to industrial concerns, depends, therefore, on the respective influence of the departments most involved in making policy. There is potentially another form of conflict here, where government regulators, including scientists and breeders from the public sector that sit on biosafety committees, for example, may be in competition with private sector firms for access to information about new products and protection of their innovations. This is something that biotech firms have expressed concern about (AIBA 2000).

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2 For example, in the Indian context, while the public sector focuses on rice, cassava, yam, sorghum (staples for poor), the private sector focus is on round-up ready herbicide tolerant varieties of soybean, Bt cotton and Bt corn. There is no significant work in private sector on drought-resistance and salinity tolerance according to Gene Campaign's Suman Suhai (Sahai 2000).

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

4 Nayak (2000) argues in the Indian context that because the country cannot compete with MNCs on the research side, the proper role of government is creating the right incentives for private sector industries to develop commercial biotech projects through tax relief, longer repayment of loans and lower interest rates or credits.

5 In the Philippines, for example, the overriding goals are to improve competitiveness of agricultural products in global markets. This explains the emphasis on export winners such as mango, pineapple, banana.

1.3 Generating trust though claims about control

Building public trust and trust in the policy process is a further purpose of regulation. As Levidow argues 'The consequent debate on risk regulation is as much about containing fears as about preventing environmental harm' (1995: 121).[6] For regulators themselves, it is important to demonstrate competence in responding to the perceived risks associated with new technological developments in order to gain public support for the technology. For businesses too, appropriate regulation is seen as necessary to instil public trust in the products of new technologies such as GMOs. Distrust of businesses' own claims about their products can run high, such that approval by government officials, as 'neutral' arbiters of the risks associated with a product, is crucial for public confidence and market acceptability. Important to building and maintaining this confidence is sustaining the belief that risks can be contained. Invoking metaphors that suggest control and predictability helps regulators to contain potential public unease such that, 'Whichever metaphors prevail in public perception will affect the acceptance of biotechnology, and perhaps in turn the extent of regulation' (Levidow and Tait 1995: 133).

For this reason, groups compete to define risks according to their worldviews. Industries have sought to portray GMOs as precisely programmed, evolutionary extensions of natural organisms that will reduce the need for chemical inputs in agriculture. This is the discourse of benign control. In general, however, the GM debate abounds with 'culturally resonant metaphors about nature being out of control' (1995: 123). The popularity of terms such as 'Pandora's box', 'Frankenstein foods', and 'superweeds' in policy debates bears this out. The perceived irreversibility of GM technologies can be seen in statements by both advocates and opponents of the technology where each buy into the notion that 'the genie is out the bottle'. For environmentalists, the concern is about the uncontrollable spread of 'GM pollution' through cross-pollination, for example. For the biotech industry, rather like the nuclear industry before it, the argument is that a GM-free future is not an option because knowledge of how to develop GM technologies is now 'out there' and cannot be 'unlearned'. Employing this rationale, the World Business Council for Sustainable Development states, 'Biotech is here to stay … no matter how many times laws are passed or how many protest campaigns are launched, no matter which course the ethical debate takes or how consumers choose, whether the industries that have arisen in response to the promise of biotech flourish or decline, someone, somewhere will be opening the box a little wider' (WBCSD 2000: 9). In combating fears about the risks associated with GM crops by appeals to the possibility of control, biotechnologists have argued that GM technologies provide a greater degree of precision and control in the trait expression of plants than many conventional approaches. Indeed the idea of 'switching on' and 'switching off' particular traits conveys this idea. Terminator, or sterile seed technologies, would be an extreme example of how this control can be exercised.

A further device to suggest control is the use of 'scientific' principles which compare the novel aspects of technologies with what we already assume to be safe. For example, the principle of 'substantial equivalence' (SE) is used to compare the risks associated with products containing GMOs with those

[6] See also Shackley (1989).

produced with traditional plant-breeding techniques. The concept of substantial equivalence was developed through a series of consultations initiated by the World Health Organisation and the Food and Agriculture Organisation in the early 1990s. Its 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.

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. The principle of familiarity 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, according to Barrett and Abergel, 'familiarity closely binds regulatory oversight with industrial interests and market imperatives' (2000: 10). These authors find then, that both substantial equivalence and familiarity, in practice, 'support decisions to de-regulate GE crops by promoting biotechology as an innovative and competitive technology, while simultaneously downplaying concerns for environmental hazards' (2000: 2). For them, these concepts serve commercial rather than safety-based goals, whereby familiarity and SE function as a type of 'international currency that facilitates the trade and exchange of GE crops' (2000: 3). They also act as powerful gate-keeping tools in so far as risk assessments are only mandatory for GE crops not considered to be familiar or SE. Ironically, of course, while trade barriers are removed on the grounds that there is nothing new about GM products, for the purpose of protecting intellectual property they have to seen as novel and innovative.

Focussing on near-term impacts is a further device for demonstrating that potential risks can be known and managed. Conventional approaches tend not to view effects beyond an immediate, visible impact on ecosystems, regard long-term studies as an unnecessary burden, and potential harms as restricted to those that are predictable or precedented. Through these devices all uncertainties can be portrayed as controllable risks such that 'the need for further investigation or meaningful public participation is effectively dismissed' (Barrett and Abergel 2000: 2). The process is, in many ways, a private one between applicant and regulator with the latter very much dependent on the integrity of the former. Information submitted is not in the public domain and much of the information is, in fact, confidential business information. Assessments are conducted on a case-by-case basis using information submitted by the developer of a GM crop which draws on private tests and field trials also conducted by the developer. The EPA in the U.S, for example, accepts the lab and field studies of biotech companies, which show no occurrence of harm, as a basis for policy. Voluntary private consultations with the agency before a product is marketed are considered adequate (Levidow 1999; Hammond and Fuchs 1999). This amounts, in many ways, to self-regulation, where product developers determine whether a product is SE and familiar and hence whether it requires a risk assessment. Hence, once again, we find that what is constructed as a

science-driven objective process, exposed to scrutiny, appears to be a politically-directed, though somewhat arbitrary, set of exercises aimed at garnering trust and promoting trade.

