
**ESRC Centre for Analysis of Risk and Regulation**

# The Impact of Regulations on Firms. A Study of the Biotech Industry

Filippa Corneliussen



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# The Impact of Regulations on Firms
# A Study of the Biotech Industry[1]


## Abstract

This paper investigates how the rapidly expanding biotech industry is regulated, and how these regulations impact on firms in practice. More specifically, it considers how much is known and understood about the regulations and their provisions, and about the regulatory apparatus in place for their implementation. Drawing on semi-structured interviews carried out with founders, managers and senior scientists in start-up biotech firms, the paper illustrates that the socio-legal literature's characterisation of small firms as less compliance orientated is too neat. Small firms do not necessarily have a limited knowledge and comprehension of the law. Nor do they necessarily have low levels of motivation to improve and maintain health and safety standards. In fact, the opposite may be true. Small firms may approach the regulatory ideal where the routines, procedures and precautionary measures prescribed by regulations permeate the organisations.


## Introduction

In its 1993 report *Growth, Competitiveness, Employment – The Challenges and Way Forward into the 21st Century*, the European Commission stated that 'biotechnology has emerged as one of the most promising and crucial technologies for sustainable development in the next century'. Biotechnology can raise the quality of life of Europeans by, for example, improving the quality of healthcare and reducing the impact of pollution. It can improve the standard of living by increasing the efficiency of production processes and by creating new products with more value-added. Moreover, biotechnology can create new jobs through the establishment of firms to exploit the technology or through the investment by non-specialist firms in new Research and Development (R&D) and production facilities. The use of biotechnology can also improve the competitiveness of existing industries, so helping protect existing employment in them. Effective exploitation of biotechnology can furthermore help shift the European economy towards one based more upon advanced knowledge and skills, and depending less upon traditional sources of advantage such as low labour costs and control over raw materials (EuropaBio, 1997).

The private sector is the main developer of biotechnology – translating the promises of the technology into tangible benefits. The first biotechnology firms were mainly founded in the US in the late 1970s and some of these firms – like Genentech, Biogen and Amgen – are still


[1] I would like to thank Bridget Hutter for her helpful comments on earlier drafts of this paper. I would also like to thank my informants who gave generously of their time.

operational. Since then the industry has expanded rapidly and, at present, it is estimated that there are over 600 public and over 3,500 private firms globally, employing over 188,000 people (Ernst and Young, 2002).

The aim of this paper is to discuss how this increasingly prominent industry is regulated. More importantly, though, it is to explore the ground-level impact these regulations have on biotech firms, because, as Kagan notes, 'the real meaning of regulatory law can be determined only by observing what occurs "on the ground"' (1989: 91). The paper draws on material from a comparative study of Scotland and Norway based primarily on semi-structured interviews carried out with founders, managers and senior scientists of biotech firms in the two countries. To place this study in context, I outline, in the next section, some of the key issues arising from the socio-legal literature on regulatory impact. Bringing the focus back to biotechnology, I move on in the third section to consider the nature of the biotech industry, and to discuss its regulatory framework in general, as well as more locally in Scotland and Norway. The following section then presents data from the interviews I conducted, illustrating my informants' knowledge of the regulations and the state's regulatory structure, and indicating the influence the regulations have on their activities. In the final section, I explore the regulatory ideal where the routines, procedures and precautionary measures prescribed by regulations become internalised by firms and individuals, and the extent to which the biotech firms in the study conform to this objective.

**Assessing the Impact of Regulations**

To investigate the impact regulations have on biotech firms, this paper explores how much is known and understood about the regulations and their provisions, and about the regulatory apparatus in place for their implementation. To date, there have only been a small number of socio-legal studies focusing on employee knowledge and comprehension of the law (Sitkin and Bies, 1994). An early study was Brittan's (1984) work on water pollution control exploring knowledge of the law in industrial and agricultural businesses. She found that 'most of the trade effluent dischargers claimed to know the law in general terms but certainly not ''word for word''' (p.75). Yet, none of her informants actually volunteered the titles of the legislation or its substance. Many said they had, probably, ''got copies of it somewhere'', while others replied that they had a file on water pollution control.

Similarly, Hutter's (2001) more recent study of occupational health and safety on the railways found that the overarching Health and Safety at Work Act was generally known about: 30 per cent of her 121 informants referred to the Act spontaneously, and, when prompted, an additional 54 per cent said they had heard of it. Yet, few were able to name more specific regulations. Investigating how much was known about health and safety legislation beyond a simple naming of specific laws, Hutter found that most informants understood that regulations place responsibility on them. Yet, 'a notable proportion of respondents were unable to give very detailed or substantive replies about the nature of this responsibility. For example, they merely stated that they were required to follow the law; or "be an enlightened employer"; or be the place where the "buck stops"' (ibid.). One informant responding to the question: 'Do you know what responsibilities it [the Health and Safety at Work Act] gives your workforce?' answered: 'Not offhand, not without looking it up. I would have to look all of this up.… This is not a prime part of my work and I wouldn't carry that information around on a day-to-day basis but it is readily available if I want to look it up'.

