The Governance of Agro- and Pharmaceutical Biotechnology Innovation: Public Policy and Industrial Strategy

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ABSTRACT
Multinational companies in the life science sector are heavily influenced by government policies and regulations and in turn attempt to influence these actors nationally and internationally. This paper focuses on recent and on-going research, principally on the agro-biotechnology and, to a lesser extent, on the pharmaceutical industries, covering the evolution of policy and regulation in Europe, how policies are influenced by stakeholder pressures and how policy in turn influences company strategies for product development. We focus particularly on new ‘governance’ agendas in Europe and consider the relative impacts of enabling, constraining, discriminating and indiscriminate policies on company strategies as part of our development of an integrated approach to policy and governance. We also consider changes in external operating environments for multinational companies and compare past histories and present pressures on agro-biotechnology and pharmaceutical companies. The paper argues, with evidence, that a more enabling and discriminating policy and regulatory environment can achieve public goals more efficiently and effectively, taking account of impacts on innovation, than more blunt policy instruments. This type of environment takes into account the resources and capabilities available to firms and research laboratories rather than relying on broad brush carrot and stick approaches.

1. Introduction

Innovation is proceeding rapidly in the life sciences leading to new breakthrough technologies and innovation trajectories. The shifts of emphasis from innovation based on chemical knowledge towards, for example, informatics and biotechnology knowledge bases creates turbulence in company product development strategies. At the same time governance processes are becoming more complex and are placing greater constraints and uncertainties on developers. Yet citizens seem to be increasingly concerned about the lack of control over science and technology. We clearly need new modes of
governance to cope with this level of complexity. We also need new rules of engagement in the governance process for the various stakeholder groups involved, and a greater willingness by governments and regulators to take complex and sometimes unpopular decisions.

This paper is based on a series of research projects studying the interactions between: science, technology and innovation strategies in multinational companies; policies, governance and risk regulation; and public and stakeholder attitudes and concerns; mostly in the development of pesticides and GM crops. In those projects, we described the range of policy and regulatory instruments to which industry is subject, how they have interacted with strategic decision making in the multinational companies affected by them and the implications, if any, of our approach and findings for the pharmaceutical industry. The aim here is to use the data from these research projects to make a case for policy and regulatory practices that more consciously take account of impacts on innovation.

The recent background for this research has been the emergence of new governance structures and policy processes in Europe and North America under a variety of labels at different institutional levels. This change has involved a move away from policy and regulatory environments largely influenced by a so-called government agenda (a more top–down legislative approach led by the institutions of the state) which tends to regulate the behaviour of people and institutions in quite detailed and compartmentalised ways) towards a more governance-based influence (which attempts to set the parameters of the system within which people and institutions behave so that self regulation has a greater chance of achieving the desired outcomes). Put more simply, the replacement of traditional ‘powers over’ with contextual ‘powers to’. A consistent theme throughout this new governance agenda is the need for more integrated or ‘joined up’ policy approaches to remove contradictions, inconsistencies and inefficiencies caused when policies or regulations emerging from different government departments or different levels of government (regional, national, international) contradict one another or provide incompatible signals to policy targets. Policy integration is also needed to deal with the complexity and uncertainty associated with many decisions concerning science and technology.

We argue that some agricultural and medical developments such as those associated with biotechnology are evolving faster than relevant policy and regulatory systems and many of the new emerging products cross the boundaries of existing regulatory systems. Despite the importance of new ‘governance-based’ policy initiatives to the promotion and regulation of scientific research and innovation, academic analysis and new policy thinking has been focused mostly on the social policy arena and on local and regional politics. Overall, there has been less evidence of new governance thinking being applied to science, technology and innovation (STI) policy development although there is significant research on broad science and technology policy and on relations between universities, industry and government, sometimes referred to as the triple helix. Neglected areas include interactions between public policy and company strategy, and the integration of STI promotion policies with the regulation of health and environmental impacts of technology. Thus, in some of our areas of interest, we had little previous academic research on which to draw, and have in some cases developed our own analytical frameworks for the interactions between industry strategies, government policies and stakeholder pressures.
2. Categorising Policy and Regulatory Signals

The agro- and pharmaceutical biotechnology industries still operate against a background of intense and very restrictive regulation operating on a global scale. As policy and regulatory systems have become more complex, the need to categorise the increasingly wide range of instruments being considered or used nationally and internationally has become more urgent, particularly as a means to analyse the effectiveness of different policy approaches and their impacts on policy targets.

All classifications reflect the purposes and perspectives of those who develop them and our approach here derives from a systemic, interdisciplinary perspective on policy analysis with the purpose of contributing to the understanding and improvement of regulatory processes as they impact on their target groups. As part of several different analyses we have categorised the various policy and regulatory instruments that are relevant to the life science industries. Given the diversity of policy contexts and stakeholders involved it is not appropriate to attempt to develop a single set of policy categories that would answer all our analytical needs and would cover all the circumstances relevant to the life science industries. This would have required over-simplification of our data and loss of the richness of understanding of the industry and its management contained within them.