2 Approaches to regulation

Given the variety of purposes that regulation serves, and the political and economic importance of the technology being regulated, it is little wonder that regulatory approaches to crop biotechnologies have taken different paths. As Dunlop argues (2000: 149) 'While the release into the environment and marketing of genetically modified organisms – GMOs – and their derivative products, represent issues with global relevance and implications, no singular approach had developed to regulate them in the two decades since gene-splicing technology became commercially-viable'. This reflects the different 'paradigms of assessment and control' (Jasanoff 1995: 313), whereby approaches to regulation reflect and are embedded within distinct frameworks of cultural givens, economic imperatives and institutional structures that differ between countries. Nevertheless, two approaches have emerged as predominant models that frame the global debate on regulating GMOs: those of the U.S and Europe.

Firstly, there is the product-oriented system adopted in the U.S. Here the focus is on the intended use of the end product rather than the recombinant technology deployed to create it. The notion behind this is that all organisms carry equivalent safety considerations, an approach that has allowed the U.S government to claim that existing laws and agencies are sufficient to cope with any novelties of genetic modification. Dunlop argues that this understanding of the technology has been largely secured by the pivotal role of scientists in the US's early regulatory experience and highlights the central importance of the well-grouped scientific constituency that formed around genetic engineering (Dunlop 2000). She notes how the regulatory focus on product was matched by the 'undeviating pro-product pressure from both the scientific lobby and that of the biotech industry' (Dunlop 2000: 151). The IBA (Industrial Biotech Association) and the Association of Biotech Companies (ABC), which were set up in the early 1980s to represent the industry, helped to create an 'organisational defence' in favour of prevailing policy that made it easier to keep political and public challenges in check.

The second broad approach, adopted by the EU, is the process-oriented approach, concerned with the nature of GM technology itself. Dunlop notes;

> 'Under process-informed regulatory regimes, emphasis rests firmly upon formal authorisation along with case-by-case health and environmental risk assessments both before and after a GM product's release into the environment or a market. The (pre-) caution which underpins this approach is reflected in the contingent nature of the legislation it yields with many of the process regulations being characterised by reviews and revision, in response to scientific developments, popular opinion and the commercial world' (2000: 151).

A precautionary approach is one in which risks are assessed in advance and attempts made to reduce or eliminate them. Controls are put in place even in the absence of information on the extent of the risks

posed. EU regulation implements this precautionary approach by adopting a strategy of individualised assessment and approval rather than the formulation of rules which attempt to prescribe in advance what is, or is not, permitted or to set out particular safety requirements that have to be met (Black 1998: 629).

This approach to regulation is more precautionary 'by virtue of anticipating hazards not already documented for GMOs, even prior to any consensual cause-effect model for identifying potential harm' (Levidow 1995: 179). The process-based system regulates all products that have been genetically-modified. In other words, every proposed release requires prior consent and risk assessment applying broad ecological criteria. Regulators had emphasised the genetic novelty of GMOs as a source of ecological uncertainty, and by analogy to harm already caused by some non-indigenous organisms, 'regulators could justify a precautionary approach in 'preventive' terms' (Levidow 1995: 180).

The path towards this process legislation was not a smooth one. In fact, individual European countries and the E.U adopted regulatory tones very similar to the U.S. throughout the 1980s concerning end products and research. The EU drew lessons on research regulation directly from the U.S. The change in Europe's approach derived from political pressure from the European Parliament, which challenged the notion that the identification of research alone is enough. Concerns were also expressed that some experimental releases had already taken place without binding legislation being in place regarding safety, and there was concern that genetic engineering brought with it 'special risks' (Dunlop 2000: 152). Within Directive 90/220, covering the procedures for the approval of new GM products and releases, 'national competent authorities' assess the implications for GMO authorisation on a case by case basis. In contrast to the US, these assessment bodies are often composed of interested parties such as environmentalists (Dunlop 2000: 152). Dunlop describes a key difference in the regulatory philosophies underlying the two approaches; 'The insider status of selected lay actors brings into relief a key difference between the process and product-oriented systems, with critics of the former arguing that it entails more than a straight forward appeal to 'objective knowledge', that is, science' (ibid).

In the European case, the regulatory process also takes on a more transnational dimension in that licences for commercial releases may only be granted with the approval of member states by majority vote where an objection is raised by another country. The EU conducts a fine balancing act between the need for harmonisation and retaining scope for national discretion in its approach to regulation. Dunlop notes (2000: 152) 'while the supranational level ensures EU states are covered by a 'process' umbrella, it is these individual countries which control the manner in which it is implemented. Thus states can give some degree of expression to their own conceptualisation of risk, leading to various strains of process style housed under one roof'. In this sense, EU regulators have had to wrestle with 'divergent norms' that have arisen from national differences in regulatory style and institutional framework (Levidow *et al.* 1996: 135).