Knowledge and comprehension of the law has emerged as an important explanation of patterns of compliance. Genn's (1993) study investigating the impact of health and safety regulations on industrial and agricultural businesses is illustrative. She found there was 'a clear and sharp distinction' (p.222) between highly motivated, proactive employers and less motivated, reactive employers. High levels of motivation to improve and maintain health and safety standards tended to be present where companies were large, well-established, highly visible to regulators and the local community, and thus mindful of their public image. High levels of motivation tended also to be present 'where poor safety standards might threaten the very existence of the site' (p.223) or 'where the health risks for workers and the local environment are so well-established and grave that safety concerns are necessarily a major priority' (ibid.), such as in oil refineries, chemical works, and lead smelting works. Low levels of motivation to improve and maintain health and safety standards tended, in contrast, to be characterised by small, low-profile firms with no obvious *major* hazard or well-recognised risk. Knowledge and comprehension of the law was found to differ significantly between the two models of employer. Highly motivated, proactive employers – according health and safety a high priority and commonly having specialised safety personnel – tended to have a number of sources of information. These companies saw the necessity of keeping up-to-date with regulations and understood the need to actively seek information in order to remain well-informed. Less motivated, reactive employers – regarding health and safety as low on their list of priorities and lacking specialised safety personnel – typically did not seek out information and made little effort to keep up-to-date. There were, however, some well-intentioned employers without safety personnel who attempted to keep themselves informed. But in contrast to the large companies and those with safety personnel who reported little difficulty in comprehending the information and disseminating it to management, these employers often seemed weighed down by the volume and complexity of information about health and safety standards.

The broad large firm/small firm dichotomy outlined by Genn has been echoed in other studies of corporate compliance. Work by Dawson et al (1988), for example, found there was a considerable gap between health and safety standards in large and small firms. To illustrate, in one of their case studies focusing on the construction industry, they showed a positive relationship between site size and observance of the safety helmet rule – which is, as they note, 'perhaps the most easily monitored working rule in industry' (p.127). In other words, the larger the construction site, the more attention was paid to complying with the health and safety regulations.

Yet, Dawson et al suggest that the existence of safety specialists in large firms is not necessarily an indicator of compliance, as they may not be backed up by senior management commitment or a real development of workforce involvement. Indeed, another study found that 'many safety representatives did not have a good understanding of the structure of health and safety regulations, and… many of them were confused about what the HSE [Health and Safety Executive] did, what an inspectorate was or the identity of the factory inspector for their place of work' (Genn, 1993: 230). In this paper I bring the focus to small firms to illustrate that the large firm/small firm dichotomy is also more complex here. Small firms do not necessarily have a limited knowledge and comprehension of the law, and they do not necessarily have low levels of motivation to improve and maintain health and safety standards. But before I present my respondents experiences of the regulatory framework, I consider the nature of the biotech industry and its regulatory framework.

## The Biotech Industry and its Regulatory Framework

### The Nature of the Biotech Industry

There is not one definition of biotechnology. The most widely accepted definition – and the one I use in this study – was provided by the OECD in its 1982 report entitled *Biotechnology: International Trends and Perspectives* where biotechnology is defined as 'the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services'. This definition covers traditional uses of microorganisms – such as the production of cheese and wine and the production of antibiotics and enzymes through fermentation – and the modern gene and hybridoma technologies, but it does not include traditional methods of breeding in plant and animal husbandry.

The diversity of distinct areas included within 'biotechnology' – among which are agriculture, bioscience, pharmaceutics, diagnostics, environment, food, and marine – can make it difficult to refer to biotech firms as belonging to their own specific industrial sector. Nevertheless, it is possible to group the firms according to the kind of technology they use – whether it is traditional biotechnology, biochemistry, or modern gene and hybridoma technologies – and according to their level of operation – whether it is research, development or production. These two dimensions form a matrix as shown in Figure 1.

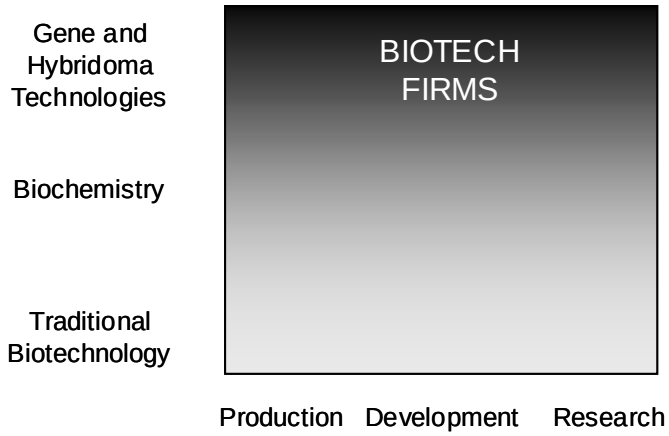


**Figure 1: Categorising biotech firms**

The nature of biotechnology and its private development – the range of technologies, the various operational levels, as well as the numerous applications, and the assorted products and services – is such that the terms 'biotech firms' and 'biotech industry' are fluid constructs. I use the term 'biotech firms' to refer to firms that mainly use gene and hybridoma technologies and the term 'biotech industry' to refer to the collection of these firms – whether they are in research, development or production. These definitions are broadly in line with the ones adopted, but rarely specified, by industry associations, policymakers, industry analysts, and investors.

In order to achieve a comparable set of firms for the study, the Norwegian firms were selected first and these were then matched to appropriate Scottish firms. This strategy was primarily chosen because the Norwegian biotech industry is much smaller than the Scottish industry, and it would in theory, therefore, be easier to match Norwegian firms with similar Scottish firms, than vice versa. The Norwegian universe available for sampling was fairly

limited and seven firms were selected. All agreed to be part of the study. These firms were then matched as closely as possible to seven Scottish firms based on area of activity, age, and size. The sample used for the study comprised firms that worked in the areas of pharmaceutics, bioscience, diagnostics, environmental biotechnology and marine biotechnology; were established between 1996 – 1999; and ranged in size from five to thirty employees. See Table 1 for a breakdown of individual firm characteristics. The sample selected is a fairly typical sample of both Norwegian and Scottish biotech start-ups. Interviews were carried out with the founders, managers, and senior scientists of these firms in the period November 2000 – March 2001.