This section outlines four approaches to classification of policies and regulations, each being relevant to a particular set of circumstances and reflecting a particular analytical perspective on life science industry sectors, their regulation and the interactions with policy makers, innovation communities and product markets. Section 3 develops a more integrative approach based on experience outlined in Section 2, attempting to bring together government- and governance-based approaches.

2.1 Reactive and Precautionary Signals to Industry

This classification emerges from differences in the ways regulators respond to evidence of harm or uncertainty about potential harm.

The regulatory systems that have developed over the years for pesticides can be described as ‘reactive’, where the agrochemical industry and its products are controlled by a system set up in response to quantitative evidence of adverse impacts that have arisen in earlier generations of products. New products are screened to ensure that they do not give rise to similar hazards. The regulatory system is built up slowly in a piecemeal fashion as new products exhibit different, often unexpected hazards and decisions about the need for, and level of, regulation are taken in relation to the relevant costs and benefits.9

The regulatory systems for pesticides were set up in response to evidence accumulated in the 1960s and 70s that organochlorine insecticides were harming wildlife.10 Once this evidence had been accepted by government policy makers, regulations were introduced to ensure that chemicals which were persistent in the natural environment, previously seen as a desirable attribute, would not be approved for use.

This was necessary particularly to take account of experiences described by our interviewees who were policy makers at national and EU levels and senior managers in the agro-biotechnology and pharmaceutical industries.
More recently, once pesticide residues began to appear in drinking water the EC Drinking Water Directive (80/778) was introduced to prohibit the use of any chemical residues that appeared in drinking water at more than a very minimal level. Once again, screening systems for new pesticides were adjusted so that mobility in soils became a reason for early rejection of a chemical in development pipelines.

This inexorable intensification of pesticide regulation, an example of old style government, has continued throughout the period when many other regulatory and policy areas were being subjected to de-regulation initiatives as part of a switch to more governance based systems. In the case of pesticides, the overall form of the regulatory system remained and the constraints it placed on industry were gradually extended.

In the 1980s, governments were beginning to consider how to regulate the emerging agro-biotechnology industry, in particular genetically modified (GM) crops. The European policy and regulatory response to this new technology was determined partly by the experience of pesticide regulation in the 1960s and 1970s. The delay in recognising the ecological damage being caused by organochlorine insecticides and the very rigorous standards required for evidence of harm before action was taken had undermined the public image of the chemical industry and also public confidence in regulators in this area. As a result the precautionary principle began to make an appearance in policy dialogues and it has now achieved a formal status in several European and international treaties and regulatory frameworks.

As the companies developing GM crops were those that had previously produced organochlorine and other pesticides, it is not surprising that they became the first industry sector to be systematically subjected to a precautionary approach to its regulation. Tait and Levidow described the precautionary approach as applied to GM crops as follows:

The industry concerned, and its products, are controlled by a system set up to avoid potential hazards, predicted in advance of the development and/or marketing of products, and before there is any empirical evidence for the existence of such hazards.

An early policy document produced under the auspices of the European Commission and a report from the UK Royal Commission on Environmental Pollution among many other documents produced around this time, confirmed the precautionary nature of the proposed systems being developed in Europe.

The precautionary approach to the regulation of GM crops was initially accepted by most industry managers, scientists and regulators on both sides of the Atlantic. However, as products grew closer to market readiness in the late 1980s, regulators in the USA and industry managers in Europe and the USA began increasingly aggressively to support a much more reactive approach based on the existing regulatory systems for foods and pesticides. This confrontation has often been expressed as being between product-based and process-based approaches to regulation and interviews conducted with policy makers and industry managers in the late 1980s indicated that the former equated to a reactive risk regulatory system and the latter to a precautionary system.

This fundamental disagreement over how GM crops should be categorised for regulatory purposes is as strong today as it was in 1990 and underlies the current US challenge to the EU through the World Trade Organisation.

In the context of the shift from government-based to governance-based policy and regulatory systems the precautionary approach, although it could not by any means be
described as part of a de-regulatory agenda, has allowed many other aspects of governance-based approaches to be incorporated into GM crop regulatory systems, particularly the much stronger role of public consultation and stakeholder dialogue in government decision making on science and technology issues.\textsuperscript{17}

The precautionary principle has made it possible to bring arguments based on ethics and values into risk debates in ways that were not previously possible and, in the UK at least, environmental and other non-governmental organisations (NGOs) have been able to dictate the terms of the debate to an unprecedented degree.\textsuperscript{18}

At least in the context of GM crops in Europe, the adoption of the precautionary principle and of a range of mechanisms associated with the new governance agenda has not yet improved their governability, despite the introduction of a new EC Directive (2001/18) and several additional supporting pieces of legislation.

