BIOPESTICIDES, REGULATORY INNOVATION AND THE REGULATORY STATE

Dr Justin Greaves, the University of Warwick

This paper looks at regulatory innovation in the area of pesticides. It considers, in particular, how the Pesticides Safety Directorate (PSD) can be encouraged to innovate, especially in the area of biopesticides. It uses material from a Rural Economy and Land Use (RELU) funded research project being undertaken at the University of Warwick by a research team led by Professor Wyn Grant. The first section of the paper considers various aspects of regulatory theory: for example, the work of Weber, Moran's model of the regulatory state, and the literature on regulatory innovation (such as the work of Downs). The second section outlines the research project being undertaken at Warwick. It summarises our objectives, gives the background to the project, and considers why there has been a poor uptake of biopesticides in Britain. The final section of the paper links the theoretical perspectives more closely to our work. Moran considers regulation to be a key activity in the contemporary state which means that our work has a broader significance. The key link, however, is with the regulatory innovation literature. The paper separates out analytically the exogenous and endogenous pressures for change, bearing in mind the emphasis in the regulatory change literature on champions that can overcome inertia. It considers how the executive has intervened in order to promote more use of biopesticides and how pressure is also being exerted within PSD. It also looks at the role played by the Royal Commission on Environmental Protection (RCEP) report on the effect of crop spraying on the public (published in September 2005), and systematic reviews of provision, such as the Hampton Review on UK Regulation (which reported in April 2005).

Introduction

Bureaucrats and regulators are naturally risk averse. Their desire to avoid things going wrong means they are not natural innovators. In other words, being risk averse does not create an encouraging environment for regulatory innovation. This paper looks at the possibility of regulatory innovation in the area of the pesticides. More specifically, it considers how the Pesticides Safety Directorate (PSD) can be encouraged to innovate, particularly in the area of biopesticides. As one grower put it, PSD have an attitude of "we would like to do that, but we can't. (They) are civil servants that regulate, they cover their backs". Based in York, PSD are an agency of the Department for Environment, Food and Rural Affairs (DEFRA), and deal with the registration of agricultural pesticides. In addition, they are also responsible for advising Ministers on the development and enforcement of pesticide policy and legislation, and advise Ministers on all aspects of pesticides approvals policy." The paper also makes mention of the Advisory Committee on Pesticides (ACP). This was established in its current form in 1977 to advise ministers on major issues relating to the control of pests. The law requires that ACP be consulted about new regulations and any changes in the approval of pesticides.

Pesticide is a broad term referring to a range of products used to control pests. Under the Food and Environment Protection Act (1985), "a pesticide is any substance, preparation or organism prepared or used, among other uses, to protect plants or woods or other plant products from harmful organisms; to regulate the growth of plants; to give protection against harmful creatures; or to render such creatures harmless" (cited <u>http://www.pesticides.gov.uk/approvals.asp?id=329</u>, accessed 13th June 2006). Stakeholder organisations do not hold a common view on the definition of 'biopesticides'. There is also disagreement within the bioscience community regarding an appropriate definition of biological control. In its broadest sense it can include semiochemicals and pesticidal substances obtained from plants; indeed, some practitioners (such as the IBMA) make no distinction between 'biopesticide' and 'biological control agent' in this widest sense. Some authors consider biopesticides to consist only of pathogens (i.e. micro-organisms). Such agents, however, should ideally be referred to as *microbial* biopesticides. There is also dispute as to whether the term should include biological control agents that rely on a numerical response for pest control. Waage (1997, p. 13), for example, implies that it should and defines biopesticides as "any mass produced and marketed natural enemy, including predators, parasitoids, nematodes and microbial agents".

The paper uses material from a research project, *Biological Alternatives to Chemical Pesticide Inputs in the Food Chain: an Assessment of Environmental and Regulatory Sustainability*, currently being undertaken by this author and others at The University of Warwick. The project is funded by the Rural Economy and Land Use Programme (RELU), which brings together the Economic and Social Research Council (ESRC), the Biotechnology and Biological Sciences Research Council (BBSRC) and the Natural Environment Research Council (NERC). Collaboration between natural and social scientists is a requirement of receiving funding under the programme. The project, therefore, is interdisciplinary and brings together Professor Wyn Grant and Dr Justin Greaves from the Department of Politics and International Studies; Dr David Chandler and Gillian Prince from Warwick HRI (Horticulture Research International), and Professor Mark Tatchell from Biological Sciences.

This paper outlines, firstly, various aspects of regulatory theory: for example, the debate about Weberian bureaucratic theory, Moran's model of the regulatory state, and the notion of 'regulatory innovation' (including the work of Downs). This is followed by a discussion of the research project being undertaken at Warwick. The paper looks at the background to the project, and considers possible reasons for the lack of uptake of biological alternatives in Britain. The third section of the paper links the theoretical perspectives more specifically to the subject of biopesticides, and considers in particular, how regulatory innovation could be encouraged. This section of the paper separates out analytically the exogenous and endogenous pressures for change. The focus throughout is on the domestic context. Pesticides policy is determined, in part, by the European Union (and, in a sense, organisations such as the OECD). This, however, is outside the scope of this paper, which concentrates on the domestic context.

Levels of Analysis

There is, at the outset, a level of analysis' problem. There is, firstly, what may be termed 'macro' or 'grand theory'. This covers, for example, the debate about Weberian bureaucratic theory, involving both the advantages and dysfunctions of bureaucracy (such as the risk of mechanisms replacing goals). Secondly, there is 'middle range' theory. This covers Moran's theory of *The Regulatory State*, and work

on regulatory innovation by writers such as Downs. Thirdly, there is the 'micro' level of analysis: in this context, the role of PSD and ACP and their approach towards biopesticides.