The difference in approach between Europe and the US partly reflects the delayed efforts of the European biotech industries to organise themselves to influence the legislation. Indeed Dunlop argues (2000: 152) 'The very existence of directive 90/220 undoubtedly reflects the absence, for most of the 1980s, of any powerful biotech lobby organisation in Europe'. The industry organisation EuropaBio spent most of the 1990s attacking what they refer to as 'catch 220' and its protracted approval processes. Since

then, there has been much discussion of the need for clearer procedures for biotech firms marketing GM products. 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 the process legislation, putting the EU at a competitive disadvantage in relation to the US and Japan in particular.[7]

The biotech industry will doubtless continue to seek to 'minimize regulatory constraints, in particular to treat GMOs as otherwise normal products' (Levidow 1995: 177). They will also argue against European regulations that the BioIndustry Association describe as 'based on old science and reflect concerns that have not proved justified' (quoted in Black 1998: 630). Indeed, 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 U.S, with a clear preference for product-oriented rather than process-oriented regulations. They are coordinating their lobbying of officials through transatlantic business dialogues (Levy and Newell 2000) aided by the increasingly trans-Atlantic integration of biotechnology investment (Levidow *et al.* 1996: 140). Where convergence takes place, GMO regulation may, in turn, facilitate trans-Atlantic capital integration and exports to Europe.

What is apparent from the discussion about different approaches to the identification and scope of risks, is that assumptions made about risks, the nature of the technology and its probable impacts, have a large impression on the breadth and depth of regulation. They help to explain the differences in regulatory approach described above. Levidow (1995), for example, shows how assumptions embedded in ethical frameworks are present throughout the regulatory process. First, regulators draw on different assumptions about biological processes in determining the appropriate scope of risk assessment procedures, for example, by anticipating direct harm from a GMO or inserted genes, not indirect harm from agricultural practices associated with the GMO product. Second, in seeking adequate evidence of safety for each proposed GMO release, regulators 'judge available evidence, seek additional evidence or set priorities for risk research. In so doing they judge whether to treat some hypothetical effects as plausible and/or as acceptable' (ibid: 181). Third, 'in anticipating hazards, regulators draw upon cognitive frameworks for conceptualising genetic novelty and the environment'. Cognitive frameworks inform the range of ecological uncertainty deemed relevant to risk assessment. Fourth, regulators face judgements on the acceptability of unintended effects. Which effects matter and for what reasons? 'The answer to such a question is not simply the evaluative stage of risk assessment because it predefines the types of hypothetical hazards which warrant more research. For risk assessment procedures, a team must first generate possible consequences, then decide which ones are unacceptable and then seek realistic causes for any unacceptable consequences' (Levidow 1995: 181).

Despite regulators claims to the contrary, we find evidence of values guiding fact-finding and the structural interdependence of facts and values. Even if it is often not acknowledged by policy-makers,

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[7] These claims have been challenged on the grounds that competition in the biotech sector increasingly occurs within Europe rather than between the US and EU companies (Levidow *et al.* 1996).

conflicts over the plausibility of different knowledge claims inevitably extend into 'the regulatory procedure which was designed to resolve them' (Levidow 1995: 182). For example, in response to concerns about patent rights on GMOs, the UK Environment Minister said 'We stray into debating the ethical problem again. It has always been easy for me to handle that by separating ethics from the environment and the environment from patents' (quoted in Levidow 1995: 184). This rhetorical device, whereby emphasis is laid upon objectivity and the fact/value distinction, has been a recurrent technique for diffusing public disputes over biotechnology regulation.

Embedded within these different value systems lie distinct approaches to the use of science for resolving regulatory disputes. Industries have attacked the process-based approach to regulation for lacking any rational scientific basis. The product-based system is considered to be preferable because it allows each GMO to be classified according to its product use and assesses it according to its inherent product characteristics. Behind this is the notion that hazards can be objectively identified by knowing the genetic composition of a product when released into the environment. It also allows risk assessments to be portrayed 'as objective by restricting the relevant uncertainties to available scientific knowledge' (Levidow 1995: 184). Jasanoff's comparison of the US, UK and Germany shows how competing value systems and approaches to the use of expertise and interpretation of risks are reflected in different regulatory orders:

> The focus in the United States was increasingly on the products coming into the market place and the physical risks they may pose to human health or the environment. In Britain, regulators appeared initially more prepared to accept the process of genetic modification as the frame for policy-making, with concurrent attention to the physical and social dimensions of risk. But this acknowledgement of the technique's specialness was undercut to some degree by a bureaucratized hazard evaluation procedure that stressed routine and internalized possible opposition from environmentalists. German political debate on biotechnology was unique in taking as its domain the entire programmatic relationship between technology as society, as mediated by the state, a position that led to a full blown discussion of risks.
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> (Jasanoff 1995: 324)

Given the way in which biotechology regulations are embedded within particular value systems, it is important to consider what happens when they are adapted to new policy environments where different values and belief-systems prevail. There is much evidence to suggest that regulatory standards and approaches are being exported to developing countries in particular. This can occur either through bilateral pressure, which has happened in relation to strengthening IPR protection, for example, or through the efforts of international organisations, such as the OECD, to standardise and harmonise approaches to risk assessment. The export of regulatory models through national, regional and international regulations provides a key transfer mechanism. Evidence for this can be seen in the advice given to countries about how to design biosafety regulations, in regional settings in conflicts between the

imperatives of supranational harmonisation and national discretion, and internationally in disputes, for example, over 'sound science' as opposed to precautionary approaches to regulation.