Regarding the regulation of drugs, there is currently a trans-Atlantic consensus. However, the potential for disputes, as happened in the agro-biotechnology sector, is likely to emerge as disruptive new technologies such as stem cell-related products emerge in the USA and EU.

Stem cell technology is highly relevant to future developments in the pharmaceutical industry. For example, if stem cells are effective in providing cures for major diseases like diabetes and Parkinson’s disease, they will undermine existing ‘block-buster’ drug markets. At present, this has not become controversial because no formulae have been found for making money from stem cell therapies, but when this becomes a possibility, the issue of regulation is likely to attract more interest.

There are already differences between the USA and EU in the emerging regulatory systems for stem cells. In the USA, for example, with echoes of the GM crop debate, stem cells are being treated as a ‘product’. The FDA has claimed jurisdiction over them with the implication that they will be treated as drugs for regulatory purposes.\textsuperscript{19} In Europe, on the other hand, stem cells are likely to be treated as devices with the implication that they will be regulated as analogous to surgical procedures/processes.\textsuperscript{20}

\subsection*{2.2 Outcome and Sector Based Policies and Instruments}

An alternative categorisation of policy and regulatory instruments, again arising from the policy maker’s perspective, focuses on the desired impacts on target groups such as European agricultural systems, the agro-biotechnology or pharmaceutical industry sectors. We adopted it in the context of policy analysis relevant to innovation in agro-biotechnology companies.\textsuperscript{21} On this basis, policies are categorised according to the target to which they are directed and types of outcome sought.

\subsubsection*{2.2.1 Science, technology and innovation (STI) policies}

A cluster of different STI policies are relevant to biotechnology innovation in industry and public sector research: intellectual property rights; special support programmes for biotechnology research; support for small biotechnology companies; special R&D programmes for public health improvement or better crop protection; and restructuring of public research systems for health or agriculture.

The pharmaceutical and agro-biotechnology industries claim that better intellectual property (IP) protection of biotechnology inventions is needed to provide an incentive for investment in biotechnology research and that weak protection in the EU leads to a
competitive disadvantage for European industry. However, an EU proposal to strengthen IP protection was opposed in the European Parliament because of ethical objections to genetic engineering and the appropriation of life forms. After 10 years of debate, the European Directive on the Legal Protection of Biotechnology Inventions (Directive 98/44/EEC) was approved in May 1998 but there have been long delays in implementing the Directive in several European countries.

The question of IP rights is closely related to public promotion of biotechnology research at EU and national levels. Life sciences are considered key enabling technologies that can generate economic growth and can help achieve societal goals in the areas of health care, agro-food and environment. Likewise, an important component of STI policies is financial support for small dedicated biotechnology firms, justified on the basis of encouraging innovation and its more rapid commercialisation. However, at least in Europe, the difficulties experienced in gaining approval for GM crops has discouraged small companies from working in the area of agro-biotechnology and most are working in the area of human health biotechnology where the prospects of long term viability seem slightly better.

STI policies are most relevant in the early research stages of new product development. If applied effectively, they enhance fundamental and applied knowledge in the field of biology, chemistry, genetics, and biotechnology, and are justified politically on the basis of indirectly improving living conditions and national and international competitiveness.

However, despite the stated aims of government agencies, an alternative view of policies supporting small, dedicated biotechnology firms is that they provide indirect support to the development costs of multinational companies. Because of the high regulatory hurdles, both reactive and precautionary, small firms are dependent on multinational companies for the commercialisation of their products and generally their ultimate aim is to be taken over by one of them. The need for small companies to make themselves attractive acquisition targets constrains their innovation strategies and restricts them to products that are compatible with strategies of multinational companies, rather than potentially competing with them.

2.2.2 Policies regulating industry and farming (Environmental protection, public health and safety)

Section 2.1 discussed the types of policy represented here according to whether they are reactive or precautionary, based, as noted there, on responses to evidence of harm, or lack of it. The focus here on policy targets and outcomes draws attention to the motivations of key actors such as farmers and industry managers in responding to these policies and regulations.

In addition to the straightforward, direct effects of product regulatory systems in keeping unsafe products off the market, these regulatory systems also send signals to the developers of future products, guiding them in particular directions. Thus, the US Food Quality Protection Act, 1996, among other incentives set up a ‘fast track’ regulatory procedure for new pesticides deemed to have reduced risk of harm to the environment or human health. This creates a considerable advantage to firms that have developed such products and disadvantages rivals that have failed to do so.

Banning particular products can also create advantages for some innovative companies. It is rare for a product to be banned or restricted while still enjoying patent protection. For an innovative firm, banning an older, off-patent product may open up opportunities to
introduce a new, patented and hence more profitable product to replace it. In such cases there are always winners and losers but the more innovative companies are usually the ones that benefit most.