**SCOTLAND**

| Area of Activity | Year Founded | Size |
|---|---|---|
| Pharmaceutics | 1999 | 5 |
| Pharmaceutics | 1997 | 30 |
| Bioscience | 1997 | 6 |
| Diagnostics | 1998 | 25 |
| Diagnostics | 1997 | 6 |
| Environmental Biotechnology | 1999 | 7 |
| Marine Biotechnology | 1999 | 10 |

**NORWAY**

| Area of Activity | Year Founded | Size |
|---|---|---|
| Pharmaceutics | 1997 | 10 |
| Bioscience | 1998 | 12 |
| Bioscience | 1996 | 5 |
| Diagnostics | 1998 | 6 |
| Diagnostics | 1998 | 6 |
| Environmental Biotechnology | 1996 | 10 |
| Marine Biotechnology | 1996 | 18 |

**Table 1: Sample of Scottish and Norwegian biotech firms**

## Regulating Biotechnology

As individual biotech firms adopt different technologies and operate at different levels, their activities are often regulated by quite disparate regulations. Of course biotech firms, like all firms, are regulated by what may be termed generic regulations. These are regulations covering business and financial aspects such as registering firms, filing accounts and annual returns, registering for VAT, National Insurance and tax, etc. Generic regulations also cover employment, premises, health and safety, and environmental considerations[2]. Biotech firms

[2] See, for instance, URN 00/737 Setting up in Business: A Guide to Regulatory Requirements Produced by the Department of Trade and Industry.

involved in development and/or production are in addition regulated by clinical or field trial regulations, production regulations, product and services regulations, marketing regulations, and import and export regulations. The biotech firms I focus on in this study, ie, small start-up biotech firms mainly located towards the upper right-hand corner of Figure 1, are in addition to the generic regulations principally regulated according to their various research activities. Most biotech firms, independent of the level they operate at, are also regulated by intellectual property regulations. See Figure 2 for a general overview of the regulations controlling the private development of biotechnology.

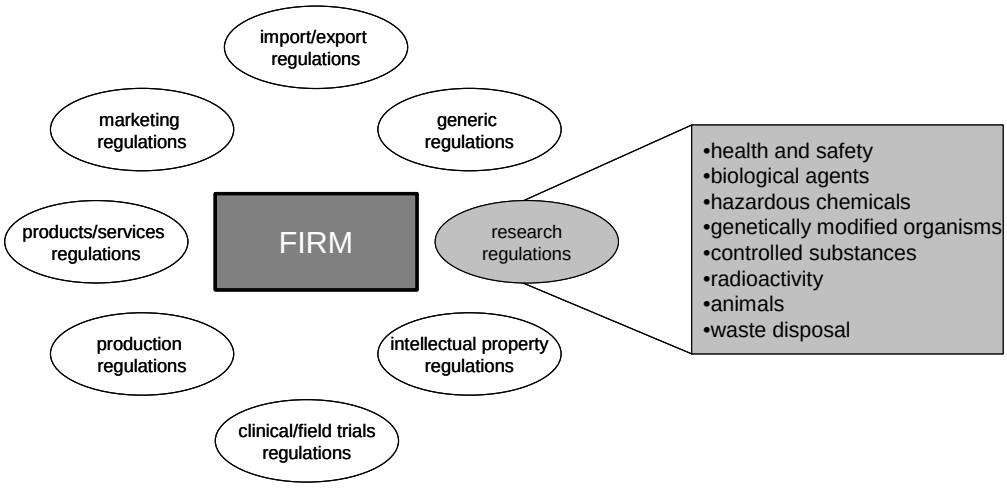


**Figure 2: Regulations controlling the private development of biotechnology**

In the rest of this section I identify the regulations[3] controlling the research activities of start-up biotech firms in Scotland and Norway more specifically, as it is these that are of most relevance to the study. In narrowing the focus to this specific aspect of the regulatory framework, it is, however, important not to lose sight of the actual breadth of the regulations controlling the firms.

The research activities of all Scottish and Norwegian biotech firms are regulated through general health and safety legislation. In Scotland this legislation is the Health and Safety at Work Act implemented by the Health and Safety Executive, while in Norway it is the Working Environment Act implemented by the Norwegian Labour Inspection Authority. These acts require the firms to ensure, as far as reasonably practicable, the health and safety at work of their employees. This might involve, among other things, implementing appropriate preventive and protective measures, providing appropriate training, supervising workers and monitoring standards, health surveillance, appointing competent biological safety officers, and drawing up emergency procedures (in case of, for instance, fire or flooding).

The waste produced by the research activities of all biotech firms is also regulated. Liquid discharges, solid wastes and emissions to air are in Scotland, regulated by the Scottish Environmental Protection Agency through the Environmental Protection Act and the Control

[3] The statutes outlined pertain to the research period. Some have since been replaced, and some of the regulatory bodies implementing the statutes have been changed.

of Pollution Act. In Norway, waste is regulated by the Norwegian Pollution Control Authority through the Pollution Control Act.