The Debate about Weberian Bureaucratic Theory

Systems of regulation can have unintended consequences. Weberian bureaucratic theory points to a tendency for mechanisms to displace goals, for processes to become more important than outcomes. There may be consideration of policy instruments in isolation from their wider effects. In many ways, of course, Weber had viewed bureaucracy favourably (especially in relation to the historical ideal types it displaced). He referred to its 'technical superiority' stemming from a combination of specialist skills subordinated to the goals of the organization. There was an exclusion of personal emotions and interests which might distract from the attainment of those goals. Nevertheless, the uniform nature of bureaucratic practice largely prevented spontaneity, creatively and individual initiative. He saw the danger of bureaucrats becoming preoccupied with uniformity and order, and losing sight of all else. Much subsequent writing on bureaucracy has been an extension of the work of Weber. Crozier (1964), for example, considered the difference between the bureaucrat at the top of the organisation and the bureaucrat at the bottom. The latter sought 'a quiet life' which may best be ensured by a rigid adherence to the rules, whatever they may be. The former may have more 'elevated' aims which are frustrated by an inability to make the routine employer have the same aims for the bureau. Generally, means could become ends in themselves. It has also been argued that there could be budget maximisation effects. Niskanen (1971), for example, argues this, noting that the politician to whom the bureau reports would like to control its costs but faces what economists call an 'agency problem'. The only reliable information on the costs of the bureau come from the bureau itself, unless a second bureau is constructed by the politicians to check on the costs of the first (but who then is to check on the costs of the second agency, or check that the audit agency is not conniving with the agency it is auditing?).

Moran: The Regulatory State

Given the potential problems of bureaucracy and regulation, it is helpful to consider Moran's notion of 'the regulatory state' (Moran, 2000; Moran 2002; Moran, 2003; Moran 2005). As Moran puts it, the essential idea of the regulatory state is conveyed in its name, namely the idea of the state as a 'regulator' (Moran, 2005, p. 528). A regulator in any system essentially balances the system: "it receives information from the environment, and adjusts system performance in light of that information and in the light of the pre-set aims of the system" (Moran, 2005, p. 528). In Moran's words, the regulatory state is a "kind of pilot for society, not actually supplying the motive power but providing overall guidance about direction" (Moran, 2005, p. 528). Or, to put it another way, it can be seen as a state that is not 'rowing' but 'steering' (Osborne and Gaebler, 1992, p. 35).

Moran describes how the regulatory state came into being (Moran, 2005, p. 528). The economic crisis of the 1970's resulted in Margaret Thatcher's Conservative administration being elected in 1979. During her premiership the state withdrew from many areas of economic control. It 'privatised' important industries and public

utilities and sought to guide the economy according to free market principles. It, thereby, tried to adopt a key notion of the regulatory state: that government would set the overall direction of economic life providing the background conditions for markets to operate, but allow the wider institutions of civil society to do the 'rowing': (or, in other words, to produce goods and services for offer in the marketplace). Greater regulation occurred also in a more immediate institutional way. The government developed specialized regulatory bodies for the privatized industries whose purpose was to steer the privatized sector in certain key directions. Such changes were confirmed by her successors, John Major and Tony Blair. Major continued the privatization programme and the Blair government established a number of new regulatory agencies, such as the Food Standards Agency. In summary, the new 'regulatory state' is marked by three features (Moran, 2005, p. 156):

- New executive agencies which are contracted to deliver policy, and regulated to measure how effectively they manage delivery
- A newly privatized sector subject to a network of specialized regulatory agencies
- Government has turned to the specialized regulatory agencies to control large areas of economic and social life.

Moran (2005, p. 529) also explains how the British economic crisis of the 1970's was part of a wider change in international economic conditions which resulted in economic difficulties throughout the advanced industrial world. Many countries responded in the same way by withdrawing the state from areas of economic control and adopting a more regulatory approach. Linked to this, Majone (1996) argues that the British crisis of the 1970's was part of a wider crisis which threatened the 'Keynesian welfare state'. This combined a large welfare state with a commitment to close control of the economy, including substantial public ownership. In the 1970's this state found it increasingly difficult to achieve the goals of full employment and low inflation. Britain's problems, therefore, whilst extreme, were only part of a wider crisis. This led, therefore, to 'the regulatory state' which was strengthened in Western Europe by the rise of the European Union (EU). As Majone puts it, the EU is necessarily a regulatory state; it simply does not have the resources to act as an interventionist state. It has a small budget and a small bureaucracy and cannot, therefore, directly shape the vast economy of the Union.

As Moran himself points out, some accounts of the regulatory state "offer a fundamentally benign view of the state, picturing it as a way of standing back from, and empowering, civil society" (2005, p. 530). Indeed, as Grant points out, it is possible to read Moran's work in this way and view it as the story of a progressive, if imperfect and incomplete, transition towards modernity. In ideal typical terms, the 'command' or 'Keynesian welfare state' is displaced, in part due to the exhaustion of the paradigm, by the regulatory state (Grant, 2005, p. 14). Its progressive features include the displacement of 'club' government and the replacement of self-regulation which was viewed to have failed both in terms of public accountability and economic efficiency (Grant, 2005, p. 15).