2.2.3 Policy interactions and impacts on companies
The consciously integrated or ‘joined up’ policy approaches that are part of new governance agendas are not much in evidence in these industry sectors. However, unplanned interactions are common and the two policy areas outlined above can deliver conflicting messages to industry decision makers.

The ‘Foresight’ process adopted when big multinational companies plan their product development strategies, usually over a 15–20 year time scale, is based primarily on new opportunities presented by fundamental research and technological innovation, and new market opportunities. Policies directed to industry and the research community influence the former and policies directed to farmers influence the latter.

Policies directed to industry and innovation communities in the public sector include: regulatory and approval systems for new products entering the market, e.g. for pesticides, GM crops and drugs; and national and EU policies to stimulate knowledge production, technological innovation and international competitiveness.

Policies directed to farmers or health systems will influence their purchasing decisions and will thus indirectly affect industry and innovation communities, for example: restrictions on the use of some products regarded as damaging to the environment or to health; the availability, and the basis of, subsidies and other production-related supports; and, policies designed to direct producers to rely on world food commodity prices.

In agriculture, for example, the policy environment is sending confusing or contradictory signals to the companies developing new technology and the farmers who might use it. Under WTO rules, reforms to the CAP have in the EU shifted the justification for agricultural support away from the encouragement of food production and technological innovation towards rural development in disadvantaged areas and specific environmental objectives such as the preservation of species and habitats.23 The general policy trend is to direct farmers away from technology-based, conventional farming systems towards organic and associated integrated systems. The assumption driving most agricultural policy initiatives seems to be that food surpluses will continue to be a problem rather than an asset for the foreseeable future, at least in those developed countries that dominate international agricultural policy making.

The main European policy contradiction facing the biotechnology industry is between policies that attempt directly to promote technological innovation by companies, and those that operate through the market to undermine such developments. Regulatory policies constrain the use of certain products but they can also be used constructively to promote certain types of innovation, for example, as noted above, encouraging the development of products which have a better environmental performance or are safer to use. Although strongest in agriculture, it is also possible to see the beginnings of such tensions emerging in the health-related life science industry sectors.

2.3 Transboundary Risk Regulation
Drugs, agrochemicals and GM crops are produced by multinational companies and traded globally. For a recent project24 we developed a categorisation of trans-boundary risks that
facilitated analysis of international policies and regulations, including examples based on pesticides, GM crops and drugs.

This system categorised trans-boundary risks according to whether the items generating the risk are traded across international boundaries (Traded Risks), or can cross without restriction (Public Risks). The traded category is appropriate to medicinal products, pesticides and GM crops that are traded across boundaries with the knowledge and consent of national authorities, backed up to some extent by internationally coordinated standards and regulations. Transboundary regulation in these cases is about controlling the mechanisms of trade, avoiding risks but also avoiding the use of national regulations to discriminate unfairly among suppliers and, as we note below, about providing an explanation of the new abilities of consumers to influence international trade, perhaps more powerfully than some government bodies.

Within this traded risk category we describe two classes, product-based and production system-based, which raise different issues and require different approaches to management. These categories, as described here, can be useful for analysis at both national and international levels. The production system based category has obvious connections to the precautionary, process-based approach to the regulation of GM crops (see Section 2.1), but this approach to categorisation gives a new set of insights into the motivations underlying the trade-related actions of some stakeholders.

1. For traded, product-based risks the product itself is considered potentially hazardous (pesticides, food contaminated by pesticide residues, GM food or seeds, medicinal products). National authorities can sample and test for products that have been identified by regulatory agencies as presenting hazards to health or the environment at the frontier and can restrict entry if necessary.

2. For traded production system-based risks the hazard is only symbolically attached to the traded product (e.g. food products that have been produced by intensive farming methods, GM crops). In most such cases there is no internationally accepted basis for national authorities to reject such products at customs control points. However, if the origin of the products is identified by labelling, environmental and other pressure groups can campaign against it and individual consumers can exercise their right ‘not to buy’. In this case, the risk itself does not cross national boundaries but public concerns do—people want to have an influence on what happens in other countries or on the strategies of multinational companies, often from an altruistic basis of concern for global or local environmental sustainability or for the health or well being of workers in other countries.

The US opposition to process-based, precautionary systems of regulation has been at least partly motivated by the recognition that these can be used very effectively by governments, sometimes in response to public pressures, to restrict trade. International regulation through the World Trade Organisation is progressing, somewhat fitfully, to deal equitably with such restrictive practices. However, at the level of individual consumers who can exercise their right not to buy particular products, this phenomenon is much more difficult for a would-be exporter to deal with. If European consumers will not buy GM foods then supermarkets will not stock them and farmers in Europe and elsewhere will not grow them, regardless of their regulatory status.
It is by no means clear that this would be the outcome if GM foods were widely available in European supermarkets but it is very clear that many European citizens want this choice, which requires labelling produce on the basis of its GM content. Industry and US regulators strongly oppose labelling such products, ostensibly on grounds of cost but the recognition of the power that labelling gives to consumers is at least part of the story.