'Mutual recognition' has provided one means of avoiding problems that arise when regulatory orders collide. It allows countries to recognise risk assessments made elsewhere, even if they embody different assumptions and value-systems, as they inevitably do. These mechanisms of policy transfer reflect different regulatory styles and cultures that shape what types of regulation are considered necessary and appropriate. The different emphasis attributed to precaution in the U.S and the E.U. is an example of the importance of this. It draws attention to the way in which many supranational regulatory approaches reflect and internationalise the preferred policy mechanisms of influential states. In this case, 'The result has been two management systems co-existing in GMO regulation, vying for the support and conversion of other countries' (Dunlop 2000: 154). This has important implications for developing countries, given that what is imported through policy transfer is not just a tested set of rules and procedures, but a set of values and assumptions about biological processes and prior assessments about which risks are socially acceptable that, in turn, result from a series of context-specific compromises and trade-offs. While there is clearly scope to adapt regulatory models to national needs, however these are defined, it remains the case that certain practices, values and assumptions get internationalised by these means.[8]

The relationship between national and international regulation brings to the fore another key feature of global biotechnology regulation; the tension between domestic autonomy and international harmonisation. This comes up in debates, mentioned above, about appropriate modes of risk assessment and their impact upon trade relations. There are a set of global pressures for establishing common means by which to identify and manage the risks associated with GM products emanating from the OECD, the 'Miami group' and leading industries in the biotech sector. 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'. On the other hand, in the biosafety negotiations, the like-minded group and African nations, in particular, wanted to retain the right to restrict entry of GMOs into their markets where there is reason to believe they may have injurious socio-economic effects (Stabinsky 2000). Opponents of this position argued that it is open to protectionist abuse and that any deviations from the free trade in GMO products should be justified according to 'sound science', i.e. WTO, criteria. This tension remains between governments' autonomy to restrict the entry of GMOs into their markets on grounds of the detrimental socio-economic and/or environmental implications they may have, and the regime that now governs their choices in this regard which determines acceptable and unacceptable rules of trade and transfer, deriving from the relationship between the WTO and the Biosafety Protocol.

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[8] Describing a similar process, Garcia-Johnson (2000) shows how corporate environmental voluntarism has been 'exported' from the U.S. to Mexico and Brazil in the chemical sector.

Within the broad parameters set by the Protocol, however, there remains substantial scope for individual countries to evaluate national needs in light of available information, previous experience with biotechnologies, and national priorities for the use of biotechnologies. Moves by bodies such as the OECD towards the harmonisation of risk assessments, which may be considered to be restrictive, still permit scope for different national approaches, as long as the process is transparent, non-discriminatory in WTO terms, and relies on 'sound science' and the approaches spelt out in the TBT and SPS agreements. It is also alleged that even the controversial article 27.2 and 3 (b) of the TRIPs agreement provides flexibility in determining the suitability of patents in particular national settings. The experience of countries, such as India, that have successfully resisted pressures to permit patenting of living organisms, suggest that this is so (Ghosh 2001). WTO members do, however, have to put measures in place by a specified date, even if LDCs with less capacity have a larger amount of time in order to implement the terms.

The extent to which the Cartagena Protocol on Biosafety and the TRIPs accord, in particular, serve to constrain or enable governments' autonomy of action and ability to respond to the needs of the poorest, remains an open question, therefore. The Protocol is not yet in force, even if many countries have signed it, and many developing countries are still in the process of evolving patent protection legislation in line with TRIPs. There is concern that some of these initiatives act as vehicles for standardising measures, regulations and protection that fail to address the concerns of many developing countries. While many poorer nations participated in negotiations towards both agreements, the agenda was driven by key industrialised countries. The Protocol is very much a product of compromises struck between Europe and the U.S., deals that do not necessarily accord with needs and priorities of developing countries, despite the vocal inputs of key individuals such as Tewolde Egziabher from Ethiopia. This may help to explain the overwhelming trade focus of the Protocol which, in places, reads rather more like an investment agreement for biotechnology, confirming the entry and exit options of MNCs, than an environmental accord. It is also important to note that the process is organised in such a way that many developing countries are effectively excluded from active participation in international decision-making. This is so because of the financial resources required to send enough delegates to attend all the relevant meetings, which often run in parallel, and to have access to the high levels of legal and scientific expertise necessary to make effective interventions.

Despite the limits of multilateralism as a process for delivering regulations that developing countries want, however, there is an argument that developing countries can better defend and represent their interests and priorities in multilateral fora than in bilateral exchanges with more powerful countries. Bilaterally, countries such as the U.S. can use Super 301 provisions relating to trade to endorse unilateral retaliatory measures against alleged shortcomings in foreign IPR legislation. The renewal in 1989 of the bilateral Sino-American Science and Technology agreement also provided leverage to pressure China to improve its patent system. In many ways, in terms of trying to shape domestic regulatory arrangements for biotech, the preference of powerful countries may be for bilateral relationships pressures where they are in a stronger position. They can threaten trade sanctions and suspend technology cooperation, for example,

which may have a greater impact than initiating action through the WTO or WIPO (World Intellectual Property Organisation). Levels of IPR protection 'agreed' bilaterally are often higher than those provided for in either WTO or WIPO and they can also come into force almost immediately.

