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Re-thinking Regulatory Governance for the Age of Biotechnology

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1. Introduction

The rapid development of biotechnology in the last thirty years, with applications to human health and reproduction, and to the agricultural, insurance and security sectors, has generated varied policy responses from governments in the OECD countries. Though often labelled 'biotechnology regulation' the vast bulk of the policy literature is concerned with the construction of only one element of a regulatory regime – the normative structure of principles, standards and rules. Biotechnology regulation, as a field of public policy, has not yet matured to the point where other elements of regulatory regimes – notably processes for monitoring and mechanisms of behavioural modification– are routinely considered or problematized.

This pattern of neglect of the machinery for implementation of regulatory policy is common to the emergence of earlier regulatory regimes - for example occupational health and food safety (Paulus 1974). As with those earlier stories it creates risks that the norms, elaborated after much advice and discussion, may not be rendered effective in practice. On the other hand there is an opportunity to consider an array of mechanisms, going beyond traditional instruments of command and control, through which regulatory norms might be made effective. Such an analysis reveals not only variety in the mechanisms of regulatory implementation, but also highlights the possibility that norms agreed through

state decision making processes might be by-passed and even destabilised by alternative mechanisms for the generation and application of norms over biotechnology.

2. Biotechnology and Regulation

Biotechnology is not especially new. The fermentation of alcoholic drinks and the creation of cultures for making cheese and yoghurt are early applications which date back to antiquity. Similarly the selection of animals for breeding, and the development of new or better crops and flowering plants have occurred for many hundreds of years. Processes of genetic modification are extremely well established within human activities and accordingly might be thought to raise few entirely new ethical and political issues (Nuffield Council on Bioethics 1999).

Notwithstanding the long history of biotechnology there has been, in the last 20-30 years, a qualitative change in the policy debates, linked to concern and even panic about the potential application for new techniques for the engineering of plant and animal life, and in particular genetic modification (Ungar 2001). It is significant that the term biotechnology was coined as late as 1919.

This chapter provides an initial set of observations about the development of biotechnology regulation in response to these heightened policy concerns from the perspective of contemporary scholarship within the generic field of regulation. Within regulation scholarship there is a tendency to take policy objectives as given and to focus on the means by which they may be delivered – What types of rules? What types of regulatory institutions? How to monitor for compliance? What mechanisms of enforcement? (Baldwin and Cave 1999).

It seems to me that those embedded within the world of biotechnology policy have a nearly opposite set of preoccupations which focuses on the development of the appropriate normative structures (an exception is provided by the

regulatory analysis of (Salter and Frewer 2003)). Both approaches have weaknesses, of course. The latter risks neglecting how implementation of the policy might be made effective. The former tends to neglect the extent to which policy is made, implicitly or explicitly, through processes of implementation. Both approaches exhibit a bias towards privileging state norms and institutions – with an implicit assumption that governments can be and should be the main focus both for policy making and implementation. An alternative perspective on regulation starts with the observations that in many and perhaps most regulatory domains the resources relevant to the capacity to regulate are widely dispersed among state and non-state actors, and that control within regulatory settings is not restricted to the development and enforcement of legal rules (Scott 2004). So, for example, whilst governments have a monopoly over the power to legislate, biotechnology firms possess much of the information which makes regulation possible, retailers exert considerable contractual power over food producers and, in some instances, NGOs possess some of the capacity to make regulation legitimate and to enforce either official or unofficial norms, for example through direct action. The chapter does not claim to provide an authoritative analysis of the state of biotechnology regulation. Rather I have taken my brief to be to use knowledge developed in the generic field of regulation to stimulate thinking about biotechnology.

The policy issues surrounding contemporary applications of biotechnology to human health and food production are concerned with five main sets of issues. The array of issues are concerned with safety of new technological applications (in particular in respect of food), the protection of the environment from irreversible change (in particular in respect of crops), the protection of consumers' economic interests (largely focused on issues of disclosure and labelling), the protection of intellectual property rights and the complex ethical issues concerned with such issues as genetic testing, cloning and therapeutic applications of recombinant DNA.