However, there has been a shift in the way Moran has seen the regulatory state. In his first writing on the subject (2000, pp 1-13) he clearly sees the regulatory

state as benevolent, and a considerable improvement (if still imperfect) on what went before. As he puts it:

As for the old world of command, good riddance to it: good riddance to the men in Whitehall who know best....The world of command infantilised us all – never let us grow up from subjects to citizens (Moran, 2000, p. 12)

Moran, however, has become more impressed by its authoritarian potential¹ In his most recent work (2005, p. 530) he points to difficulties in picturing the regulatory state as a 'light touch' steering state. Programmes such as privatization may have led to a significant retreat from 20th century style state intervention. Nevertheless, there has also been greatly widened legal regulation, usually through agencies empowered by statute, and the state now has new means of control over areas of civil society. Moran suggests, therefore, that we look to the authoritarian strand in regulation. Indeed, his recent textbook argues that his 2003 book The British Regulatory State recognised this strand and "paints the British regulatory state in a threatening and interventionist light" (Moran, 2005, p. 530). Moran now accepts that this remark does not quite gloss it accurately.² Nevertheless, he believes that *The British Regulatory* State (2003) argued that the regulatory state had a Janus face: a democratising quality, because it enforces more transparency on elites; but an authoritarian quality because it also centralises and controls. To complicate matters further, the latter feature encourages it in the direction of failures and catastrophes which, in turn, subverts its control capabilities.³ His 2003 text also points to the 'hyper-innovation' of the regulatory state leading to fiascos. Furthermore, he argues that "the British regulatory state, far from being smart, is, therefore, often remarkably stupid". He adds, however, that "it succeeded a governing system that was even more stupid" (Moran, 2003, p. 26).

Regulatory Innovation

Innovation is a key part of the 'reinventing government' debate (Osborne and Gaebler, 1992). It also has a key role in debates on regulatory reform (eg: OECD 1995, European Commission 2002), and public agencies have been told that innovation should become one of their 'core activities' (Cabinet Office, 2003). But just what is 'regulatory innovation'? There are many competing images of the concept, in the same way that there are competing images of regulation (see Black, 2005, pp. 3-4). Black, however, understands it to be "the use of new solutions to address old problems, or new solutions to address 'new' (or newly constructed) problems, but not old solutions to address old problems. This helpfully brings out the distinction between 'change' and 'innovation'. Hall identifies three forms of policy change: first order changes are changes to the levels or settings of basic instruments (Hall, 1993, pp. 278-9). Second-order policy changes involve changes in technique or instrument, but not in the overall goals of policy or understanding on which it is based. Third-order changes involve changes in the goals of policy and understandings on which the policy is based. Regulatory innovations, in Black's mind, are second or third-order changes in the performance of regulatory functions, institutional structures

¹ Email correspondence with Wyn Grant, Dec 2004.

² Email correspondence with Wyn Grant, Dec 2004.

³ Email correspondence with Wyn Grant, Dec 2004.

and organizational processes which have an impact on the regulatory regime" (Black, 2005, p. 15). Our focus, in this paper, is predominately second order changes.

So what forms might 'regulatory innovation' take? Black understands regulation to be "the sustained and focused attempt to alter the behaviour of others according to standards or goals with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard setting, information-gathering and behaviour modification" (Black, 2005, p. 11). Regulatory innovation is innovation in any aspect of the regulatory system or regulatory regime (Black, 2005, p. 12). ⁴Admittedly, this is a wider definition of regulatory innovation than that of Sparrow (innovation in modes of risk regulation: Sparrow 2000), or Moran (innovation in institutional arrangements: Moran 2003). More specifically, regulatory innovation consists of innovation in the performance of regulatory functions, institutional structures and organizational processes in the regulatory regime. It is clear that regulatory agencies/organisations often have scope to innovate within existing legislation (eg: there is scope for discretion, and so on). However, other types of innovation may require changes in statute. It is important to be clear about these different levels of regulatory innovation. Both are appropriate to our study but this paper is concerned mostly with the former.

Much of the regulatory reform literature gives an 'innovation as success'. Mohr, for example, influentially defined innovation as "the successful introduction into an applied situation of means or ends that are new to that situation" (eg: Mohr, 1969, p. 112). It is defined by the Cabinet Office, moreover, as 'new ideas that work' (Cabinet Office, 2003, para 2.1). Moran's thesis, however, is that innovation has been a 'fiasco', arguing that the last 30 or so years in the UK have been an era of 'hyper-innovation', 'the frenetic selection of new institutional modes, and their equally frenetic replacement by alternatives' (Moran, 2003, p. 26). Black puts forward the following considered view:

Innovation, quite clearly, need not be successful, and moreover being in a constant state of innovation can itself be counterproductive: initiatives are not given the time to be properly implemented; costs are imposed through the constant need to change systems and processes to implement new policies, and no policy is around for long enough for its success or failure to be properly assessed (Black, 2005, p. 14).

Furthermore, how and when 'success' or 'failure' is measured, and from whose perspective, are all moot points. Assessments of success or failure often depend on where you stand: in other words, innovations will all have winners and losers. Therefore, innovations are not necessarily successes or failures, but "who judges what is 'good', at what point in the innovation's 'life cycle', and against what criteria, inevitably remain critically open questions" (Black, 2005, p. 15).

Returning to how innovation can occur, policy network theory suggests that policy networks are good at managing incremental change, but tend only to innovate in conditions of crisis or exogenous shock. Policy communities have high entry

⁴ A regulatory regime is the set of interrelated goals which are engaged in joint problem solving to address a particular goal, its boundaries are defined by the definition of the problem being addressed, and it has some continuity over time (Hood et al, 2001, pp. 9-17).

barriers around them and can become rather exclusive networks made up of wellestablished insider groups. As Daugbjerg puts it (1998, p. 79), "Policy networks structure the decision-making process and provide outsiders and insiders with different opportunities for respectively changing or maintaining the existing order within a sector". Therefore, for defenders of the status quo, "a sectoral policy network which has a high degree of cohesion among its members is a very powerful political resource" (Daugbjerg, 1998, p. 79). Grant has argued that what emerges is an approximation of an elite cartel where participants collude so as to preserve the existing parameters of the policy-making process (Grant, 2000, p. 51). In the words of Stringer and Richardson (1982, p. 22): "The objective of the policy-making process within these communities is often not the solving of real problems, but the management of avoidance of conflict, the creation or maintenance of stable relationships, and the avoidance of abrupt policy changes".

