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Justifying Non-Compliance. A Case Study of a Norwegian Biotech Firm

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Abstract

This paper draws on an incident of non-compliance in a Norwegian biotech firm to explore the justification behind regulatory infringement in a small, high-tech organisation. A number of interpretations are possible: the firm may lack attention, ability or knowledge to comply; it may have violated the regulations on the basis of principled disagreement, or on the basis of an interpretation of adequate compliance; the non-compliance may have resulted from a rational calculation of risks and opportunities. Rather than supporting one particular interpretation, the case study highlights the very complex, messy and 'un-boxable' nature of firm behaviour.

Introduction

Our understanding of corporate decisions to violate the law has suffered from a lack of access to firms and limited information about their decision-making processes. As Vaughan notes:

> Documentation of misconduct within an organization prior to an enforcement action or public investigation is and always has been difficult for researchers to obtain. After a violation has become public knowledge, an offending organization is understandably reluctant to have a sociologist loosed in its midst, and evidence documenting internal activities that is obtained by social control agents is not always admissible in judicial proceedings, let alone open to perusal by social scientists. Moreover, the information that does become available is, at best, a partial record. Like historians, we are constrained by missing data: critical conversations never recorded; records undiscovered, distorted, destroyed.
>
> (1992: 132)

There is, unsurprisingly therefore, only a limited number of empirical studies exploring the underlying reasons for organisational non-compliance. Often these have focused on large, complex organisations, like Vaughan's (1996) own study of NASA's decision to launch the space shuttle *Challenger*. To gain different views of why corporations violate the law we need to vary the level of analysis. That is, we need to consider 'case studies of misconduct in organisational forms of differing size, complexity, and function' (Vaughan, 1992: 134). In this paper, I present a case study of the interactions between a biotech firm and a public

[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.

regulator before and after non-compliance was uncovered. Their interactions, in the form of written correspondence and on-site visits, allow us to investigate the justification behind regulatory infringement in a small, high-tech organisation.

I came across the case when, as part of another project, I interviewed Norwegian biotech firms about the impact the regulatory framework was having on them. The firms I spoke with did not in general experience the regulations as adversely impacting on them, but many referred to one particular firm that had encountered a number of difficulties. This firm was not part of my sample, but I decided to approach it anyway. During interviews with the firm, it became apparent that it had not complied with some of the regulatory requirements imposed on it, and that the regulators had been to visit the firm as a result. I decided to explore this further, and spoke to the person in charge of the case at the Ministry of Health and Social Affairs.

She was extraordinarily helpful and provided me with her file on the firm – only removing a handful of papers with confidential information – and a photocopier. I was thus given access to the firm's application forms; responses from various parties to the ensuing consultation exercises; the letters and responses of the firm, the field regulators, and the Ministry following the discovery of the breaches; and the field regulators inspection report. The case study presented here is based on the information I acquired from these documents, as well as on interviews with the firm and the regulatory authority[2].

To investigate why the biotech firm violated the regulatory requirements imposed on it, it is helpful to review the main explanations for compliance and non-compliance suggested in the regulatory literature. Having provided this overview in the next section, I present the details of the case study. I then go on to discuss how the firm's response to the regulatory requirements imposed on it relate to those in the literature, and further explore the beliefs underlying that response by drawing on concepts from the neo-institutional analysis of organisations.

How do Firms Respond to Regulation?

Portraying firms as amoral profit-seekers whose actions are motivated by rational calculations of costs and opportunities, Kagan and Scholz (1984; see also Scholz, 1984) suggest that firms will comply with regulations if the anticipated legal penalties of *not complying* exceed the costs of complying. Similarly, other research has shown that firms will also comply if the risks of non-compliance are so great as to involve destruction of the entire site, as in the case of oil refineries, chemical works, and lead smelting works (Genn, 1993), or if they have substantial incentives to comply, as in the case of metal recovery works preventing the emission of valuable metals to the atmosphere (Hutter, 1997). On the other hand, if the anticipated legal penalties of not complying are *less than* the costs of complying, firms are less motivated to comply.

Geis' (1994) classic study of the 1961 heavy electrical equipment antitrust cases lends support to this argument. Presenting the first in-depth view of executives' thoughts and perceptions about their violations, Geis illustrates that the Chief Executive Officers (CEOs) colluding about price fixing were clearly aware of the illegality and its harmful social

[2] The written documents I draw on are available from the Norwegian Ministry of Health (previously the Ministry of Health and Social Affairs). Permission to quote was obtained from all informants.

consequences. Twenty years later, another prominent case involving the car manufacturer Ford gives further substance to the correlation between competition, production pressure, and violative behaviour. Here, written documents explicitly show the calculations made by executives of the costs and benefits in a redesign decision that juxtaposed the cost of redesign against the quantified loss of human life in accidents if the redesigns were not done. Even though lives had already been lost, the final decision was to continue production (Cullen et al, 1987). A number of more recent empirical studies also support the 'amoral calculator' model of the firm (for example: Braithwaite and Makkai, 1991; Burby and Paterson, 1993; Gray and Scholz, 1993; Helland, 1998; May and Winter, 1999; Winter and May, 2001).