3. Biotechnology and the Field of Regulation

The striking thing about this regulatory field is that so much of the public policy discussion focuses on epistemological issues concerned with what we know about these technologies and how we know it (Black 1998). In contrast with other fields of regulation a remarkable proportion of attention is devoted to the development of institutional structures for advising on and making policies and remarkably little to the machinery for implementing or enforcing the policies (Levidow, Carr and Wield 1999). Thus, much attention is devoted to the important question as to what biases should operate in developing protective norms (and in particular whether to adopt the precautionary principle) but little attention is devoted to asking to what extent the protective norms are actually protective or to problematizing the machinery through which the policies are delivered.

We might go so far as to suggest that biotechnology policy has not yet matured into a field of regulation at all. In particular it does not seem to have encountered the severe doubts experienced in so many domains about the capacity of the state to exert public interested control over social and economic actors (Baldwin 1997). These doubts are expressed in many different ways. An early and well-known form of critique, sometimes labelled the Economic Theory of Regulation, focused on an apparent tendency (particularly in the US) for regulatory agencies to serve the interests not of the public, but rather of powerful private interests (Peltzman 1976). Sociologists of law have developed analyses of regulatory governance which focus on the communication problems between the various differentiated social-sub-systems, including law, to communicate as between each other so as to question the very possibility of deploying law for instrumental regulatory purposes (Teubner 1998 (orig. pub 1987)). My own perspective on this particular issue is shaped by empirical work in which we have noted how widely dispersed are the resources of authority, information, wealth, organisation and

capacity to bestow legitimacy which make regulation possible among a variety of state and non-state actors (Scott 2001).

Anxieties about the capacity of what we might call 'classical regulation' to exert effective control has generated much discussion about the development of 'new instruments' for regulation. A recent analysis of new instruments in the environmental domain deployed a continuum comparing the extent of constraint imposed on firms ranging between the highly constraining stick approach of classical regulation with the less constraining carrot approach of economic instruments such as subsidies, tradeable permits and taxes with the least constraining sermon approaches which promote the dissemination of information as means to promote or shape choices in the market (Jordan, Wurzel and Zito 2003). The promotion by the state of voluntary agreements features somewhere in this spectrum.

Casual usage of the term regulation often makes us think of regulatory agencies exercising control by reference to legal rules. In the biotechnology area much formal legal authority remains with government departments, rather than with agencies. Law is used:

- (1) to impose bans: eg on human cloning and on commercial planting of GM crops;
- (2) to permit activities only within agreed limits: eg controls over the use of the results of genetic testing by insurance companies;
- (3) to permit activities only with a licence
- (4) to permit marketing of products only subject to certain conditions: eg labelling of GM products

We can see that these various uses of law take in the full range of the continuum of 'old' and 'new' regulatory instruments. This highlights a weakness in both the classical and the new instruments approaches to regulation, which is a relatively narrow focus on the conduct of government departments and agencies and on

the deployment of law as setting normative standards or incentivising compliance with such standards.

Given the anxieties raised by the development and application of biotechnology it is surprising that more has not been said about the capacity of classical regulation to exert control. It is not as if the biotechnology sector is without its regulatory fiascos. An American *cause celebre* is the Starlink case. Starlink is a patented variety of genetically modified maize given regulatory approval in the United States for animal feed, but not for human consumption. A pressure group detected strains of the proteins unique to Starlink in taco shells marketed in the fast food outlets of *Taco Bell* in September 2000. The manufacturer withdrew the products and subsequently other manufacturers detected similar proteins in their products and recalled them (Bratspies 2003).

The Starlink case is interesting because it demonstrates the failure to consider appropriate techniques for checking that restrictions imposed on the product were applied. The emergence of the product in human foodstuffs was not detected by a regulatory agency, but by a pressure group which proved itself to be the effective monitor for violations. The internal procedures of the various manufacturing firms involved had apparently not detected the problem. The consequences in terms of costs of recalls and for public confidence in regulation and in food markets were severe and international sales of American corn slumped when the relevant proteins were detected in shipments to Japan. (Bratspies 2003).

The Starlink crisis was permitted to occur by the establishment of a regime of standard setting and authorization without paying attention to the methods of monitoring and enforcement (Bratspies 2003: 631). This is not to say that vigorous agency monitoring and enforcement was the only appropriate mechanism for addressing the issue, but rather that some attention has to be paid to the processes for implementing regulatory norms once they have been

agreed. It is clear here that the state does not have a monopoly of power – there are major firms and interest groups with capacities for control. It is also apparent that the mechanisms which might have affected behaviour in this story are not restricted to legal oversight and might also include concerns with protection of reputation, transmission of emergent community norms, and the interplay of forces in the market.