Of course, bureaucracies have to cope with considerable forces of inertia, as outlined in the classic text *Inside Bureaucracy* by Downs (1967, pp. 195-197). These give some indication as to why reform is not easy. Firstly, like most organisations, bureaucracies have a powerful tendency to continue doing today what they did yesterday. This is because established processes represent an enormous previous investment in terms of money, time and effort. If new behaviour patterns are adopted, these costs must be faced again. Downs believes that the more officials that are affected, the greater resistance will be to significant change. Therefore, the larger an organisation is, the more reluctant it will be to change, and small bureaus tend to be more flexible and innovation minded than larger ones.

Secondly, self-interest motivates officials to oppose changes which would result in net reductions in things they personally value, such as personal power, prestige and income. Therefore, officials will tend to oppose changes that would lead to a net reduction in the amount of resources under their own control; and changes that would decrease the number, scope or relative importance of the social functions entrusted to them. Downs explains that this is why transfers of functions from one section to another are often resisted from the sections losing functions. Interestingly, Downs points to some of the advantages in inertia. As he puts it, "inertia imparts a measure of stability to social organisations which helps them perform vital functions, such as maintaining a pattern of order in social life, and preserving important ethical and cultural values. Such functions are especially significant in modern societies marked by strong pressures toward rapid change emanating from technical innovations" (Downs, 1967, p. 197).

What, however, of the forces of change? Down's suggests the following (Downs, 1967, pp. 198-200). Firstly, the desire to do a good job. This could be due to loyalty to specific parts of the bureaucracy, to specific ideas, or to society as a whole. This motive will be particularly prevalent in the creation of new bureaus or new sections within an existing bureau. Secondly, the desire for aggrandizement. As Downs writes, "we have seen that self-interest is a powerful cause of inertia, but it can also motivate change if officials receive greater rewards for altering the *status quo* than preserving it. The greatest of such rewards are gains in power, income and prestige associated with increases in the resources controlled by a given official or a given bureau" (Downs, 1967, p. 198). Politicians, however, are more reluctant than officials to increase the total size of the government budget. Officials, therefore, have

a better chance of getting their resource expanding innovations improved if they can reduce expenditures elsewhere. Therefore, proposed innovations must carry out social functions performed elsewhere, leading officials with a powerful motive to 'capture' functions performed by other bureaucracies. A third motive for change in bureaus is self-defence against pressure from external agents, for example abolition or threats to reduce its resources. Bureaucracy threatened with abolition, for example, must find new functions or reinstate the importance of its present ones.

Put simply, Downs believes bureaucrats to be rational utility maximizers, optimizing benefits net of costs. "Every individual acts at least partly in his own self-interest, and some officials are motivated solely by their own self-interest (1967, p. 83). Their 'general motives' include five self-interested motives and four potentially altruistic goals:

Self-interest motives

Power – inside the bureau or outside it. Money income. Prestige. Convenience – minimising personal effort. Security – defined as a "low probability of future losses of power, money income, prestige or convenience".

Broader Motivations

Personal loyalty – to the immediate work-group, bureau as a whole, the wider government, or the nation.

Identification with a specific programme of action, or 'mission-commitment'. Pride in proficient performance of work.

Desire to serve 'the public interest' – that is, what the official believes the bureau should be doing to carry out its social function.

In order to see how parts of agencies or whole bureaus behave, these microlevel propositions are scaled up. Every section of an organization is in partial ecological competition for more funding, staffing, policy 'territory' or other resource (Downs, 1967, pp. 53-4). Similarly, with whole agencies: "Bureaus tend to invest excessive resources in territorial struggles (to defend their existing functions or acquire new ones. Also, as stated above, bureaus tend to be inertial, "to continue doing today what they did yesterday" (1967, p. 149), and like other organizations, they have inherent tendencies to expand but fewer than normal constraints on their ability to do so (1967, p. 149).

It is possible, however, to criticise Downs's analysis. As Dunleavy has put it, his list of bureaucrats' utility functions is 'excessively loose (Dunleavy, 1991, p. 165). Dunleavy points out how four other elements "clearly incorporate other-regarding elements which are simply illegitimate within a public choice perspective" (Ibid., p. 165). 'Personal loyalty' is defined in a way which makes it broadly a non-rational motivation in public choice terms. 'Desire to serve the public interest' is on a par with regarding 'civic duty' as a part of rational voters' utilities. If Downs is allowing such factors, it is hard to think of any action which is formally non-rational! Downs's final two components – pride in one's programmes and commitment to specific

programmes – appear to be behavioural traits which a public choice model of bureaucracy should be aiming to predict as likely or unlikely to occur, as opposed to incorporating them directly into the model assumptions. ⁵

The Biopesticides Research Project

As stated at the outset, the research project being undertaken is entitled *Biological Alternatives to Chemical Pesticide Inputs in the Food Chain: an Assessment of Envionmental and Regulatory Sustainability.* The objectives of the project (from the Political Science perspective) include assessing the limitations of the chemical pesticide driven regulatory model in terms of encouraging the wider use of biopesticides; identifying the processes that may sustain regulatory innovation (within a broader framework of the regulatory state); and comparing public policies on pesticide reduction in countries such as the UK, US, Denmark and the Netherlands. Our bio-science colleagues, moreover, are:

- Seeking to understand how habitat type affects the diversity of natural populations of soil-borne insect pathogenic fungi.
- Examining fungal life history: in other words, how do insect pathogenic fungi survive in soils?
- The impact of spraying a crop with a biopesticide on indigenous fungal populations and genotypes of the past insect that feed on non crop plants. In other words, are there any effects on insect pathogenic fungi already present in the soil. ⁶.