It is not only governments that are in a position to exercise these forms of bilateral pressure. Biotech firms themselves play an important role lobbying simultaneously at the national and international levels for forms of risk assessment that are least trade-restrictive, for example. Barrett and Abergel note that the life science industries are 'hugely influential in international trade organisations such as the Codex Alimentarius Commission and the Intellectual Property Committee of the WTO' (2000: 10). What is significant, however, is that the 'congruence of interests, as well as the pivotal role of the OECD in establishing and promoting familiarity and SE as international regulatory principles, suggests that these concepts may be intended and may be more effective, as tools for harmonising trade standards than assessing environmental safety' (ibid). Firms can also facilitate the spill-over of regulatory models from one country to the next. Where they have adapted production processes and management systems to standards elsewhere (in terms of labelling and reporting, for example), they may be reluctant to expend resources meeting new regulatory requirements, even if they are less burdensome, and so continue to adopt imported practices with which they are in compliance.

When thinking about international influences on biotech regulation, we should not neglect the role of regional bodies in promoting particular approaches to regulation. There is regional cooperation on information exchange, collaborative research, with focal point secretariats[9] and model regional biosafety laws, between East and South Africa for example. Regional cooperation and support is often key given the lack of capacity at national level in many developing countries. Regional approaches such as this can also serve to ensure that biosafety regulations are compatible with regional trade agreements such as SADC in the Southern African context, and coordinated with the activities of regional bodies such as the OAU (Organisation for African Unity) and the Economic Commission of Africa. Model biosafety guidelines are useful as a basis for formulating national regulations and for regulating the cross-boundary effects of biotech applications. Just as with international regulations, they still need to be adapted to the needs of particular countries and imply, therefore, a process of translation.

An interesting aspect here is how the priority accorded to different issues by, and the relations between, the international bodies managing biotechnology policy have a bearing on the balance of power between government agencies at state level. The fact that the Protocol is framed by trade concerns, despite being principally an environmental agreement, means that new patterns of cooperation and coordination may be required of national agencies working in the areas of trade and environment respectively. The relations of power that exist between those departments are likely to have a strong bearing on the balance of priorities that is accorded to environmental and social, as opposed to trade concerns in the handling of GMO products. Where key tensions remain unresolved in international

[9] There is a regional focal point for biosafety in Harare run by the Scientific and Industrial Research and Development Centre of Zimbabwe (SIRDC). It functions as a centre for information exchange, provides capacity-building for safety and hosts a regional standing committee.

accords, as they do in the Protocol, and where there remains scope for diametrically opposed interpretations of what is meant by the terms of an agreement, conflicts are likely to be re-played at the national level as agencies supporting divergent agendas compete to get their version of a country's commitments accepted.

Clearly the relationship between international rules and patterns of national regulation is not linear. Bureaucracies resist change and regulatory cultures significantly shape the formation of policy in practice through the process of translation. The interesting issue is what happens when competing ideologies of regulation conflict, where international rules challenge national priorities, or where different agencies within the same national government compete to interpret their international obligations in ways that consolidate and advance their own interests. It is during these moments that power reveals itself, when priorities can be deciphered and agendas exposed. What happens when demands for protection from domestic constituencies such as farmers groups and NGOs, for example, conflict with international trade rules about the use of agricultural subsidies, the legitimate grounds for restricting trade in GMOs, as laid out in the Protocol on Biosafety, or the criteria that governments may draw on in making risk assessments promoted by the OECD and the Codex Commission? These policy moments, where international and domestic pressures collide, provide a sense of where the power lies and how priorities are set with regard to the appropriate regulation of crop biotechnologies.

Accepting international obligations also forces a debate about implementation and the available capacity to oversee agreed-upon obligations. Many international agreements assume a level of state capacity, in terms of resources, personnel and powers of surveillance, that squares poorly with the reality of weak state structures that exist in many developing countries, in particular. Delays in the implementation of biosafety guidelines are often due to the lack of expertise for assessing the possible risks posed by the new technology. In India, for example, risk assessments are said to be vague or defective. Most studies on risk assessment were done only after the guidelines were in place and many trials were carried out over just one to two seasons, yet to understand pollen transfer and horizontal gene transfer they have to be conducted over several seasons for each crop (Sahai 2000). Unlike many international agreements, the Biosafety Protocol has provisions for addressing issues of enforcement capacity. Attempts at capacity-building, however, can be expected to alter the course of the policy process because foreign actors will be involved in strengthening countries' capacities to monitor the trade in GMOs and to meet their commitments in relation to documentation and certification. Bodies such as UNIDO's biotechnology advisory committee, provide 'independent' advice on specific applications for developing countries. These efforts, aimed at facilitating the implementation of international accords, can be expected to act as a vehicle for exporting practices endorsed by more industrialised countries. There was also a lively debate at the Nairobi CBD (Convention on Biological Diversity) COP5 negotiations about the involvement in the private sector in building capacity to implement the Biosafety Protocol. While it was agreed that support should be available for those developing countries that want to develop the capacity to monitor and control the trade in products containing GMOs, the issue of how far it is appropriate to involve the private sector went unresolved. Nevertheless, business groups are lining up to

ensure that measures to strengthen the capacity of developing countries to meet the terms of the Protocol (to engage in AIA [Advance Informed Agreements], to monitor the trade effectively) are supportive of open trade rather than creating opportunities to restrict trade.

3 Processes

From a discussion of the purposes and functions of regulation in the first section to a consideration of different approaches to the development and export of regulation in the second section, this section looks in more detail at the processes by which decisions about the regulation of GMOs are made, in order to help us identify key policy processes. Such an enquiry should be guided by the need to understand 'regulation in practice.' This means going beyond a focus on formal procedures and models of policy-making and looking instead at the day-to-day negotiations between actors that can either bring policy to life or subvert its intent through neglect (deliberate or otherwise). It also means questioning some of the 'givens' in the policy process, the assumptions that are made about GMOs and their implications that structure policy, but are rarely explicitly articulated. It requires us to critically interrogate which problems get into the decision-making circle, in what form and why and which framings of regulatory problems are subject to non-decision-making (Bachrach and Baratz 1962).