2.4 Carrots, Sticks and Sermons

One existing framework that seems potentially applicable in the context of policy impacts on industry strategies is that developed by Bemelmans-Videc et al. This classifies policy instruments according to their mode of operation and also the nature of their impact on the targets. Thus, regulations are described as ‘sticks’, economic instruments as ‘carrots’ and information campaigns as ‘sermons’. Unfortunately as the analysis proceeds through the book, some semantic confusion emerges in the framework with both regulations and economic means described as either ‘affirmative’ or ‘negative’, implying that each can act as either carrots or sticks (see Table 1).

For this reason we found this approach less useful than others described here for helping to understand policy impacts and the behaviour of policy targets.

In our research, company managers described their responses to different regulatory systems in Europe and the USA in a way that implied the need for a more subtle categorisation of regulatory instruments than this, to recognise the continuing need to regulate pesticides and drugs as products, but at the same time to guide policy makers and regulators towards a more effective, more governance-based approach to the design of policy instruments.

3. A Governance Based Categorisation of Policy Instruments

To assist in understanding the perspectives of industry managers and policy makers, we propose an alternative categorisation of policy instruments. Its focus is on the effectiveness and efficiency of the governance achieved by a particular policy or regulatory instrument. We categorise policies and regulations according to whether they are perceived as enabling or constraining by industry managers (equivalent to ‘affirmative’ or ‘negative’ in the classification of Bemelmans-Videc et al.). This can have a major impact on the extent to which they are effective and on the cost of implementation.

Our second basis for classification is whether regulations and policies are indiscriminate or discriminating among products; or in some cases whether they discriminate on an inappropriate basis (i.e. inappropriate to the policy overall aims). Indiscriminate policies or those which

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<th>Affirmative and negative variants</th>
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<td>Regulation (the stick)</td>
<td>Affirmative (prescriptions)</td>
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<td>Negative (proscriptions)</td>
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<td>Economic means (the carrot)</td>
<td>Affirmative (subsidies, grants, in kind services)</td>
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<td></td>
<td>Negative (taxes, fees, physical obstacles)</td>
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<tr>
<td>Information (the sermon)</td>
<td>Affirmative (encouragement)</td>
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<td>Negative (warnings)</td>
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Table 1. Carrots, sticks and sermons
discriminate on an inappropriate basis are likely to be less effective than intended or to have negative, counter-intuitive effects on the target of regulation. An appropriate basis for discrimination among pesticides would, for example, be one that takes account of the toxicological profiles of different pesticides for human health and the environment.

Figure 1 shows where we would place some of the pesticide regulatory and economic instruments discussed above on these two dimensions—enabling/constraining and discriminating/indiscriminate. Note that these are not fundamental, immutable categories. They relate to the perceptions of policy makers and managers. Even in the same company, one manager may see a particular regulatory policy as constraining while another sees it as enabling. For example, the Food Quality Protection Act was perceived as enabling, encouraging a particular type of development strategy, by the managers we interviewed. However, for those companies who did not have appropriate products in their pipeline, it was constraining. The following sections expand on these categories in more detail.

3.1 Enabling Policies which Discriminate on an Appropriate Basis (Figure 1, Box 1)

In our interviews with European policy makers, we discussed the need to introduce regulatory measures for pesticides that would favour (i.e. encourage the development of) products with a reduced risk to human health or the environment and thus influence industry strategies in that direction. This approach was seen by EU policy makers to be impossible to implement in an evidence-based system because of the lack of agreed indicators by which to judge the potential environmental harm from individual pesticides in use. Thus, regulators believed that such an approach would be open to legal challenge because it was not based on sound science, a complaint that was also heard from companies whose product development strategies were not favoured by this approach.