Research by Fisse and Braithwaite (1983) on the impact of adverse publicity on corporations suggests that firms are not only motivated by maximising profits and making money, but also by maintaining a good reputation. Summarising this research in another book, Ayres and Braithwaite write:

> Interviews with executives of large corporations that had been through adverse publicity crises concerning allegations of corporate wrongdoing showed that both individual executives, and the corporation collectively, generally valued a good reputation for its own sake. There was some concern that adverse corporate publicity might do serious damage to profits, but neither this subjective concern nor the objective fact of economic damage to the corporation from adverse publicity was widespread. Nevertheless, the informants cared deeply about the adverse publicity; they viewed both their personal reputation in the community and their corporate reputation as priceless assets.
>
> (1992: 22)

Desire to earn approval and respect of others as a motivation for compliance is also supported by other studies, such as those of Di Mento (1986)[3] and Winter and May (2001).

Kagan and Scholz (1984) argue that while some firms at some times act as if they are amoral calculators, it is not necessary to act this way, and in fact most firms at most times do not act this way. Bardach and Kagan go so far as to suggest that amoral calculators, or 'bad apples', only 'make up about 20 per cent of the average population of regulated enterprises in most regulatory programs… This distribution almost certainly overestimates the proportion of bad apples in most regulatory programs, but it does square roughly with what commentators have said and with much regulatory practice' (1982: 65). The model of the firm as a value maximiser – of profits or of reputation – clearly does not go far enough in explaining corporate responses to regulation.

It has been suggested that in addition to value maximising, firms are also motivated by social responsibility (Brittan, 1984; Braithwaite, 1985). As Ayres and Braithwaite explain: 'Corporate actors are… also often concerned to do what is right, to be faithful to their identity as a law abiding citizen, and to sustain a self-concept of social responsibility' (1992: 22). They elaborate, drawing on Braithwaite's work on pharmaceutical companies (Braithwaite, 1984), on coal mining companies (Braithwaite, 1985), and on nursing homes (Braithwaite et al, 1990):

> Business informants repeatedly argued that the common characterization of them as motivated only by money was a simplistic stereotype. Conceding that their primary motivations were economic, they claimed that they and their colleagues took seriously business responsibility, ethics, and obligations to abide by the law and to be responsive to

[3] Gunningham et al, 2003

> non-shareholding stakeholders in the corporation. This was true even of respondents who admitted widespread law breaking in their company or their industry.
>
> (1992: 22)

The sense of social responsibility may even be stronger than economic considerations, and as Ayres and Braithwaite observe, the variants of elevating social responsibility above economic costs are many:

> It can be the responsibility to obey the law whatever the cost, the responsibility to scientific integrity for pharmaceutical industry scientists, the responsibility to patients for nurses working for a nursing home corporation, the responsibility to professional ethics for company lawyers, or the responsibility of a coal mining executive who says he has never put profits ahead of the lives of his workers.
>
> (1992: 24)

The firm is here pictured as a 'political citizen', 'ordinarily inclined to comply with the law, partly because of a belief in the rule of law, partly as a matter of long-term self-interest' (Kagan and Scholz, 1984: 67). Compliance depends, however, on the acceptance of the law as legitimate and fairly administered, an argument introduced by Bardach and Kagan (1982) in their discussion of regulatory unreasonableness and further illustrated in studies by Levi (1988, 1997), Tyler (1990), Scholz and Pinney (1995), Winter and May (2001), and May and Wood (2002). In short, compliance motivated by a sense of social responsibility depends on firms perceiving the regulations as necessary and as consistently interpreted and applied by regulators. The flip-side of the social responsibility motivation is what Kagan and Scholz (1984) have labelled principled disagreement. They suggest that business managers have their own strongly held views regarding proper public policy and business conduct. Sometimes, they violate rules and regulations from principled disagreement, because they find them arbitrary and/or unreasonable. Firms interviewed by Kagan and Scholz repeatedly mentioned:

> … instances of governmental arbitrariness: ill-conceived and conflicting regulations; officious and poorly trained government inspectors; unreasonable paperwork requirements; bureaucratic delay; governmental indifference to the disruption or inefficiencies in productive processes caused by literal enforcement of regulations. Businessmen refer indignantly to regulatory officials who impugn the credibility of corporate data provided in support of criticisms of the technical underpinnings of proposed regulations. They refer equally indignantly to inspectors who treat them 'as if we were criminals'. They ask why they should waste time and money complying with regulations that might seem to make sense in theory but that are impractical or unduly costly in particular cases.
>
> (1984: 75)

Sometimes firms that are disposed to be law-abiding, violate the law because of ignorance, managerial incompetence, misunderstanding of laws, or improper attention to regulatory requirements (Kagan and Scholz, 1984; for empirical studies see Cranston, 1979; Hawkins, 1984; Hutter, 1988, 1997; Winter and May, 2001). Stone's (1975) study on major corporate scandals involving breach of duty is illustrative. He showed that a substantial number of the organisational misconduct cases resulted from managers not being told of, or not adequately monitoring, 'short-cuts' taken by subordinates. Indeed, sometimes bad news and the illegal remedial action were actively hidden from superiors. Organisational misconduct also resulted from the production department not understanding the law the same way as the general counsel's office did, and from the quality control or safety testing engineers not being given adequate authority to insist on attention to their concerns. Other studies have shown that specialisation and division of labour might result in employees being unaware of their illegality because their action is part of a chain of actions by invisible others; each individual

act is legitimate, but together all the acts constitute a violation of which some individual participants are ignorant (Gross, 1980; Finney and Lesieur, 1982; Vaughan, 1983).