Depending on the kind of research carried out, the biotech firms may also be regulated by any number of more specific regulations. Most prominent among these are those covering the use of genetically modified organisms, biological agents, hazardous chemicals, controlled substances, radioactivity, and animals. Some of these regulations form part of the health and safety legislation. In Scotland the use of genetically modified organisms, biological agents and hazardous chemicals is regulated under the Health and Safety at Work Act. In Norway, the use of biological agents and hazardous chemicals is also regulated under the health and safety legislation, but the use of genetically modified organisms is regulated through a separate act. This act, the Gene Technology Act, is implemented by the National Institute of Public Health. The use of controlled substances and animals in research activities is, in Scotland regulated by the Home Office through the Misuse of Drugs Act, and the Animals (Scientific Procedures) Act and the Protection of Animals Act. In Norway, it is the Norwegian Medicines Agency that regulates the use of controlled substances through the Medicines Act, and the Norwegian Animal Health Authority that regulates the use of animals through the Animal Welfare Act. The use of radioactivity is in both countries regulated through specific acts, the Radioactivity Substances Act in Scotland and the Act on Radiation Protection and Use of Radiation in Norway, and implemented by specialised regulatory bodies. See Table 2 (overleaf) for an overview of the various regulations and the bodies implementing them.

| | Scotland | Norway |
|---|---|---|
| **General Health and Safety** | Health and Safety at Work Act<br>Health and Safety Executive | Working Environment Act<br>Norwegian Labour Inspection Authority |
| **Waste** | Environmental Protection Act and Control of Pollution Act<br>Scottish Environmental Protection Agency | Pollution Control Act<br>Norwegian Pollution Control Authority |
| **Genetically Modified Organisms** | The GMO (Contained Use) Regulations, Health and Safety at Work Act<br>Health and Safety Executive | Gene Technology Act<br>National Institute of Public Health |
| **Biological Agents** | Control of Substances Hazardous to Health Regulations, Health and Safety at Work Act<br>Health and Safety Executive | Regulations on Protection against Biological Agents, Working Environment Act<br>Norwegian Labour Inspection Authority |
| **Hazardous Chemicals** | Control of Substances Hazardous to Health Regulations and Chemicals (Hazard Information and Packaging for Supply) Regulations, Health and Safety at Work Act<br>Health and Safety Executive | Regulations on Chemicals, Working Environment Act<br>Norwegian Labour Inspection Authority |
| **Controlled Substances** | Misuse of Drugs Act<br>Home Office | Medicines Act<br>Norwegian Medicines Agency |
| **Radioactivity** | Radioactive Substances Act Scottish<br>Environmental Protection Agency | Act on Radiation Protection and Use of Radiation<br>Norwegian Radiation Protection Authority |
| **Animals** | Animals (Scientific Procedures) Act and Protection of Animals Act<br>Home Office | Animal Welfare Act<br>Norwegian Animal Health Authority |

**Table 2: Regulations controlling the research activities of Scottish and Norwegian biotech firms**

The regulations covering the use of genetically modified organisms, biological agents, hazardous chemicals, controlled substances, radioactivity, and animals are in general very similar between Scotland and Norway. To work with microorganisms, for example, firms in both countries have to carry out risk assessments to determine the containment measures required to control the identified risks (containment level 1-4). These containment measures in turn decide the classification of the activity (Hazard Group 1-4), and it is this classification that determines notification requirements. The use of controlled substances, like hormones and drugs of abuse, requires firms to apply for a licence; ensure the substances are appropriately secured, for example, in a safe; and keep records of the amounts used and for what purposes they are used. Similarly, firms using radioactivity are required to register their

premises; display documents and keep records; and observe the conditions set on the accumulation and disposal of radioactive waste. Perhaps most specific to biotech firms, the regulations covering the use of genetically modified organisms require firms to undertake risk assessment. Here, the organisms must be classified into Group I – where recipient or parental organisms are inherently safe, ie, non-pathogenic, and the vector used and the inserted DNA are well characterised, poorly mobilisable and free from harmful consequences – or Group II[4] – all organisms that for any reason, eg, pathogenicity, do not fall in Group I. In addition, the activity undertaken must be classified as a small-scale Type A operation, or a large-scale Type B operation. Firms intending to use their premises for genetic modification for the first time are required to notify the regulatory authorities. Whether the specific activity needs to be notified or whether it requires written consent from the authorities depends on the pathogenicity of the organism and the scale of the operation. See Table 3 for further details. Having outlined the main regulations controlling the research activities of start-up biotech firms in Scotland and Norway, the next section considers how the firms I interviewed experienced these regulations on a day-to-day basis.

| Description of Work | Classification | Scottish Requirements | Norwegian Requirements |
|---|---|---|---|
| First time use of premises | | Notification | Notification |
| Non-pathogenic organisms on a small-scale | Group I Type A | Annual retrospective notification | Notification |
| Non-pathogenic organisms on a large-scale | Group I Type B | Notification | Simplified application for consent |
| Pathogenic organisms on a small-scale | Group II Type A | Notification | Simplified application for consent |
| Pathogenic organisms on a large-scale | Group II Type B | Consent | Consent |

**Table 3: Requirements for work with GMOs in Scotland and Norway**

## The Firms' Experiences of the Regulatory Framework

To gauge the impact of the regulatory frameworks on the biotech firms in my sample, I initially asked my informants to outline the regulations controlling their research. This is one informant's (MP) response:

> MP: It is just the ISO really. And that covers every aspect of the company. But other than that there are no other regulatory requirements.
>
> FC: There are no other government regulations?
>
> MP: Not that I can think of, other than the ones that affect every business.

[4] In Norway Group II is further subdivided into Group II-2, II-3 and II-4.

FC: What about health and safety?