Regulation is more than just a set of norms. Cybernetic approaches to regulation suggest that a viable control system must have: some goal, norms, standards or rules; some mechanism for monitoring or feeding back information about the performance of the regulatory system against the goal, norm, standards or rules; some means by which to modify behaviour which deviates from the required goal, norms, standards or rules (Hood, Rothstein and Baldwin 2001).

Law's role in the monitoring and behaviour modification components of regulation is not unimportant. Here law is deployed to empower government agencies to engage in monitoring and collection of information and to empower departments, agencies, or courts to impose penalties or provide rewards for certain types of behaviour. But law also underpins self-regulatory regimes where firms come together to create binding rules and processes for themselves within an associational regime. The next section of the chapter offers an analysis of the full range of potential forms of control which might apply to any particular regulatory domain.

4. Variety in Control

Once we open up regulation into its components of goals, feedback and modification it is clear that in addition to the limited legal controls the regulation of the biotechnology sectors is, to varying degrees, subject to control through the pressures of competition and society. So, for example, rivalry between firms might be as important factor in explaining the take-up and development of new

technologies as a governmental regulatory regime. Such rivalry might even be harnessed for public purposes, for example through a tendering process to determine which firm should win the contract to supply new seeds to a particular region's farmers.

This variation in the development of social norms relating to the development of GM crops appears to be a major explanatory factor in understanding the contrasting behaviour of firms in the United States and Europe. A striking example is provided by recent events in respect of GM maize in the UK. The UK government has indicated it is prepared to licence GM maize for commercial crops, but Bayer, the main supplier of the technology, has decided to withdraw from the UK market. European governments at both EU and national level have taken a cautious approach to permitting the development of commercial GM crops, making reference to the application of the precautionary principle (Bernauer and Meins 2003). American frustration at the evidence that European consumers are even more cautious is spilling over into international trade litigation in which the right of European governments not only to ban GM crops, but also to require labelling of GM products (and thus inform doubtful consumers of which products to avoid) is being questioned (Prakash and Kollman, 2003). Again the commercial actors appear at least as responsive to societal pressures as to governmental regulatory facilitation, as with Monsanto's decision to abandon its investment in herbicide-resistant GM wheat globally (Stokstad 2004).

Any adequate understanding of regulation should be able to accommodate the pressures based in rivalry and the application of social norms, capable as they are of bypassing the state altogether. To put the point another way, the biotechnology sector is subject to regulation whether or not the state does the regulating. Indeed, extensive standard setting by state agencies, risks crowding out the capacities of businesses and civil society organisation to participate in or

determine standard setting processes, and risks missing opportunities to promote 'ownership' of regulatory norms.

Attention to the diverse modalities of control is not restricted to the level or norms but also on the feedback and modification machinery. It is the disaggregated behaviour of buyers and sellers or of users and objects of competitive information in wider social settings which make competitive forces work. With social norms monitoring tends to be implicit, with social sanctions such as ostracization forming central mechanisms of behavioural modification (though community-based regulation can be formalised and linked to non-state hierarchy within self-regulatory rules also). Key examples are provided within the application of biotechnology to human health. The machinery of public regulation is highly dependent on professional norms and monitoring within the medical and research communities (Kerr and Cunningham-Burley 2000). Inspection functions of the kind carried out by the UK Human Fertilisation and Embryology Authority are in essence a form of meta-regulation over the community-based control exerted through the professions.

Additionally, and acting on the insight of Lawrence Lessig that control can be built into the 'architecture' of products such as software (Lessig 1999), the behaviour of users of biotech products can be regulated by design features. The potential for using design to control behaviour has long been recognised in settings as diverse as prisons and DisneyWorld (Shearing and Stenning 1985). A key commercial application of control-through-technology in the biotechnology sector is provided by the the 'trait protection system' or 'terminator technology' which prevents the re-planting of gm seeds from year to year, thus requiring farmers to make fresh purchases each year. The use of technology provides an alternative mechanism to legal enforcement to protect intellectual property rights in new products (Pendleton 2004: 1, 10).