The project is scientifically concerned with microbial bio-insecticides, based on entomopathogens, for the control of insect pests. Similar microbial agents exist for controlling plant diseases (eg: bio-fungicides) and weeds (bio-herbicides). Collectively such agents are referred to as microbial biopesticides. These tend to be applied inundatively, in a way similar to chemical insecticides, but many exhibit desirable biologically-based properties. (eg: specificity, reproductive potential, low impact on non target organisms, compatibility with other natural enemies, limited toxic residue) (Dent 2000). Furthermore, they offer some broad social advantages for the social economy: "Because of its flexibility of scale, the biopesticide business can have the desirable properties of exploiting local biodiversity, creating employment and wealth in agricultural communities, and reducing the need for import of pest control from distant centres of production" (Waage, 1997, p. 14). Due to their host specific nature, they have the benefit of minimal direct effects on non target organisms. However, they could have unwanted indirect effects (Pearson and Callaway, 2003), especially on naturally occurring microbial agents occupying the same niche. Alternatively, the local adaptation of natural microbial agents, already known to be important to generating biodiversity in host-pathogen systems (Dybdahl and Storfer, 2003), could prevent biopesticide genotypes from persisting and expressing desirable biological effects. It should be noted that we are using the leafy salad crop model system. Leafy salad crops grown in the UK are infested by four

⁵ The 'rational actor' model is at the heart of all public choice accounts.

⁶ Further information can be found on the project website at <u>http://www2.warwick.ac.uk/fac/soc/pais/biopesticides</u>.

species of aphid (Parker et al, 2002). Aphids are susceptible to entomopathogenic fungi, some species of which have been investigated as microbial bio-insecticides. We are looking in our scientific work at *Metarhizium flavoviride* (= M. anisopliae) var pemphigum, for control of the lettuce root aphid Pemphigus bursarius, a pest of outdoor lettuce crops.

Background to our Project

Consumers are concerned about the possible health effects of pesticide residues on food. Such a concern is picked up by retailers who often push for levels of pesticide reduction more rigorous than those required by regulators, which in themselves are very stringent. Pesticide residues are regulated in the EU by Maximum Residue Levels (MRLs) agreed internationally by the Codex Alimentarius. Arguably, the MRLs are so rigorous that they provide huge margins of safety so as to deal with a worst case scenario. Despite this, many NGOs point to the harmful effects of pesticides on human health (an argument that rests on an interpretation of the precautionary principle that requires scientists to prove a negative), and such arguments are often picked up in popular literature by journalists such as John Humphrey's (see, for example, Humphrey's, 2001). There is a risk that such perceptions (amplified by the media) will affect the consumption of fresh fruit and vegetables which are desirable for health reasons.

In short, there is no scientifically acceptable evidence of effects on human or animal health Why, therefore, reduce the use of chemical pesticides? Firstly, there is a requirement to integrate chemical pesticides with alternative methods in order to develop systems of crop protection which are sustainable. There has been much debate regarding the meaning of the term 'sustainability' but in this context pesticides are required which do not damage the environment and which prevent the development of resistance by the pest to the control agent. Broad spectrum pesticides can also reduce populations of beneficial, naturally occurring predators and parasitoids. The focus of our project, it should be noted, is the role of pesticides in the food chain. There have also been concerns, however, about the leaching of pesticides into groundwater and thereby into water supplies; effects on biodiversity; and health and safety concerns for sprayer operatives or members of the public accidentally affected by spraying operations (eg: the RCEP report which we return to later).

Returning to the matter of resistance, following the implementation of European Directive 91/414/EEC, there has been a significant decline in the number of active ingredients permitted for use in crop protection products. Moreover, because of the expense of research and registration, manufacturers are unlikely to develop new chemical products on a large scale. For various reasons, therefore, there has been a reduction in the number of pesticide products available for use. This increases the problem of pesticide resistance. When an effective pesticide is applied to a crop and the majority of the pest population dies "sometimes a few individuals remain that are physiologically different and can tolerate the pesticide. The 'new strain' of the pest that has been created is reapplied" (Hajek, 2004, pp. 7-8). The elimination of pesticides would have a substantial impact on the quantity and quality of available food and its price. Of course, pesticides have other positive effects other than increasing crop yields, e.g.: protection against the harmful effects of food

contaminated by toxic pest organisms. The broad solution to such problems, therefore, is to use the ecologically based pest control management strategy known as 'Integrated Pest Management' where "the basic goal is to use control tactics against pests only when necessary" (Hajek, 2004, p. 319). Grant writes, "There is a role for chemical pesticides in IPM when infestations cannot be controlled by any other means, but they should be used as a last rather than as a first resort. There is also scope for increased use of alternatives to chemical pesticides such as biological controls and in particular biopesticides" (Grant, 2005, p. 10).

Why Such a Low Take-Up?