Processes provide the means to pose questions and to guide the search for answers to those questions. In relation to regulating risks, they determine what is to be looked at and why and the tools for identification. As Black notes (1998: 621), 'one of the most striking aspects both of the debate about genetic technology and of its regulation is the number of different conceptualisations of the 'problem' which genetic technology poses and thus of the solutions that should be found'. A key function of regulation, therefore, is facilitation; creating the means of managing different understandings and languages that people bring to the regulation of GMOs. What we find in practice, however, is that this process of facilitation only takes place between a bounded community by virtue of the relationship between regulator and applicant which is often discrete and individualised. Applicants have made extensive use of exclusions on grounds of commercial confidentiality (Barrett and Abergel 2000), as well as occasionally withholding information from regulators themselves. And while some information is made public, there remains a tension between providing transparent regulation and protecting the confidentiality of those being regulated (Black 1998: 627). In this sense, 'The principal way in which the public enters the area of decisions as to the research and development of genetically-engineered products is as a consumer' (ibid: 628). Participation in the process for most publics takes the form of exercising consumer rights to buy, or refuse to buy, a product that has already been approved for market entry.

The key 'knowledge-brokers' (Litfin 1994) in this risk spectacle are scientists, variously defined, bringing to the process different degrees of expertise. The capacity of scientists to influence regulation relates to their ability to frame problems in a particular way and to suggest solutions and appropriate regulatory paths (Haas 1990), often including risk assessment and monitoring, in which they are further involved. Some of their influence also derives from their ability to present themselves as knowledge

brokers, able to determine truth claims from falsehoods, in conditions of high uncertainty. This promise confers significant agenda-setting power on those charged with defining risks that are translated into political calculations of costs and benefits. Mollecular biologists, biochemists and ecologists all emphasise different risks which reflect the values and assumptions that characterise the disciplines to which they belong. However, while it is clear that most regulatory systems privilege technical and scientific measurements for risk assessment, 'given the uncertainties that pervade consideration of the possible impacts of GMOs on human health and the environment, much of the assessment is necessarily qualitative rather than quantitative in nature' (Black 1998: 631), a fact that is often not reflected in the backgrounds of those who make decisions. The other key set of knowledge brokers on the commercial and trade side of biotechnology regulation, are legal professionals. They are involved in assessing the extent to which biotech products meet the requirements of novelty and inventiveness for patent protection. They are also at the centre of disputes over whether plant (and animal) varieties should be excluded from patenting and over the scope of patents that are being granted. Once again, while the issues being dealt with pose ethical dilemmas and imply social choices, they are treated as commercial-legal transactions.

The scope of risks that different regulatory approaches consider, is not just a question of whether the model followed is product or process oriented. The cultures of participation associated with different regulatory regimes also appear to affect the nature of the regulation that emerges.[10] The importance of who gets consulted and who is entitled to determine relevant risks is underscored by Levidow who argues that Britain, for example, has a 'long-standing regulatory procedure incorporating diverse views about how the environmental risks should be conceptualised, assessed, regulated' (1995: 121). Jasanoff argues that by inviting an environmentalist to sit on an advisory committee, the UK 'affirmed the state's acceptance of the lay public's interest in biotech as significant enough to be represented in future negotiations over safety' (1995: 319). Key to this was the formation of the committee by the most participatory of Britain's regulatory agencies, one more accommodating to different perspectives than scientific committees under MAFF (Ministry for Agriculture, Forests and Fisheries), for example. This more proactive approach has provided spaces for critics of biotech to raise wide-ranging concerns beyond the terms of traditional environmental risk assessment. Processes involving non-scientists are better, for instance, at anticipating and averting potential harm for which there may be no prior scientific evidence. The use some governments have made of participatory tools to encourage public debate on biotechnology, also indicates the significance of political culture in shaping regulatory environments. Levidow argues, for example, that the use of consensus conferences by the Danish government is indicative of a 'political culture in which technological decisions are held accountable to public debate' (1998: 218).

Nevertheless, concern has been expressed about widening the regulatory circle too far, especially by industry. The UK BioIndustry Association warned 'Clearly the final decision on whether a product licence

[10] See Levidow (1998) for more on the use of participatory exercises by governments and others to broaden the debate around biotechnology policy options.

should be granted may become largely political ..we are concerned that this will pose a serious threat to the competitiveness of the European biotech industry' (quoted in Levidow and Tait 1995: 133). While the European Commission conceded that, in special cases, it may also 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' (quoted in Levidow and Tait 1995: 134). 'From industry's standpoint social need should be determined by the free choice of consumers in the market' (ibid). Clearly then the methods and means by which we seek to 'measure', gauge and comprehend risks are contested and have very different implications for the forms of regulation that emerge. There appears to be a strong set of links between the scope of regulation, the range of risks that are taken into account and those who are involved in policy consultations.

Each policy process has had to confront the issue of what are the new, unique or additional challenges that GMOs pose for existing regulatory authorities? What new regulatory demands do they give rise to? This, in many ways, is the central issue behind the debate over substantial equivalence discussed above. What is interesting, politically and bureaucratically, however, is how these challenges change relations between existing regulatory authorities. Are they seen to call for changes in the existing decision-making procedures? (involving new actors, drawing on new types of expertise and evidence perhaps). We saw above, how in the U.S. system, existing regulatory agencies and their mandates are considered to be up to the task of handling the development of GMOs. In other words, there is a strong presumption against the idea that GMOs pose serious novel risks that require fresh approaches to regulation.