It would, no doubt, be possible to build technological controls into GM crops for other than commercial purposes. Consequently, as with design features built into software to control the way it is used, design has at least the potential to form a basis for control. Indeed, technology-based controls could be used to promote regulatory compliance. It appears theoretically possible to build into GM products such as the famous Starlink corn, discussed above, features which would inhibit its marketing for purposes for which it is not licensed. In the case of Starlink if we assume that when animals are given corn (authorised) it is raw but that when it is prepared for humans (unauthorised) it is always cooked it is possible to imagine accompanying the license for growing and marketing the product with a requirement that technology is built into it such that it discloses itself as genetically modified when cooked. For example it might turn blue after exposure to heat.

Thus, following Lessig's analysis of modalities of control (Lessig 1999) (with adaptations (Murray and Scott 2002)) it is possible to suggest that the hierarchical mechanisms associated with state law are but one of four possible modalities of control, the others being competition, community and design. (See table 1 below).

Modality of Control	Regulatory Form	Biotechnology Examples
Hierarchy	Prior Approval Compulsory disclosure	Licensing (eg pharmaceuticals, gm crop planting) – controlling access to market Mandatory labelling (eg GM Crops) – controlling information distribution
Competition	Market rivalry	Generic production of genetically engineered drugs – effects on price
Community	Public opinion - represented in direct action, spending decisions, etc	Determining acceptability of commercial GM crop planting – affecting viability
Design	Built in controls on use of products	Terminator technology in gm crops – controlling farmers capacity to re-plant

Table 1: Modalities of Control in Biotechnology Regulation

These modalities are often not applied in pure form, but rather in combination. So, for example, hierarchical requirements relating to disclosure of information about GM foods are an important precondition to controls based both on competition and the application of community norms. The idea discussed above in respect of Starlink of designing technology-based controls into products so as to aid their regulation by hierarchical means is also a hybrid mode, combining hierarchy and design.

An objection to the analysis based in modalities of control might be to argue that relative to hierarchical control the other modalities are rather trivial. This may be

true in some settings. But the field of biotechnology appears to be one in which the potential for control through community norms, through competitive pressures and through design does yield important examples. Hierarchical regulation may be rather more visible because it is formalized and institutionalized. This does not mean that it is always effective or that the explanation of how actors in a particular domain behave is explicable by reference to a regime of hierarchical regulation. The examples involving GM crops, discussed above, where governments have authorised commercial crops but firms have decided not to proceed, provide the clearest examples where, we might hypothesise, some other form of control is at play and is dominant in shaping the behavioural response. Indeed, in this case, some interplay between community norms and the market is undermining official government regulatory policy.

In some instances state regulation of one form or another underpins control based in competition or community or design. This is true in the case of licensing decisions underpinning competition through generic drugs and mandatory labelling underpinning consumer decisions on GM foods. But in other cases the application of modalities of control other than hierarchy appears to be spontaneous, in the sense that it was not initiated by the state for state purposes. In such instances it may or may not be right to refer to the mechanism of control as regulation, but it is surely impossible to wholly ignore such controls where they affect behaviour within regulatory regimes, in some instances enhancing the publicly set objectives and in other cases undermining them.

In addition to the descriptive objections to recognising other modalities of control, there are also normative objections. It might be argued that if we subscribe to some version of the rule of law then it is wrong to permit other modalities of control to undermine public policy as it is set down in legal instruments. There are additionally moral objections to mechanisms of control which do not all the subject of control choices as to their conduct (discussed in more detail in Roger Brownsword's contribution to this volume). These objections apply most

particularly to design-based control where the subject is physically inhibited from doing anything other than that permitted by the designer (Tien 2004). To a greater or lesser extent this objection, and the underlying argument that the subject is robbed of their responsibility for their actions by such mechanisms, applies also to control based in community or in competition, since participation in both markets and communities often requires us to accept their norms as a condition of participation, and non-participation may not be a viable option.

In the next section of this chapter we investigate the experience of hybrid forms of control in different regulatory settings and evidence as to the effects of such regimes. Central cases are likely to involve the combination of hierarchy with other modes of control. But equally interesting in the case of biotechnology regulation are instances where hierarchy is not present. We focus on experience of environmental regulation because of its proximity to some of the issues in biotechnology regulation.

5. Effects and Effectiveness

Stories of attempts by governments to exert control over social and economic activities are littered with accounts of counterproductive regulation (Grabosky 1995), fatal remedies (Sieber 1981) and catastrophes (Moran 2001). Unintended effects are a pervasive consequence of human activity (Elster 1989) The focus in biotechnology regulation on the use of law to set norms, with the neglect both of other aspects of a viable regulatory regime, and of other modalities of regulation than law is liable to risk such unintended effects in these sectors too. The central questions addressed in this section are how to use the awareness of the potential of unintended effects and how to think about potential mixes of control types so as to maximise chances of producing intended effects.