Whilst Microbial biopesticides have been commercially available for over twenty years, they "represent less than 1% of the global market for agrochemical crop production" (Hajek, 2004, p. 331). 90% of world sales are derived from commercial preparations based on an entomopathogenic bacterium *Bacillus thuringiensis* (Advisory Committee on Pesticides, 2004, p. 15)

One explanation for the low take-up is the 'market failure hypothesis' In other words, the market size is too small to provide economies of scale and encourage firms to enter. Given that biopesticides are niche products with very specific applications, the market size for any one product is small. Such issues are being pursued by a parallel RELU project being undertaken at Imperial College at Wye (and also involving Rothamsted Research and The Game Conservatory Trust). An alternative hypothesis (and the one we are concerned one) is that of regulatory failure. In other words, there are systemic problems arising in regulation along with specific problems in the case of biopesticides. A key concern, pointed out by Waage, is that "biopesticide development is locked into an inflexible and unimaginative chemical pesticide model. In this position, all of the shortcomings of biopesticides relative to chemicals emerge and none of the benefits" (Waage, 1997, p. 14). He goes onto say that (p. 16), "it is not the industry alone, but the entire pesticide regulatory process which has not adapted itself to the new opportunities which biopesticides provide. In their emphasis on high efficacy standards typical of fast-acting potent chemical products, registration procedures make little allowance for new products whose effect is a combination of direct kill and the conservation of natural enemies". To put it another way, there is a potential government failure as the entry costs to the market are raised by an onerous registration process designed for chemical pesticides (Grant, 2005, p. 13). We do not deny that market failure plays its part. However, we believe that the "economies of scale argument are well understood and they will not provide a major focus of this project".

(<u>http://www2.warwick.ac.uk/fac/soc/pais/biopesticides/projectoverview/rationale</u>, accessed on 10th June, 2006).

It is helpful to look at the regulatory factors in more detail. Jones (2001), for example, argues that the registration fee for alternative control methods may act as a barrier to developments. Certainly, small companies perceive it to be a particular problem. The pilot scheme has resulted in a reduced registration fee for biopesticides.

⁷ Argubly, however, it is still too high. The International Biocontrol Manufacturers Association 's recommendation is that registration fees should not exceed 1% of the expected sales during the five years following commercial introduction (Agrow, 2001). Current sales levels suggest that for most alternatives registration costs amount to 40% of annual sales (Advisory Committee on Pesticides, 2004). However, the big cost is in the testing required to meet registration requirements. The United States Environmental Protection Agency tests biopesticides for safety, but nor for efficacy. It is interesting how, as a result, over a twenty year period, the trend line for biological registrations has been upwards whilst conventional registrations have gone down. It could be argued that there should be no pesticide testing in pesticide regulation and that market forces should be allowed to determine which products are efficacious. One option, therefore, would be to eliminate efficacy testing in the EU, leaving the market to decide whether a product was viable. Alternatively, it could be argued that pesticide application is so important to farmers that need a basic level of reassurance that the product works PSD, for example, believe that regulation is a cost-benefit analysis and judgments about efficacy constitute the benefit analysis. They also claim to be bound by the Food and Environment Protection Act 1985 which says that methods of controlling pests must be efficient as well as safe.

Efficacy testing, however, results in higher costs for biological than chemical pesticides. An industry consultant commented in one interview, "Chemicals can use quite small treatment plots, but biologicals need larger plots to get statistical significance because individual replicates are more variable (micro-organisms are present in the soil anyway)". Their efficacy is also low when compared to conventional methods. One such consequence of incomplete pest control is that there may be increased evidence of pest damage on good. Would such physically damaged/blemished food be acceptable to retailers and consumers? ⁸The ACP believe that existing guidelines allow for products with reduced efficacy to be permitted, but that the issues relating to user and consumer acceptance could be more difficult to overcome (2004, p. 30). One practical measure to deal with user expectation (e.g., farmers and growers) could be to include expectations of efficacy on the label (ACP, ibid). There is no legal reason why the label cannot state that the product does not provide complete control. From a regulation point of view this would be acceptable, but it remains unclear whether it would be commercially attractive. Perhaps users, however, would be more open-minded than we may think. As a grower commented in interview, "If a product was safe but we didn't know it would work we'd have a look at it'

Finally, a point made by developers of alternatives relates to the requirement for crops used for trials to be destroyed "if an assessed experimental approval has not been obtained". This may make sense for conventional products, as those which have been unapproved cannot be permitted to enter the food chain. However, it has been argued that the health risk from some alternatives is very small, and therefore that these regulations are not relevant. It should be noted that the requirement to destroy

⁷ The Pilot Scheme (launched by PSD) investigated best practice for processing biopesticide applications.

⁸ Waitrose launched in June a range of 'ugly' fruit at a discounted price. The range of strawberries, tomatoes, plums and other fruit would normally be rejected as visually unappealing. The fruit is marketed for use in cooking or jam making but could appeal to bargain hunters or those concerned about food waste.(see <u>http://news.bbc.co.uk/1/hi/business/5095428.stm</u>, accessed 29/07/06).

crops after trials results in a financial burden to the developer, as they must compensate the farmer, thereby adding to the financial disincentive to develop alternatives. The ACP argue, however, that the regulations are more flexible on this than many believe, and that crop destruction is not necessarily required. The PSD are happy to consider things on a case by case basis (2004, p. 31).

Biopesticides, Regulation and Innovation

Having outlined various levels of regulatory analysis and summarised the project being undertaken at Warwick, we turn to ways in which the two come together. Under the chemical pesticides regulatory model, specific and short-term goals may prevail over long-term aims of environmental protection and social benefits (as one would expect under Weberian analysis). Hood, Rothstein and Baldwin, meanwhile, argue that PSD provide an example of a budget-maximising approach within a risk regulation regime. They argue that it is "a notable case of a bureaucracy prospering from risk regulation. The organization, which charged for its product approvals on a 'full cost recovery' basis, saw its scientific staff quadrupled in the six years to 1992 and adopted an 'entrepreneurial' stance in the EU pesticide approvals market. Within the EU's mutual-recognition framework for regulatory approval', it sought to be the market leader and took an active part in pesticide standard-setting" (Hood, Balwdin and Rothstein, 2003, p. 126). It is debatable, however, whether Hood et el provide sufficient evidence to back up such arguments.