The US Food Quality Protection Act (FQPA) 1996 had, according to some of our industry interviewees, fundamentally changed the way companies respond to signals from the Environmental Protection Agency (EPA) in the regulation of pesticides. The new safety

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<td>Box 1</td>
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<tr>
<td>Food Quality Protection Act, 1996; selective fast track registration</td>
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<td>Pesticide Registration/ Re-registration/ Review</td>
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<td>Promotion of integrated pest management</td>
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<td>Selective Pesticide Tax</td>
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<td>Pesticide Registration/ Re-registration/ Review</td>
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<td>EC Pesticide Regulation (91/414/EEC)</td>
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<td>Box 3</td>
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<td>Previous Farm Price Support Systems aiming to increase agricultural productivity (e.g. CAP)</td>
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<td>Box 4</td>
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<td>EC Drinking Water Directive (80/778/EEC)</td>
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<td>Indiscriminate Pesticide Tax</td>
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<td>Overall, un-targeted reduction of subsidy (CAP reform)</td>
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<td>Promotion of integrated pest management</td>
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Figure 1. Pesticide policy dimensions
standard—reasonable certainty of no harm—that is to be applied to all pesticides used on food crops is coupled to a system which expedites the approval of safer pesticides (www.epa.gov/oppfead1/fqpa), i.e. pesticides that can meet this requirement can have their products registered on a ‘fast track’ basis. Such instruments selectively enable some companies to gain an advantage over others and can in a very short space of time alter the behaviour of a whole industry sector. This Act was reported by some managers to have had a major impact on the pesticide development strategies of their companies. They described a situation where the number of candidate products with these desirable properties was enough to ensure that any product without these benefits was unlikely to be registered by the EPA in a reasonable time scale. For the companies we interviewed, the FQPA was thus enabling and discriminating (Figure 1, Box 1).

We have tried, so far unsuccessfully, to find evidence from policy decisions by the EPA that the FQPA is indeed operating to improve the environment and health related properties of new pesticides being regulated. Although the FQPA seems to be a regulatory instrument that works in the governance sense, this seems to be a marginal outcome from legislation intended for other purposes. Improved environmental performance of pesticides does not seem to have been an important enough policy aim for the EPA to be collecting evidence of its success, even although some industry managers perceived it to be operating in this manner.

3.2 Constraining Policies which Discriminate on an Appropriate Basis (Figure 1, Box 2)

Most pesticide regulatory systems, e.g. the EC pesticide regulatory system based on Directive 91/414/EEC, did not discriminate on the basis of whether particular chemicals can be regarded as ‘safer’ than currently available products—at the time of our research, any product capable of passing the pesticide regulatory process was deemed ‘safe enough’. Thus, pesticide regulations did discriminate among chemicals on the appropriate basis of their general safety to the environment and to human health, up to a given point, but they also acted as a constraint rather than an incentive on the behaviour of companies in that they did not encourage companies to compete with each other on the basis of continually improving the safety of their products, as was the case for the FQPA (Figure 1, Box 2).

Pesticide re-registration and review can discriminate among chemicals so as to deny ‘approved’ status to some chemicals currently on the market which are deemed to be more damaging to health or the environment. This was generally described by managers as constraining (Figure 1, Box 2), although it can be enabling for companies in that it opens up market niches for alternative and safer products (Figure 1, Box 1). Likewise, depending on how it is applied, a pesticide tax, which was invariably described by industry managers as constraining, could be either discriminating if it is applied selectively to pesticides with more damaging environmental or health impacts (Figure 1, Box 2) or indiscriminate if it is applied equally to all pesticides (Figure 1, Box 4).

3.3 Enabling Policies that are Indiscriminate or Discriminate on an Inappropriate Basis (Figure 1, Box 3)

Throughout much of its life the EU Common Agricultural Policy (CAP) has acted as an incentive to farmers to use inputs like pesticides on their crops, with no discrimination
between products (Figure 1, Box 3). It has thus been enabling as far as industry managers are concerned, providing a ready market for pesticides. CAP reforms where they are directed indiscriminately to reducing the levels of pesticide use, are likely to discourage innovation at the farm level and hence act as a brake on pesticide innovation strategies in industry (Figure 1, Box 4).

3.4 Constraining Policies that are Indiscriminate or Discriminate on an Inappropriate Basis (Figure 1, Box 4)

Policies in this category tend to discourage innovation relevant to clean technology. An example is the European Drinking Water Directive (80/778/EEC), which sets a very low and indiscriminate limit on the permitted level of contamination of drinking water by pesticides, regardless of the toxicity of the chemicals involved (Figure 1, Box 4). As a result, the screening systems set up by agrochemical companies to detect promising new pesticides will automatically reject any chemical with a tendency to be readily mobilised in soils. This is not to suggest that soil mobility is an inappropriate criterion for judging a candidate pesticide chemical, but a relatively non-toxic chemical with a high mobility in soil may not present a problem and indeed may be safer in many other respects than one that is more toxic but less mobile. Thus, a more appropriate and discriminating set of criteria would be a combination of toxicity, persistence and mobility in soils.

Zeneca Agrochemicals was able to give us an example of how this regulatory category operates in practice. Their strobilurin fungicides were widely regarded as very safe products. One of the group was the first product to be registered under the fast track system set up by the US Food Quality Protection Act and the company was awarded the UK Queen’s Award for Technological Achievement in 1999 in recognition of the qualities of this product. However, this class of chemicals narrowly escaped being rejected at an early stage of product development because of their mobility in soils and hence the danger of falling foul of the EC Drinking Water Directive.