Counterproductive effects in regulation are liable to result from a failure to anticipate how targets of regulation are liable to behave in the face of new

regulatory requirements. The history of environmental regulation is full of such examples, for example where rigorous new standards over vehicle emissions push up the cost of new cars to the extent that citizens retain older cars for longer increasing rather than reducing total emissions. The development and marketing of GM foods provides an example of a product where the interplay of market behaviour and regulatory rules has led to effects within European markets which were not anticipated by governments.

Observations about variety in the availability of modalities of control alert us to the diffusion of both capacities and techniques by which regulatory effects are secured. Part of the problem of emphasising state capacity and the use of legal rules in regulation is that it neglects or downplays not only the alternatives which might be available to do the job, but also the role that those alternatives will play in mediating whatever state regulation action is put forward in any case.

Putting the case positively systems of control may emerge which are not wholly dependent on state action and legal rules, but which nevertheless effectively address the risks which policy makers would want to address. In this section of the chapter I will make some observations about self-regulation in the biotechnology sectors and then consider regimes for environmental regulation which combine different modalities of control with apparent success. I have chosen regimes of environmental regulation to examine because they are longer established and better documented with empirical evidence than regimes for biotechnology regulation. But there are areas of overlap between biotechnology and environmental regulation and considerable potential for learning about the latter to inform regulatory policy in the former.

5.1 Self Regulation: The Case of Nuclear Power

Self-Regulation is an important and long-established form of control which draws on and develops norms within a community (for example of professionals or

businesses), often institutionalising them and establishing mechanisms for monitoring and enforcement cf(Black 1996). A very well documented case involves self-regulation in the US nuclear power industry. Following the accident at Three Mile Island in 1979 there was global panic about the risks associated with the development of nuclear power as a key sources for meeting future electricity needs. In many countries the cost and riskiness of nuclear energy, together with consideration of security issues, has led to the sector being established and retained within the public sector. In the United States, where the Three Mile Island accident occurred, there has been a long tradition of private ownership of electricity generation capacity including nuclear power. Though there have been public ownership experiments, notably in the Tennessee Valley Authority, private ownership has generally been the rule.

The characteristics of riskiness and moral panic attaching to the nuclear industry also affect some parts of the biotechnology sector. The industry response to Three Mile Island may be instructive. The circumstances of the industry response are beautifully captured in the title of Joseph Rees' book *Hostages of Each Other* (Rees 1994). The various firms within the US nuclear industry came to understand that the failure of any one of their number to act effectively on issues of nuclear safety would threaten the viability of the industry a whole. Accordingly they developed the Institute of Nuclear Power Operations (INPO) as a system of self regulatory standard setting and monitoring which, in Rees' assessment, proved remarkably cohesive and effective. It was not an entirely freestanding self-regulatory system, since it depended for its enforceability on the actions of state regulatory agencies. Rees himself has referred to this aspect of the self-regulatory regime as 'the gorilla in the closet' (Rees 1997: 519).

So, the INPO story in the US, is about the spontaneous response of an industry fearful of the consequences of inaction to the extent that the community of firms initiated tight controls which each was prepared to tolerate as the price for ensuring the future viability of the industry. The community based controls were

given added weight from the possibility of invoking the hierarchical capacity of state regulatory agencies. It is possible to argue that in some areas of the biotechnology industry the major market actors are similarly 'hostages of each other', in the sense that regulatory failures are liable to affect not just the firm responsible or whose products are directly affected, but the industry as a whole. The case is well illustrated by the Starlink affair, discussed above, where infractions of authorisation (without any evidence of harm to human health) affected the whole international market for the supply of GM maize. The production of GM crops critically requires confidence in the standards of the market as a whole in a way that is not true of other potentially risky products such as cars. Put another way a major safety failure involving a Ford vehicle may have positive effects for the market position of General Motors and is unlikely to reduce the size of the car market overall. Major safety failures in the GM crops domain could kill off the entire market. Whilst the producers of GM crops will want to compete with each other, their viability is dependent on no safety scandal affecting any part of the industry. As with nuclear safety cooperation and self-policing might be an attractive way to reduce the risks to the industry, though this will likely involve elements of governmental enforcement too. What about the possibility of a system of self-regulatory control which does not invoke the state's monopoly over legitimate force?