It is to be expected that existing relationships within governments and between agencies responsible for regulation will have a significant bearing on the shape of new regulatory requirements. The interesting question then is how new arrangements and procedures graft on to processes and mechanisms that are already in place and the relations of power that underpin them. This is important because it will help us to determine what form the approach to the regulation of biotech products is likely to take; how inclusive and precautionary it will be, for example, given existing cultures of participation and uses of expertise. The order of novelty that is ascribed to GM products will be a function of regulatory possibilities enshrined in existing practice, ways of working and bureaucratic routines as much as a 'scientific' assessment of the traits which require extra attention.

Literatures on policy-processes alert us to the way in which 'new' policy problems are often received into existing bureaucratic frames that interpret and process them in a way that advances the interests of government departments involved (Jachtenfuchs 1996). Existing policies, programmes and solutions to problems that policy-makers are already having to address, are likely to shape the repertoire of responses for the new technology. Rendering problems manageable in a policy sense will often mean identifying hazards, and methodologies associated with those hazards, that permit measurement and verification by current policy mechanisms. In this sense, frameworks for evaluating risks are as likely to reflect regulators familiarity with the properties of organism and their controllability of their possible effects, as they are a rounded and balanced assessment of possible social and environmental implications. Nevertheless, different categories of GM crops give rise to different types of risk, such as containable and non-

containable risks, requiring distinct regulatory and reporting requirements. The fact that different crops generate distinct regulatory requirements means that gaps can develop when multiple laws are drawn upon to monitor GMOs. The policy challenge becomes how to create close coordination between agencies to prevent certain risks or impacts from not being considered. A number of countries have set up institutional biosafety committees, on which experts from a range of disciplines are represented, to offer guidance on the range of impacts that need to be considered. Nevertheless, criticisms have been made about the lack of involvement of ecologists at the expense of dominance by molecular biologists and biochemists whose training guides them towards some risks, but not others.

The need to demonstrate authority and competence further encourages regulators to fall back on established procedures and routines to guide future responses. As Jasanoff notes 'In order to approve the deliberate environmental release of GMOs, regulators in the United States, Britain and Germany had to persuade their respective political constituencies that the risks of biotechnology, although novel, lay sufficiently close to their prior experience of technological risks to permit effective public control' (1995: 313). 'New' policy problems can also present an opportunity for regulators to establish and consolidate bureaucratic mandates by demonstrating competence and attracting fresh resources. In the case of the U.S EPA, a new scientific committee was created to 'shore up its credibility in the politics of regulation' (Jasanoff 1995: 325). Given the economic and developmental importance that has been attached to third generation biotechnologies in particular, there may be key incentives for regulators to establish for themselves a central role in managing GMOs, to raise their profile within government and access some of the resources available for promoting biotechnology.

Rather than viewing regulatory systems as one-off creations, it is better to view them as organic institutional configurations that evolve and learn to accommodate new pressures and needs, mediating them through familiar frames of interpretation and the imperatives of bureaucratic decision-making. It is to be expected that the scope and depth of regulation changes over time in response to new political demands, fresh scientific evidence and in the face of challenges to its legitimacy and credibility. Black (1998), for example, discusses the importance of 'sequencing' of regulation to ensure that it is tuned to changing realities of knowledge and its application. Interestingly, however, the assumption is often that regulatory needs decline over time unless new problems are identified. This serves the regulators desire to deal with whole categories of GMOs and traditional varieties, where possible, in the same way. As we have seen in the debate about substantial equivalence, the baseline for deciding on the need for additional regulatory interventions is whether there is evidence of extra risks compared with existing products on the market. But beyond responding to latest developments in scientific arenas, what mechanisms are there, if any, for evaluating the effectiveness and equity of the regulatory process? How open is it to change? How flexible is the policy process in accommodating and responding to fresh needs and challenges? Given the rapid changes taking place in the development of the technologies and the patterns of investment behind them, as well as the shifting boundaries of social and ethical debate, such mechanisms would seem to be a necessary feature of an effectively functioning regulatory regime.

3.1 Challenges for developing countries

This section explores the idea that there is a set of challenges unique to policy processes in developing countries. The construction of developing countries in many discourses in biotech debates, presumes that this is the case. Developing countries are often presented as victims of unscrupulous multinational countries seeking to exploit their economic vulnerability and lack of political capacity in order to test and develop GM products that have been rejected in the West. It is assumed, therefore, that the 'domestic' political, social, economic and cultural factors that shape and guide policy responses, are more strongly influenced by international political and economic pressures, that constrain and enable particular policy options and processes, than is the case for many Northern countries.

The reality of power imbalances between large biotech firms and developing country governments, combined with many governments' pressing need to attract foreign direct investment, means that it may be harder for developing countries to prioritise food security and poverty concerns over the imperative of capital accumulation. Aside from broader pressures to attract FDI from actors such as the World Bank and IMF, regulators in developing countries have been subject to industry pressure to speed up application procedures for biotech developments, to avoid "undue delay". There has been pressure on the Indian government, for example, to create a 'one-stop' approval process, thereby consolidating the existing sequential series of regulatory steps (AIBA report 2000). These pressures to get a speedy approval foreclose opportunities for broad and multi-level engagement with a range of stakeholders, as well as serving to narrow the range of risks to be considered. Such pressures have been applied to developed countries too of course. Writing about GMO regulation in Canada, Barrett and Abergel argue (2000: 7) 'thorough assessment of environmental hazards and meaningful public dialogue have been sidelined by the imperative to market GE crops quickly and competitively'.