MP: Yeah OK… we've obviously got health and safety… and because we're working with all the chemicals and that in the laboratory… we give each chemical a hazard rating so people will know when they use it how dangerous it is and so they'll know what precautions to take. So that's COSHH regulations… and then… cause… the products that we sell are derived from genetically modified bacteria – although there are no live organisms in the final product, they are all killed but they're made from that – so we have to comply with that as well.

…

MP: There are other regulations as well actually… Cause I've remembered now… We have to have certain drugs here to be able to test our product, so… there are regulations concerning that because some of the drugs we have here are controlled substances.

…

MP: We've got several other regulations now as well thinking about it… On the off chance that one of our customers might want to use radioactivity… we're registered to use radioactivity.

…

MP: We also have solvent waste because we generate quite a lot of solvent waste through what we're doing and that has to be all collected in drums and again that gets taken away by a specialist contractor. That's another set of regulations. We have to register with the water authority because we're a company and we have to give them a list of all the chemicals that we have… cause you're not allowed to put them down the drain. And we've been given limits on all the things we can put down the drain in terms of salts and things – this much iron, this much magnesium, that type of thing.

…

FC: Are there any other regulations?

MP: Yeah, alcohol as well. So we're covered by so many regulations, but you get used to it actually. It is not really a problem. Cause it's funny. When you started asking I was thinking well there aren't any regulations at all and then now I just think of more and more, but it's just cause they're part of the process and you just don't think of them as regulations, you just think you have to do them so I don't even sort of think of them… If you're using alcohol for commercial purposes you can actually have it duty free… so we had to register with Customs and Excise and ask them to give us an allowance of duty-free alcohol.

…

MP: That's all the regulations I can think of. There might be others but I think those are the main ones. It covers nearly every aspect of what we do really.

(Managing director and co-founder, Scottish pharmaceutics firm)

This transcript extract not only illustrates the breadth of regulations controlling biotechnology research, but it suggests the kind of impact these regulations have. At the start of the extract the informant struggles to think of any regulations controlling the firm's research, but then he starts to remember more and more, and finally comes up with a number of areas where the government directs the behaviour of the firm.

My other informants also found it difficult to list the regulations controlling their research activities. Many were unable to identify or remember the names of the actual regulations or the regulatory authority charged with implementing and enforcing those regulations. The firms working only with biological agents and/or hazardous chemicals, for example, responded that their research was not regulated at all – failing to recognise the health and safety legislation[5]. In another example an informant was disconcerted she did not know whether the regulations for classifying and labelling chemicals came under the Pollution Control Act, the Working Environment Act, or the Product Control Act, let alone which

[5] Managing director, Norwegian bioscience firm; operations director and co-founder, Norwegian bioscience firm; research director and co-founder, Norwegian diagnostics firm.

regulatory authority administered the regulations[6]. Some informants misquoted the legislation or the authority. Two informants, for instance, referred to the 'GMAG regulations' as the regulations controlling work with GMOs[7]. GMAG, or the Genetic Manipulation Advisory Group, was a central UK advisory committee established in 1976 charged with reviewing genetic modification experiments and advising on appropriate safety measures. Its functions were transferred in 1984 to the Health and Safety Executive, which remains the present-day regulatory authority for this kind of research. The 'GMAG regulations' the informants referred to are the Health and Safety at Work Act regulations that were initially introduced in 1978, but which have been substantially revised since. Similarly, a Norwegian informant referred to the Control Committee – the Norwegian equivalent of GMAG in operation between 1981-1984 – rather than the National Institute of Public Health as the regulatory authority for work with GMOs[8]. In another case an informant told me she had applied to the Norwegian Board of Health – the body responsible for overall supervision of health services in Norway – to work with pathogenic microorganisms and that approval had been granted. The body responsible for this is, however, the health and organisational work environment unit of the Norwegian Labour Inspection Authority[9].

My informants' inability – or at times *initial* inability – to recall the regulations and the regulatory authorities controlling their research resonates with previous studies on knowledge and comprehension of the law (Brittan, 1984; Genn, 1993; Hutter, 2001), and appears characteristic of Genn's less motivated, reactive employer model. The firms are all small and lack specialised safety personnel. They appear to make little effort to be informed about the regulations controlling their research activities. Does this mean the regulations do not affect their behaviour?

When I specifically asked to what extent the regulations impact on their research activities, my informants answered: 'Not massively'[10]; 'In fact, they have surprisingly little impact on us'[11]; 'I don't think any regulations really impact on us hugely'[12]; 'I can't say we've been tied up overly in regulations at all or that anything has impinged on us'[13]. Their responses suggest that the regulations do not affect firm behaviour. Yet, further probing showed this to be a hasty conclusion. The Scottish pharmaceutics firm director and co-founder from the transcript extract above explained:

> In terms of impacting on what we do then, yes, they affect what people do in the lab, but it doesn't really add any more time to people's day. In fact none of them do really because now we've got to the stage where they're really all just annual returns, so the radioactivity, the genetically modified organisms, the Home Office controlled drugs, the alcohol, they're all just like an annual return. So it doesn't really impact day-to-day.

But if the regulations controlling the research activities of start-up biotech firms 'affect what people do in the lab', why were my informants so often unable to identify, either correctly or at all, which regulations and regulatory authorities controlled their research activities, and why did they experience the regulations as having such a limited impact?