5.2 Combining Controls Based in Community and Competition: The Case of Forestry Standards

Environmental campaigners have long had concerns about the conduct of the logging industry in North American and elsewhere, and in particular with the problem of management of forestry and the environmental damage associated with excessive and inappropriate logging. The problems are global in scope, and it has proved very difficult to secure agreement on standards at the inter-governmental level.

An alternative response to national regulation or inter-governmental standard setting has come from the Forest Stewardship Council (FSC) established as a non-profit organisation in 1993 (Meidinger 2003). The regime of control administered by the FSC extends to forestry in 60 countries and is a product of internationalization of environmental campaigning and linkages to the global market place. The FSC was established by NGOs, led by the WWF, as a mechanism for certifying good practice, but is recognised as legitimate by market actors (Cashore 2002: 507) The FSC regime combines interaction of the forestry industry and environmental campaigning movement in a hybrid form of control which draws on community and competition based forms of control – referred to by one commentator as non-state market driven (NSMD) governance (Cashore 2002). The FSC rapidly spawned *industry-led* competitors in North America which sought to develop recognition for alternative self-regulatory standards (Cashore 2002: 508-9).

The normative structure of the regime derives from what are essentially community-based processes of interaction, institutionalised through the FSC, with market based mechanisms. Indeed forest-certification programmes ‘recognize officially those companies and landowners who *voluntarily* operate “well-managed” or “sustainable” forestlands according to predefined criteria.’ (Cashore 2002: 505). The market element of the regime derives from the capacity of environmental groups to ‘sell’ the virtues of FSC certification to retailers as a positive symbol of retailer commitment to the environment and a mode of boosting sales. Retailers who accept the case are then able to use their economic power to contract only with suppliers who are FSC certified or at least to prefer such suppliers (Cashore 2002: 509-10). At the supply end of the chain firms which are seeking to maintain or extend market share, and secure FSC certification are liable to apply the standards across all their activities, not just to the extent required to meet purchaser requirements in some countries. This rippling effect of the regime is an important feature and a product of globalization of markets.

5.3 Combining Hierarchy and Architecture with Community: The Case of Intentional Oil Pollution

An important question for the four-way analysis of controls and hybrid forms is to ask what does the design-based control add to the picture and to the potential for regulation. What is it that can be done through technological control that cannot be achieved through market, hierarchical or community-based controls? An important case which provides a partial answer to this question is provided by the history of attempts to prevent intentional pollution of the seas with oil. This is a domain in which there are many non-state actors with governance capacity, in addition to national governmental and inter-governmental organizations (Furger 1997).

The problem is that the operational practices of oil tankers involve the leaving of relatively small oil deposits after cargoes have been delivered. This 'clingage', representing 0.3-0.5 per cent of the original load was routinely discharged to the sea prior to collecting the next cargo, either with sea water taken into the tanks to act as ballast for return voyages or as part of the process of cleaning tanks with high pressure sea water (Mitchell 1994: 72-73). Intentional discharges accounted for a larger proportion of oil pollution to the sea than notorious accidental spills. The story of attempts to control intentional oil pollution at sea is one which demonstrates the weaknesses in depending on treaties made under public international law as mechanisms for promoting regulatory objectives. The key international treaty addressing this problem, the 1954 International Convention for the Prevention of Pollution of the Sea by Oil (OILPOL) was discredited by the 1970s because it proved very difficult to enforce discharge rules aimed at reducing pollution in the face of incentives by tanker operators to maintain their discharge practices. The weakness in the regime was identified as the human element – the requirement of a deliberate but virtually undetectable act of compliance (Mitchell 1994: 258).

Alive to the issues concerning intentional pollution the oil industry had developed two technologies geared towards its reduction. The first of these is to construct ships with segregated ballast tanks (SBT) such that a separate ballast tank is created for seawater, which never carries oil, and does not require monitoring. Residues from loads ('slops') have to be retained separately on board and are subject to monitoring. Tank cleaning is addressed by a separate technology referred to as crude oil washing (COW) which uses oil to clean tanks increasing the proportion of the load delivered (Mitchell 1994: 78-9). The regulatory solution was for the International Convention for the Prevention of Pollution from Ships of 1973 and its 1978 protocol (MARPOL 73/78) to require the use of both technologies for new tankers with a reduction in the intentional pollution by four fifths (Mitchell 1994: 79, 258). For tankers already in service the convention required adoption of one or other of the technologies (Mitchell 1994: 258).