Industries often express particular frustration, however, at the lack of know-how and experience of government officials in developing countries and the excessive caution of officials approving and controlling experiments regarding possible risks, resulting in delays in progress. Concerns have also been raised over the security and confidentiality of information and research material submitted to government and gathered during experimentation. The disjointed nature of the approval process, whereby approvals involve the cooperation of a number of government agencies, which can have the effect of slowing the time it takes for a product to reach the market, has also been criticised. Companies are worried that critical information and research material will be lost to competitors during the approval process where decision-making is fragmented across government departments. For example, the company Ciba Geigy expressed their distrust of the competence of the national regulatory authorities in Thailand. Their concern 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. These delays and perceived inefficiencies in the process, as well as the apparent lack of faith in the ability of regulators in many LDCs to process applications competently and confidentially, may help to explain allegations that some companies have bypassed government authorities in conducting their own trials and growing crops illegally. It is probable that the likelihood of being caught conducting illegal experiments is significantly

reduced in countries where resources are stretched very thinly and where monitoring such activities requires a level of capacity for surveillance that is absent in many developing countries. To the extent that this situation arises, it plays into the hands of critics who allege that many biotech companies will find the developing world an attractive test-site for technologies that have proven too controversial to gain acceptance in the North.

There is a tension here, between the gains some firms may make by benefiting from limited state capacity in relation to monitoring and enforcement, and the degree of structural power that they have over countries eager to attract investment, on the one hand, and the concerns many of them also have about the lack of capacity of states to make decisions efficiently and transparently, to follow procedures and to protect their commercial interests, on the other. In this latter regard, a key concern for many biotech firms is the regulation of IPRs that are considered to be essential in protecting their investments and in guaranteeing a return. Companies have been able to mobilise their 'home' governments to pressure 'host' countries into tightening and strengthening their patent protection. Sell (2000) provides evidence of the way in which national and international regulations in the area of IPRs have been strongly influenced by the interests of key U.S-based multinational companies. Countries perceived to be lacking adequate provisions have also been subject to direct bilateral trade pressures to accept stricter IPR norms which they often enforce in order to gain trade concessions in other areas. The ability of more powerful countries to exploit such issue-linkages by using their bargaining leverage highlights the importance of global power politics in shaping the contours of biotechnology regulation in developing countries.

The extent to which industries can shape biotech regulations in developing countries in these ways is a function of a number of key variables. One is the government's own perceived interest in the issue and the extent to which biotechnology is prioritised as an area of strategic economic importance. For a country like Argentina, gearing itself up to meet global demand for GM products, the assistance of industries in designing regulations to support this goal is, of course, welcome. Other countries are more ambivalent about their relationship with biotech firms because they are unsure of where to position themselves in the global marketplace for agricultural products. Another determinant of the extent to which industry is able to influence government appears to be the nature of their relations with key individuals within departments that are influential within the overall policy process. According to Nayak, under the leadership of Dr Manju Sharma, for example, India's Department of Biotechnology (DBT) has shifted towards the industry position regarding technology transfer, the development of regulatory frameworks and research investments in areas such as genomics (Nayak 2000). Sympathetic individuals within government, such as DBT advisor P.K. Ghosh in the case of India, provide a key point of access for lobbyists seeking to shape emerging biotech regulations.

Where a country is located within the supply chain also has a bearing on their ability to resist pressures to alter regulations according to the preferences of buyers. If developing country firms are seeking to export to Europe or North America, they may be forced to meet the regulatory requirements of those countries. Similarly, on the import side, if developing countries want access to existing biotech applications and products, they will have to address in their approach to biosafety, those human and

environmental risks related to the release of GMOs that are built into Northern regulatory requirements. What this suggests is that for many developing countries, regulations may not only be exported through bilateral governmental pressure, or through efforts at harmonisation orchestrated by international organisations, but also through the vehicle of the supply chain and inter and intra-firm trade.

4 Conclusion

This paper has drawn on literatures concerning policy processes and regulation in order to refine our thinking about the politics of regulating crop biotechnologies. It has, firstly, explored the purposes regulation serves in commercial, as well as broader social and political terms, arguing that risk management, facilitating trade and generating public trust are three of its key functions. Secondly, the two predominant approaches to the regulation of biotechnology (product-based and process-based) were analysed. It was shown how these and other approaches to regulation, such as the harmonisation of risk assessments and the standardisation of IPR protection, have been internationalised and exported to developing countries through the activities of governments, international organisations and biotechnology firms. Finally, ways of thinking about the policy process were outlined, emphasising the importance of bureaucratic politics and routine to understanding responses to the challenge of regulating GMOs. In this regard, an extra set of challenges were identified as being particularly relevant to developing countries, including issues of capacity and the power relations that characterise their relationships with other governments and multinational firms.

Future policy responses to innovations in crop biotechnology will be a product of shifting configurations of political forces operating across levels, from the national and regional to the international, and involving coalitions and conflicts between public and private actors that will shape, in significant ways, the contours of what is considered possible and desirable. Ensuring that the needs of the poorest, whose livelihoods may be transformed in positive and negative ways by the new technologies, are addressed, requires us to locate the political opportunities, institutional linkages and social coalitions necessary to ensure that those voices feature centrally in ongoing discussions about how to govern the future development of GMOs.

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