As Grant et al put it, "Our analysis is influenced, at least as a point of departure, by models of the regulatory state" (Grant, 2005, p. 14). Moran's macro level questions about the nature of democracy provide context for the more specific questions we face (Grant, 2005, p. 15). Indeed, issues raised by the regulatory state debate are relevant to the consideration of pesticides regulation (Grant, 2005, p. 15). Voluntary registration under the Pesticides Safety Precaution Scheme was replaced by statutory regulation in 1986. Furthermore, "Pesticides are amongst the most strictly regulated of chemicals" (House of Commons, 2005, p. 6). It is claimed, moreover, that "The (PSD) seems more concerned with guarding commercial confidentiality than it is with ensuring the public's right to know" (Humphreys, 2001, p. 104). One of our respondents saw both PSD and ACP as lacking in openness. As they put it, "PSD is hideously secretive" and "some aspects (of ACP) are still very secretive, due to commercial confidentiality". Our project, however, has found little evidence of regulatory capture within PSD. It has built up its own in house scientific expertise so it is able to make independent and authoritative judgments on pesticides approvals. Therefore, it seems to be relatively insulated from external opinion. One senior executive in one firm commented, "PSD have a reputation of being very stringent in the way that they interpret EU regulations. They have become much more open in the last five years, but there are lines in the sand that they won't cross".

Regulatory Innovation: The Case of Biopesticides

Perhaps the vital link, however, is between our project and the regulatory innovation literature. How, therefore, can we get from where we are to where we need to be? Using the insight of policy network theory along with interviews with key actors, our

project attempts to identify agents and processes that would create a momentum towards sustaining regulatory innovation. Put simply, our project is concerned with the conditions under which regulatory innovation can occur. In other words, is it possible for environmentally friendly scientific and technological innovations in pest control go hand in hand with appropriate regulatory regimes which meet concerns about public safety and environmental impact but do not unnecessarily constrain developments which would help achieve sustainability goals for the rural economy. How, therefore, can change come about, given that existing actors in the policy network are orientated towards chemical solutions to control pests?

It is helpful to separate exogenous and endogenous pressures for change. The intervention of the executive is an example of the former. DEFRA has been keen to encourage the wider use of biopesticides (in order to achieve sustainability goals).⁹ Given such slow progress, however, the institutions of the core executive have needed to intervene in the policy-making process. As the then Business Regulation Team (BRT) of the Regulatory Impact Unit of the Cabinet Office put it in 2002, PSD's testing requirements 'were evidently designed to cope with standard, mass- produced synthetic chemical pesticides which, by their nature, tend to deliver very high efficacy rates, and not with this group of safer alternatives'. They added that 'this appeared to be an interesting example of regulation-inspired market failure' (Business Regulation Team, 2003, p. 19). The BRT approached PSD in order to seek a solution to the problem; in Grant's words, "they used their authority to lean on PSD" (Grant, 2005, p. 15). PSD were apparently keen to discuss how the new aim could be promoted (Business Regulation Team, 2003, p. 19). Put simply, they realised they had to do something. They, therefore, launched a pilot scheme, as outlined above, and three products successfully gained approval. We interviewed one of these firms and they expressed a great deal of satisfaction with the assistance and guidance they received from PSD. The agency has recently announced the introduction of a permanent Biopesticide scheme to facilitate more alternative products to enter the market. The key elements of the scheme are:

- The appointment of a 'Biopesticide Champion' to provide initial contact for product innovators/manufacturers, and help them through the approval process.
- The provision of specific guidance to applicants (via free pre-submission meetings) identifying the best way forward..
- The provision of more accessible information on the regulatory process with a new Biopesticide area on their website.
- Reduced costs for evaluations (http://www.pesticides.gov.uk/environment.asp?id=1846, accessed 29/06/06).

One retailer put it to us, "PSD is under pressure to try and help their policies to adapt". The Regulatory Affairs Officer, meanwhile, for a manufacturer and supplier

⁹ The Government's Sustainable Development website can be found at <u>http://www.sustainable-</u> <u>development.gov.uk/what/index.htm</u>. It defines sustainable development as "'development which meets the needs of the present without compromising the ability of future generations to meet their own rneeds'

of pesticides (including biopesticides) provided an interesting insight into how PSD is beginning to change. "They want to be seen to be doing something ... (it is) now in their best interests to look at solutions. If they're the first regulatory authority to get something in place and have a way to get products to the market, other European countries will follow what they have done". The decision to make the pilot scheme formal, for example, was almost done from a "PR point of view". They were told they had to do something about it. Similarly, "someone on high said, you will have a biopesticides scheme". It would appear, therefore (and it has been reinforced by our interviews), that exogenous pressure has been exerted from the Cabinet Office. This has worked alongside an endogenous steer from within the policy side of PSD. This has been picked up by individuals on the Approvals side, some of whom are clearly more enthusiastic than others about the role and prospects for biopesticides. This could be because they want to do a 'better job' or because doing the job well may be a successful career building strategy. In a sense, this links back to some of the motivations cited by Downs. It appears, therefore, that exogenous pressures are being reinforced endogenously. Of course, PSD could go further and have a separate biopesticides unit. The United States Environmental Protection Agency (EPA), for example, has a Biopesticides and Pollution Prevention Division (BPPD). It could be, for example, that some form of unit or mission (consisting of regulators) could help PSD as a whole to innovate.