Policies to promote integrated pest management replace the use of technology-based inputs by managerial activities such as crop monitoring, rotation, mechanical cultivation and more accurate timing of inputs, to maximise the role of natural ecological support systems in crop production. Their aim is usually the minimisation of pesticide use on an indiscriminate basis (Figure 1, Box 4). However, where they direct farmers towards products that are more environmentally benign, as is the case with some contracts drawn up by food processors and distributors such as the big supermarket chains, they can have a beneficial impact on industry strategies by opening up markets for new more environmentally benign products (Figure 1, Box 1). For example, Novartis at the time of our interviews, was developing product ranges specifically directed to support integrated farming systems, described by them as ‘the farmer’s best combination of crop protection measures’ in terms of being cost effective, environmentally sound and socially acceptable.

4. An Integrated Approach to Policy and Governance

The integrated policy analysis outlined above shows that some policy and regulatory initiatives can have major, rapid and positive influences on innovation processes but they are infrequent and their value and significance may not be intended or even recognised by those who develop them. It is more usual to find that policies and regulations
emerging from one policy area have unexpected and unwelcome effects in other areas or are counteracted by constraints that were not previously recognised. Regulations will impact differently on different firms and sectors according to the resources and capabilities available to them. In this respect, the analytical approach we are developing allows for an understanding of the impact of regulation that is more nuanced and ‘resource-based’.

Figure 2 summarises some of the results of our research on the policy and regulatory instruments that have an impact on the agro-biotechnology industry based on the systems of categorisation outlined in Section 3. It demonstrates the complexity of the governance processes faced by the industry in developing new pesticides, the contradictions inherent in some policy interactions and the implications for the development of more integrated policy approaches.

The core focus in this diagram is on the key actors in innovation processes who are the targets of a wide range of policies. These actors are linked to one another in often-complex webs of interaction. The thick arrows on the diagram are a very simplified version of reality, and another part of our integrated analysis is focusing on the increasingly fluid and turbulent set of relationships and interactions among small, medium and large companies and their markets (see Section 5 below). These actors are influenced by a policy environment that includes regulations, fiscal measures, manipulation of the infrastructure, and a range of non-statutory, voluntary incentives and constraints. The overall, if unstated, aim of this mix of policies is to encourage the delivery by these actors of a set of outputs/products that are socially acceptable as well as being profitable to the companies involved.

Figure 2. Integrated policy analysis for agro biotechnology and pharmaceuticals.
The boxes and arrows on the left side of Figure 2 show which components of the policy environment were seen as enabling by our interviewees in multinational companies, whether they were discriminating or indiscriminate, and which part of the actor network they targeted. The boxes and arrows on the right side of this diagram are the components of the policy environment regarded by them as constraining. Where the same component of the policy environment appears on both sides of the diagram (finance and infrastructure policies, product and process regulation), this indicates that it was seen either as enabling or constraining by the same manager, depending on circumstances, or enabling for some managers and constraining for others. Of course, an independent observer may have a different interpretation of whether components of the policy environment are enabling or constraining from that of industry managers.

5. Governance and Innovation in Agro-biotechnology and Pharmaceuticals

The extremely demanding regulatory systems to which the agro-biotechnology and pharmaceutical industries are subject have shaped the innovation pathways in these industries. The very high costs and long delays entailed in taking a new product through the regulatory system, and related patent protection systems, ensure that only large multinational companies (MNCs) have the necessary resources to operate through the whole innovation cycle.

This barrier to entry for small companies has so far largely determined the structure of the pharmaceutical and agro-biotechnology industry sectors, leaving the large multinationals in an unassailable position and insulating them from challenges to their supremacy by smaller innovative companies. Small companies (SMEs) or researchers based in universities or public sector research establishments (PSREs) rely on MNCs to take their products, at least through later stages of the regulatory process, and then to market them. SMEs thus tailor their innovation strategies to match, rather than to challenge, those of MNCs. Regulation per se has thus been enabling for MNCs, contributing to their global dominance, and highly constraining for small companies. Indeed, where governments promote policies to encourage innovation in SMEs, the usual outcome is the provision of indirect support to the development costs of MNCs.

Pesticides and GM crops are purchased by farmers whose products then reach the consumer via an increasingly complex and internationalised distribution and marketing chain. It is difficult for consumers to have a voice in farmers’ purchasing decisions, whether for pesticides or for GM crops. However, as outlined in Section 2.3, the success of production-system based boycotts, against GM crops in particular, has enabled consumer direct action to leap across several layers in the governance hierarchy and to change the thinking of managers in agro-biotechnology about who are their ultimate customers.