[6] Senior scientist, Norwegian environmental firm.
[7] Managing director and co-founder, Scottish bioscience firm; Managing director, Scottish pharmaceutics firm.
[8] Managing director and founder, Norwegian marine firm.
[9] Senior scientist, Norwegian diagnostics firm.
[10] Managing director and founder, Scottish diagnostics firm.
[11] Managing director and founder, Scottish marine firm.
[12] Managing director, Scottish environmental firm.
[13] Managing director and co-founder, Scottish bioscience firm.

One reason is that the firms often found the regulations reasonable and appreciated the necessity of the precautionary measures imposed (Bardach and Kagan, 1982). 'You can understand why they're there, so I don't think there's a real problem with it'[14]; 'You can see why they're there and it's fine, it's not a problem, and they're not too onerous anyway'[15]; 'The regulations are there to protect both the environment and the employees so it is not as if they… are regulations imposed on you for the sake of making regulations, it is something you understand is necessary'[16]. The measures imposed by the regulations would therefore in all likelihood be implemented by the firms whether or not the regulations required them to do so.

> As far as we're concerned we couldn't have done much less in terms of complying, they couldn't have made us do much less. I don't mean we're not doing what we're supposed to be doing, but they couldn't have been, I mean basically we had to write a risk assessment and ensure that the lab meets the criteria that is set as a subsequent of that. But obviously there are certain work practices that we have to do but, they are common sense health and safety practices anyway. And as far as I can see *there aren't any additional things imposed by the regulations that we wouldn't be doing as a matter of routine health and safety*.
>
> (Managing director and co-founder, Scottish diagnostics firm)
>
> (Emphasis added)

This contrasts with Genn's (1993) findings where motivation to achieve good standards was linked with regulatory requirements. As one of her informants maintained: 'If there was no legislation I think it is fair to say that we wouldn't bother… If you got into a situation where there was absolutely no legislation you would say ''Well sod it, as many people can get injured as you like'''.

Another explanation is arguably the outsourcing of activities associated with particularly stringent regulations by the firms. Outsourced activities included experiments with high-risk pathogenic organisms:

> There are specific regulations about the use of pathogenic material, so we would have to do that kind of research elsewhere… collaborate with hospitals with special laboratories.
>
> (Operations director and co-founder, Norwegian bioscience firm)

> For research with pathogens that are so dangerous we are not permitted to use them here… we would work with hospitals who do that daily… get collaboration partners, so that we don't have to work with them [pathogens]. If we were to work with them then we would have to have much more stringent lab controls.
>
> (Senior scientist, Norwegian diagnostics firm)

> If we are going to use high-risk bacteria, then we have collaborating partners that are approved for that sort of thing that we can work with.
>
> (Managing director and co-founder, Norwegian diagnostics firm)

Outsourced activities also included experiments with animals, such as rodents and fish:

> We're not doing any animal experimentation, or if we do, it's outsourced. We go to another company that already is covered for that.
>
> (Managing director, Scottish pharmaceutics firm)

> We do most of our fish experiments at [another company]… We also work with mice and rabbits, but we do that in collaboration with [the Veterinary Institute].
>
> (Senior scientist, Norwegian environmental firm)

[14] Managing director and co-founder, Scottish pharmaceutics firm.
[15] Managing director and co-founder, Scottish pharmaceutics firm.
[16] Senior scientist, Norwegian environmental firm.

> The [fish] experiments we have done so far have been in a contained environment at the Veterinary College.
>
> (Managing director, R&D director, and founder, Norwegian marine firm)

> We'll not do any of the clinical trial work ourselves. The most we'll do is test compounds in rodents, but again not in-house, but outsource locally to maybe the Vet School, or to one of the hospitals that has that capability.
>
> (Finance director, Scottish pharmaceutics firm)

Noting that the outsourced activities are associated with particularly stringent regulations is not to suggest that the activities are outsourced *because* they are associated with particularly stringent regulations. Rather, they are generally outsourced because the firms lack internal competence or appropriate facilities. The result, however, remains the same: the regulatory requirements are not experienced as having a big impact on the firms.

The other major sets of regulations facing start-up biotech firms – generic and intellectual property regulations – also appeared to have a comparable impact for similar sorts of reasons. When I asked my informants how they experienced the impact of generic and intellectual property regulations they responded: 'It couldn't really be much less'[17]; 'The legislation side wasn't particularly a hindrance in terms of normal company legislation'[18]; 'I can't say regulation is a burden no'[19]; 'My impression isn't one of over-regulation, it's all very tedious doing VAT and PAYE and all these other things that you have to do regularly but, you know, you just do them don't you'[20]; 'It is a necessary evil you do every year and don't think very much about'[21]. In contrast to regulations controlling biotech R&D, however, the firms founders – all biotech researchers – were relatively unfamiliar with these kinds of regulations when they established their firms: 'Where I was extremely weak was with the company business background'[22]; 'Most of the people setting up biotech businesses don't have a clue about running a business'[23]. They therefore sought external expertise to ensure compliance with the regulatory requirements, rather than relying on internal competencies, as was the case with the regulations controlling biotech R&D. This external expertise was generally brought into the firm in the form of experienced managing directors and/or board members. In some cases the firms had been financed by venture companies that to a large degree managed or parented the firms until they brought in a more professionally experienced management team.