One particular way of encouraging innovation may be through systematic reviews of provision. The Hampton Review on UK regulation, set up by the Chancellor of the Exchequer, reported in April 2005 and proposed streamlining the regulatory structure on the grounds that there were too many small regulators (it does not appear to apply to the PSD given the criteria used). A Better Regulation Executive has been set up in the Cabinet Office to deliver the reforms. As Grant puts it, it is evident that the core executive, in terms of both the Treasury and the Cabinet Office, are engaged with issues of regulatory structure (Grant, 2005, p. 18). Indeed, the Hampton Review was prompted in part by the Treasury who are concerned about the cost and powers of regulators. Part of the broader political context, moreover, is the growing criticism of the government for excessive regulation. Such context could perhaps help encourage a 'lighter regulatory touch' regarding biopesticides.

Stakeholders, incidentally, hold differing views on how the regulatory structure regarding pesticides could be reformed (in this context, it should be noted that the Conservatives opposition had PSD in their list of quangos to be abolished if they had won the 2005 election.) As Downs would put it, could the threat of abolition lead to bureaucracies 'raising their game'?). One suggestion in our interviews has been to enlarge the role of PSD so that it became a more general chemical regulatory and inspection authority with functions from other government agencies combined into it. Another idea was that PSD should be subsumed into the Environment Agency, but this could change the focus of PSD work to environmental impact which, when it comes to biopesticides, could be even more costly than demonstrating efficacy. A further suggestion was for a separate agency for biological controls. As Grant puts it, however, "there might be insufficient work for such an agency on a country basis, but there might be a role in this area for the European Food Safety Agency at EU level" (Grant, 2005, p. 18).

The UK Royal Commission on Environmental Protection (RCEP) published a report in September 2005 entitled Crop Spraying and the Health of Residents and Bystanders. This received considerable media attention and recommended that stricter controls be placed on the spraying of pesticides on crops, given that they may be causing ill health to bystanders and those living near sprayed fields. One of our interviewees pointed out that a BMA report fifteen years ago said similar things but nothing happened. They added, however, that the RCEP report will go further forward "because it is a Royal Commission and they are more influential".¹⁰ The report recommended that responsibility for pesticides policy be separate from that of the approval of pesticides. One suggestion was to move the policy function from the PSD to a unit within the Environment Directorate of Defra. As the Report puts it, "the unit should have a clear remit for recognising the importance of safeguarding human health and the environment as well as the requirements for pest control; the Department of Health should have an explicit role in agreeing its remit and assessing its performance." (RCEP, 2005, p. 112). The Report adds that the remaining functions concerned with the approval of pesticides could be transferred to the Environment Agency in order to ensure better co-ordination with wider environmental objectives.

It is important to note the ACP response to the Report, published in December 2005. Whilst there were parts of it with which they agreed (ACP, 2005, p. 3), they were generally very critical. With regards to the Governance issues, they believed it to be a complex issue, and did not believe that the limited discussion in the report provided an adequate basis on which to form a judgement. They went on:

We can see that there are advantages in close liaison between the policy and regulatory functions, not least because of the technical complexities of risk management for pesticides, and we would like to see the case for separation in more detail. We would, however, emphasise the need, when making decisions in this area, to take into account the current excellence of the scientific and technical staff at PSD. In our view, their performance is as strong as that of the best government departments and agencies, and ahead of the majority. It also compares favourably with that of pesticide regulatory agencies in other European countries. We believe it would be most unfortunate if a reorganisation caused this valuable concentration of expertise to be lost (ACP, 2005, p. 33).

Of course, there is a tendency for governments to bring about institutional changes in response to criticism as a substitute for making changes in policy. In Grant's words, "If PSD was, for example, incorporated into the Environment Agency, would its functioning change that much, particularly if the same people continued to work in the same distinct office in York" (Grant, 2005, p. 18). The Government's response to the RCEP report states that, "the structure and responsibilities for future pesticides policy and regulation ... is currently being considered as part of the Government to implementing the recommendations of the Hampton Review...the Government will announce the outcome of this process in due course" (DEFRA, 2006, p. 21).

¹⁰ The Government, however, has recently published its response (see, <u>www.defra.gov.uk/environment/rcep/index.htm</u>), rejecting statutory controls in favour of a voluntary approach.

Conclusions

Our project still has over another year to run. Nevertheless, our hypothesis is that regulatory inertia helps to explain why biopesticides have not been used more widely. As we have seen, the 'regulatory state' debate provides a broad context in which the project is situated. Clearly, there are substantial links between our project and Weberian theories of Bureaucracy and the literature on innovation. Possible solutions to the biopesticides problem include lowering registration costs and eliminating efficacy testing. It should be stressed, however, that we have yet to reach any final decisions on such matters. Nevertheless, we have drawn up a comprehensive list of what ('arguably') are the inadequacies of the current system and our aim, by the end of the project, is to draw up design principles for a regulatory system that will facilitate the use of biopesticides. This will be directed at decision-makers and it is to be hoped that, in itself, the work of our project will help facilitate reform (indeed, a workshop towards the end of the project will refine the interpretation of research findings and identify next actions).

We discussed in the paper some factors that may promote the necessary regulatory innovation: ranging from government intervention (exogenous pressure) to pressure within PSD (endogenous pressure). Institutional changes may be significant but at the same time must not become a substitute for changes in policy. Whilst it is clear that substantial regulatory innovation is still required, one should not ignore the considerable progress that has been made: for example, the development of PSD's pilot scheme into a more permanent biopesticides scheme It must be hoped that as biopesticides take on a higher profile with consumers and retailers, 'self-interest' (along with professionalism) could be a significant spur to innovation and reform. At the same time it is clear that exogenous pressure from the executive will continue to be required.

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