The markets for drugs have been even less open to public direct influence by consumers than those for pesticides, although this has been changing to some extent as a result of internet-based sales of drugs. In the pharmaceutical sector we are seeing growing public concern about drug side effects and also some aspects of the behaviour of large pharmaceutical companies, leading to threats of legal action against several companies with serious effects on share values and profit margins, although no equivalent of production-system based consumer direct action has yet emerged in the pharmaceuticals sector.
The remoteness of MNCs from any public consumer base, their global reach, their sometimes arrogant attitudes in response to public concerns, and the public perception that they are, in many senses, ‘beyond governance’, have contributed to the lack of public trust in both agro-biotechnology and pharmaceutical industry sectors.

Regulatory systems are crucial to the fate of the agro-chemical and pharmaceutical industry sectors but they are not evolving fast enough to keep pace with technological change. These industry sectors are facing an array of simultaneous challenges: maturity in existing product portfolios; accommodating disruptive new technologies; and, increasing demands for more public and stakeholder engagement in the development and regulation of innovation through new governance approaches.

The more governance based European regulatory system developed for GM crops has so far failed to provide a viable pathway to market for innovative products from the agro-biotechnology industry. In addition, it has not yet succeeded in providing European consumers with the choice of buying GM foods if they wish to do so. Thus, only those who wish to see such products kept off the market at all costs would consider the shift to a new governance agenda in Europe as having resulted in better regulation of technology.

The regulatory systems in place for GM crops in the USA correspond more closely to an old-style government approach. There is no doubt that they have successfully fostered innovation in the development of GM crops and given US citizens the option to buy GM foods, although at the same time making it more difficult to avoid buying such products—the converse of the European position.

However, as GM crop technology becomes more sophisticated and the products being developed become more complex, the current comparative advantage for industry of US over European regulatory systems may no longer hold. Europe’s long and difficult experience in the development of process-based governance systems may yet pay off.

To deliver the most efficient and effective governance systems for agro-biotechnology and for the pharmaceutical industry, the US and the EU have much to learn from each other and the kind of analysis presented here could contribute to that learning process.

Our analysis would thus identify constraining, indiscriminate, product-based regulatory policies and instruments as being part of old-style government. The governance approach, on the other hand, would include policies and instruments that are enabling, discriminating and process based. The production system-based approach, although not part of a formal regulatory system, also plays an informal role in governance processes, out of the reach and beyond the influence of regulators. The precautionary principle could, in theory, be incorporated into either government- or governance-based systems, but its use so far has been mainly to support the incorporation of certain public values into European governance-based regulatory systems.

Important points to emerge from this analysis include the following.

- Some policy and regulatory initiatives can have major, rapid and positive influences on innovation processes but they are infrequent and their value and significance may not be recognised.
- It is more usual to find that policies and regulations emerging from one policy area have unexpected negative effects in other areas or are counteracted by constraints which were not previously recognised.
- Good governance is most likely to be achieved by creating a policy and regulatory environment that is consciously enabling in the desired direction, rather than being
constraining and restrictive, and also that discriminates among products on the basis of the most relevant criteria. The most successful enabling and discriminating regulation takes into consideration the resources and capabilities available to innovators.

Whether a policy is enabling or constraining appears to have less of an influence on its ability to encourage ‘cleaner’ innovation than the extent and appropriateness of its discrimination among products. However, having said that, enabling policies are likely to have a more rapid impact and to be less expensive to monitor and enforce.

A recent paper has made an important contribution to the integrated governance of technological change. It suggests that there is a need for a substantial research agenda to study the governance of technology, ‘the shifting kaleidoscope of governance structures and processes’, both as an academic study and to inform policy processes. Perri, author of the paper, particularly emphasises the need to see the whole system, to examine both control and inducement and their inter-dependencies, and also the interactions between tools and structures.

The challenge for the future is to incorporate the most useful aspects of governance-based approaches into the regulatory systems being developed to accommodate disruptive innovations in the agro-biotechnology and pharmaceutical industry sectors.

Notes and References

2. In particular, Policy Influences on Technology for Agriculture (PITA), EC 4th Framework Programme, Targeted Socio-Economic Research Programme (TSER) (see http://technology.open.ac.uk/cts/pita/ for the full set of reports from this project, accessed 12 July 2004); the SUPRA Seminars: Best Practice in Evidence Based Policy in a Devolved Context, UK Economic and Social Research Council (ESRC) (www.supra.ed.ac.uk, accessed 12 July 2004); Innogen: Centre for Social and Economic Research on Innovation in Genomics (ESRC) (www.innogen.ac.uk, accessed 12 July 2004).
12. Tait & Levidow, *op. cit.*, Ref. 9, p. 222.
27. Adapted from Bemelmans-Videc et al., *ibid.*, p. 250.
29. Bemelmans-Videc et al., *op. cit.*, Ref. 27.
31. Tait & Williams, *op. cit.*, Ref. 22.