Particular to the Scottish firms was the support received from Scottish Enterprise and local enterprise companies in establishing the firms and handling the requirements imposed by the generic regulations: '[Scottish Enterprise] have a biotechnology division who helped me right from the very beginning when I first started in the college, and they've led me through to the investors and everything.… I met with a sort of independent financial advisor, an accountant, at the Enterprise Ayrshire's premises – and this was a very experienced accountant, financial advisor – and she helped me. Enterprise Ayrshire paid for her and she helped me to start to

[17] Managing director and founder, Norwegian pharmaceutics firm.
[18] Managing director and founder, Scottish marine firm.
[19] Finance director, Scottish pharmaceutics firm.
[20] Managing director, Scottish environmental firm.
[21] Finance director, Norwegian marine firm.
[22] Managing director and founder, Scottish diagnostics firm.
[23] Managing director and founder, Scottish diagnostics firm.

think it through a bit more commercially'[24]. 'Scottish Enterprise Tayside… gave us things like help on writing business plans'[25].

The firms also ensured compliance with the regulatory requirements through the use of external professional services, such as solicitors and accountants. 'We employ a firm of lawyers who act as company secretary.… They look after that accounts have been filed and any paperwork they will deal with. And they make sure we've submitted things on time.… If there's a new or updated law… they send me a copy of it and a letter explaining the implications of it and suggesting what we should do'[26]. 'We use a payroll company to handle all the payroll stuff so that handles all your National Insurance, your income tax side of things'[27]. 'Our accountant deals with our end-of-year accounts and submits them to Company's House and things so, you know, the complicated bits we get done for us'[28]. The limited impact of the generic and intellectual property regulations is – as with the regulations controlling research – due to the firms' familiarity with the regulations, this time gained through obtaining managing directors and board members with specific expertise in the area, and to contracting out onerous activities like end-of-year accounts, patent applications, etc. The similar processes operating in the firms to limit the impact of the research regulations and the generic and intellectual property regulations, suggest that these processes might also function in a broader context, applying to other regulations and other kinds of firms, to limit the demands of the regulatory framework.

Their professional training was an explanation often offered by the informants themselves for their inability to identify the regulations/regulatory authorities and for the limited impact they experienced the regulations to have. The firm employees generally had university training – most held doctorate degrees – in carrying out experiments and in handling research organisms, solutions, and waste. This training had familiarised them with the practices imposed by the regulations: 'You know we all come here with baggage from our degrees about the use of gloves and goggles when that's needed, and the use of lab coats etc'[29]; 'Because we came out of a laboratory we knew that the regulations for what we're doing existed anyway so we're used to doing them'[30]; 'The way [newly employed graduates] operate… is actually the same as is required under these different schemes [regulations]'[31]; 'We're aware of all these things [regulatory requirements] and… people do it automatically'[32]. But if they were familiar with the practices imposed by the regulations, why were they unable to recall or identify the regulations? Why were they experienced as having a limited impact?

It is not necessarily the regulations per se that biotech researchers are familiar with from their university training, but professional good practice, and this practice correlates tightly with the routines, procedures and precautionary measures prescribed by the regulations. Confirming this, one informant noted that in biotechnology 'you have particular routines for how you

[24] Managing director and founder, Scottish diagnostics firm.
[25] Managing director and co-founder, Scottish pharmaceutics firm.
[26] Managing director and founder, Scottish diagnostics firm.
[27] Managing director and founder, Scottish marine firm.
[28] Managing director, Scottish environmental firm.
[29] Senior scientist, Norwegian environmental firm.
[30] Managing director and founder, Scottish pharmaceutical firm.
[31] Managing director and founder, Scottish diagnostics firm.
[32] Managing director and co-founder, Scottish pharmaceutical firm.

work and how much of that is based on the regulations and how much is based on convention I'm not quite sure about'[33].

Illustrating that biotech researchers are familiar with the regulatory requirements through professional practice, rather than through direct knowledge of the regulations themselves, another of my informants explained that before her firm had developed formal protocols and operating procedures for the various lab activities, safety was ensured through 'common sense and what we knew, because we all came from a university environment and knew how to handle special waste… we knew what was dangerous to work with, so in a way we just took the routines we had from the university environment and did the same thing here'[34]. She continued: 'I just knew what you had to do, I knew what was hazardous so I didn't really need to look at the laws and regulations to know that.' Referring back to earlier in the interview when she was unable to identify the regulatory authority for hazardous chemicals, she said: 'I know someone regulates this, but it's not so important for me to remember who that is on a daily basis… what is important is ensuring that the hazardous chemicals we work with in the lab [are handled safely].' This informant's familiarity with the appropriate routines for carrying out research activities safely stemmed from the practices applied in the professional environment and not from direct knowledge of the regulations and their requirements. The regulations seem to do little more than write down what everyone knows and does in practice, and therefore become largely invisible to the researchers. In an informant's words: 'It is difficult to specify exactly what is good practice and what is a regulatory imposed burden'[35]. The idea that regulations can be invisible was also raised by Hutter in her study of health and safety on the railways: 'Employees may not realise that they know about the legislation because their focus is upon company rules and documentation which incorporates the law's requirements' (2001: 90). Here, rather than professional practices acquired through training, the primary reference point was corporate risk management systems.

**Discussion**

The extent to which it is necessary that regulation is consciously thought about and understood by the regulated is unclear. For some, an awareness of legal obligations is seen as essential to achieve corporate compliance (Sigler and Murphy, 1988; Genn, 1993). This is particularly the case in systems based on self-regulation – as is the case for health and safety regulation in both Scotland and Norway. An alternative view is that while compliance with regulatory objectives is centrally important, it does not necessarily depend on a detailed knowledge of the law (Hutter, 2001). Indeed it need not rely on any knowledge of the law. It may be that there are other sources of regulation, such as private regulation, or that regulatory objectives are so well internalised that state regulation is automatically complied with. Let us explore this argument further.