The MARPOL regime changed the point for regulatory enforcement from the moment at which a discharge is made to the point at which tankers were bought and put into service. As Mitchell points out at this point compliance is dependent not only on the conduct of the tanker owner, but also the builder, a classification society (which certifies the quality of completed ships) and an insurance company (Mitchell 1994). In effect these other, non-state actors, become part of the regime for promoting compliance with the design standards. This non-state role is supported by the power of governments to detain tankers found to be in breach of pollution control standards. Thereafter the technology itself inhibits a substantial proportion of the targeted conduct. In any case, once the costly equipment is installed it is cost-effective to use it properly. Proof of the effectiveness of basing the regime on compliance with equipment standards rather than behavioural controls lies in data showing a very high degree of compliance with the SBT and COW requirements. By the mid-1980s nearly all tankers had both forms of technology on board. The critical difference between the two aspects of the regime was the way in which equipment standards were

embedded within a configuration of actors capable of detecting violations and steering violators towards compliance and that compliance with the equipment standards then made non-polluting behaviour rational (Mitchell 1994: 292). Put another way the use of such equipment standards, through transparency and the involvement of many state and non-state actors, creates a system of 'redundant prevention' (Braithwaite and Drahos 2000: 288). Rules prohibiting discharge were targeting behaviour which tanker operators could engage in privately and with few opportunities for detection.

6. Conclusions

The field of biotechnology regulation does not yet seem to be troubled by the kind of anxieties affecting instrumental regulation in other policy domains. Yet there is already evidence in respect of GM crops in Europe that state regulation designed to promote confidence and thus create a viable market for the new technology has been undermined by a combination of direct action and the preferences of a doubtful public. Effective regulation of biotechnology applications in human health has not yet been so politicised.

It is difficult to avoid the thought that some policy fiasco or catastrophe is waiting to happen, and on a larger scale than the Starlink case. The domain has in common with the Enron case the necessity of a high degree of trust in core professionals and their capacity to develop and apply norms which support the public regulatory regime. This chapter is suggestive of a more holistic approach to biotechnology regulation in which the diverse capacities for control may be deployed to the benefit of the regime as a whole, rather than remain as neglected sources of vulnerability.

Thus where NGOs have an interest in setting standards, monitoring behaviour and realigning deviant behaviour they may become a central focus of a regulatory regime (as with the Forest Stewardship Council). Such NGO regimes

of private regulation may be bolstered by the commitment of market players to use their contracting practices to recognise and give legitimacy to such regimes. This is so particularly where retailers and other big purchasers have higher brand recognition and greater public trust than suppliers. Market actors may also respond by establishing regimes in competition with NGOs, using purchaser choice as a mechanism for determining which regimes survive and develop by reference to which regime purchasers think will enhance their market positions.

Professional and other trade associations have also been demonstrably important in some environmental protection regimes, and clearly play key roles in some aspects of biotechnology, notably in medical applications. In some instances the concern for reputation of the industry as a whole may incentivize key actors to establish and develop regimes of standards, monitoring and enforcement which can effectively protect all players from the adverse consequences of a major regulatory failing or scandal.

None of this is to suggest that the state is not important. In some instances the mandating of technological controls is likely to be a governmental (or inter-governmental) function, as with controls of intentional oil pollution, which facilitates the operation of other modalities of control. In other instances standard setting may occur through community mechanisms, the capacity of the state to apply sanctions proves necessary to encourage compliance with those non-state standards, as with the US nuclear power story. Competition-based controls are liable to require some underpinning of the state, not just in competition policy in some instances, but also in the enforcement of contracts.

An intriguing question is whether we must envisage the state as always present in such regulatory settings, as a kind of meta-regulator over structures of control which have their own distinct orientation and mechanisms, but which the state can seek to fine tune to deliver public objectives. Alternatively is it likely that the incentives to operate controls over biotechnology regulation based in some

combination of community, competition and design will leave the state with no necessary role, at least for some of the industries involved. This is one of the key issues for observers of regulation as the field of biotechnology evolves.

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