A distinguishing feature of regulatory law is that it is simultaneously constitutive and controlling (Hutter, 2001). The primary objective of regulation is to define compliant structures, procedures and routines that will ultimately permeate corporations (Rees, 1994; Sigler and Murphy, 1988). Ideally, they will be internalised by firms and the individuals within them to the point where 'the distinction between the rule and the ruled activity

[33] Managing director, Norwegian bioscience firm.
[34] Senior scientist, Norwegian environmental firm.
[35] Finance director, Scottish pharmaceutics firm.

disappears' (Unger, 1975: 68-9). Building on the idea that regulation is a form of risk management, Hutter explains that regulatory law:

> Aims to provide the architecture for managing risks at the level of the marketplace and at the corporate level. More ambitiously, it aims to penetrate the organization, harness the regulatory resources of the company, and constitute risk management as part of everyday individual activity.
>
> (2001: 77)

Where compliant practices fail to constitute everyday activity, the law can intervene through more overt forms of control. Regulations provide for the external monitoring of corporate behaviour, for remedial measures where shortcomings transpire, and for legal sanctions in the event of non-compliance. Although regulatory law is simultaneously constitutive and controlling, its primary purpose is to remedy rather than to punish, and the control aspect is therefore secondary to the constitutive objective.

In her analysis of occupational health and safety on the railways, Hutter develops a three-phase model of corporate responsiveness to the constitutive objectives of regulation. The *first phase* of the model involves designing and establishing systems, procedures and rules to ensure risk management becomes part of organisational scripts. Typically, this is where committees are set up and specialist personnel and departments are appointed. The main players at the corporate level are senior management and specialist risk managers. State regulatory involvement in this phase is high, and educative and persuasive strategies by inspectors are likely. The emphasis is to a large degree constitutive. The *second phase* of the model is where the risk management systems, procedures and rules are operationalised or implemented. Committees meet; audits are undertaken; and rules are enforced. The main players in this phase are all levels of management, as well as worker/community representatives. State regulatory involvement is medium to high, and insistent to sanctioning strategies by inspectors are likely. The emphasis here is both constitutive and controlling. The *third and final phase* is where compliance with risk management procedures and rules are part of normal, everyday life. Regulatory objectives and systems are taken for granted; there is corporate understanding of risks and individual awareness throughout the organisation; and everyone in the firm is involved. State regulatory involvement is minimal, as there is a strong reliance on corporate self-regulation.

British Railways, in Hutter's study, was, at the time of main data collection, early in the second phase of corporate responsiveness. However, post-privatisation, the railway industry moved 'back' to phase one as the industry was restructured and new systems had to be established afresh. This highlights the possibility of moving both forwards and backwards through the different phases – although the ideal is obviously a movement from the first phase to the third phase.

The data presented in this paper suggests the biotech firms were operating in the third phase. The regulatory requirements were so well internalised in the firms through professional practice that the regulations were automatically complied with. The routines, procedures and precautionary measures prescribed by the regulations were part of normal, everyday life; regulatory responsibility had been institutionalised (Rees, 1994). The firms' risk management systems largely stood alone without legal intervention. None of the five Scottish firms and neither of the two Norwegian firms in my sample working with GMOs had been inspected. None of the 14 firms working with biological agents had been inspected. None of the seven Scottish firms and none of the five Norwegian firms working with hazardous chemicals had

been inspected. However, two out of the three Scottish firms working with controlled substances had been visited as part of routine inspections, while the one Norwegian firm working with controlled substances had not been visited. The two Scottish firms working with radioactivity had also been visited as part of routine inspections – there were no Norwegian firms in my sample working with radioactivity. See Table 4 for an overview. For the biotech firms in this study a detailed knowledge of the law was not necessary to achieve compliance.

**SCOTLAND**

| COMPANY | GMO | BA | HC | CS | R/A |
|---|---|---|---|---|---|
| Biopharmaceutics | √ | √ | √ | √ | √ |
| Biopharmaceutics | √ | √ | √ | | |
| Bioscience | √ | √ | √ | | √ |
| Diagnostics | | √ | √ | √ | |
| Diagnostics | | √ | √ | √ | |
| Environmental | √ | √ | √ | | |
| Marine | √ | √ | √ | | |

**NORWAY**

| COMPANY | GMO | BA | HC | CS | R/A |
|---|---|---|---|---|---|
| Biopharmaceutics | √ | √ | √ | √ | |
| Bioscience | | √ | √ | | |
| Bioscience | | √ | √ | | |
| Diagnostics | | √ | √ | | |
| Diagnostics | | √ | | | |
| Environmental | | √ | √ | | |
| Marine | √ | √ | | | |

**Table 4: Firms in sample inspected by regulators (circled)**

**GMO – genetically modified organisms, BA – biological agents, HC – hazardous chemicals, CS – controlled substances, R/A – radioactivity**

The paper has illustrated that small firms do not necessarily have a limited knowledge and comprehension of the law. Nor do they necessarily have low levels of motivation to improve and maintain health and safety standards. In fact, the opposite may be true. Small firms may approach the regulatory ideal where the routines, procedures and precautionary measures prescribed by regulations permeate corporations. It should be noted that Genn recognised that because it is fundamentally the *nature* of the risk which leads to high levels of motivation, the highly motivated, proactive employer model is not exclusive to large enterprises, but may also include smaller firms that carry out hazardous processes, or, for example, store explosive materials. In addition to this, I suggest highly motivated, proactive employers may also include small firms that are, like biotech firms, highly dependent on increasing public confidence in their technology and gaining social support for the creation of new markets.

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