The three main models of the firm outlined here – the amoral calculator model, the political citizen model, and the organisational failure model – do not provide a comprehensive guide to corporate responses to regulation, but they have been recognised in the regulatory literature as providing rich heuristics. The models also correlate to a large extent with field inspectors' working theories of compliance and non-compliance (Hawkins and Hutter, 1993; but see Braithwaite et al, (1994). Braithwaite and colleagues summarise these models – 'actors may decide to maximize their profit margin at the expense of regulatory compliance, or they may decide to listen, discuss, and negotiate, or they may simply fail to apply themselves to regulatory objectives through lack of attention, ability, or knowledge' – and argue that the particular responses, or 'regulatory postures', are behavioural and 'unlikely to exist without an underlying set of cognitions to buttress them' (1994: 377). They continue:

> Underlying each of these postures one would expect to find a set of beliefs about motives, beliefs about self, values, or attitudes that are used to justify the stance to others and to self[4]. While it may be difficult to measure socially unacceptable regulatory postures directly through self-report, it is not unreasonable to attempt to capture the attitudes and beliefs that are brought into play to justify non-compliance to oneself and others.
>
> (1994: 377-8)

Braithwaite and colleagues try to capture the attitudes and beliefs of regulatees, or more specifically of nursing home directors, that are brought into play to justify non-compliance through questionnaires and statistical analysis. In this paper, I try to capture the attitudes and beliefs of management that are brought into play to justify non-compliance in a small, start-up biotech firm through documentary analysis and semi-structured interviews.

Case Study: regulating the large-scale contained use of GMOs in a Norwegian biotech firm

The biotech firm involved in this case study is Norwegian, and was originally established in the mid-eighties as a contract research centre for the development and production of various products, such as fish vaccines and organic acids. In the mid-nineties it began specialising in contract fermentation, and offered to manufacture biological products on a small scale or in commercial quantities of up to 30,000 litres.

The manufacture of biological products generally involves the use of genetically modified organisms, or GMOs. In Norway, the contained use of GMOs is only permitted in approved laboratories, and, in addition, the individual projects must be either notified or approved depending on the level of risk involved[5]. The case study firm was the first centre in Norway to apply for the *large-scale* contained use of GMOs. It applied for three projects, the first to produce the enzyme xylanase, the second to produce the amino acid tryptophan, and the third to produce shikimic acid. The projects all involved the use of similar low-risk genetically

[4] Rokeach, M. (1973); The Nature of Human Values. New York: The Free Press.

[5] Lov 2. April 1993 nr.38 om fremstilling og bruk av genmodifiserte organismer (Genteknologiloven). Forskrift 11. Februar 1994 nr.126 om meldeplikt eller godkjenning ved innesluttet bruk av genmodifiserte organismer. Forskrift 11. Februar 1994 nr.127 om sikkerhetstiltak, klassifisering og protokollføring ved laboratorier og anlegg for innesluttet bruk. These regulations were amended in 2001 (Forskrift 21. Desember 2001 nr.1600 om innesluttet bruk av genmodifiserte mikroorganismer), but the new requirements are outside the time frame of the case study.

modified *E.coli* bacteria, but because they were on a large-scale and therefore considered to involve a higher risk, the projects required approval from the Ministry of Health and Social Affairs, rather than merely notification to the Institute for Public Health.

Approval for all three projects were subject to the Gene Technology Act and its regulations, as well as conditional on a set of specified requirements[6]. The Ministry of Health and Social Affairs stipulated that[7]:

- All waste and environmental releases should only contain inactivated genetically modified organisms.
- After autoclaving the waste at low pH levels (1-2), the treated waste should continually be tested for bacterial viability.
- All accidents and unforeseen events should be reported to the Institute of Public Health.

The Norwegian parliament had in June 1997 resolved 'to prohibit the production, import and sale of all genetically manipulated products containing genes coding for antibiotic resistance' and the approval requirements for the projects therefore also stated that:

- The waste should not contain any DNA fragments large enough to comprise intact antibiotic resistance genes.

The firm's licence to produce xylanase expired after three years, and the firm applied for another three-year licence. As part of the ensuing consultation process, carried out by the Institute of Public Health, the firm was asked for better documentation on routines and methods of testing production waste, as well as documentation on the effectiveness of the waste treatment. The Institute also requested a copy of the protocol showing the test results[8].

The firm responded within a few days[9]. It noted that Standard Operating Procedures (SOPs) had been developed for all waste treatment including routines and methods of testing the waste, and enclosed copies of the procedures in the letter. The firm informed the Institute that it had not, however, analysed the effectiveness of its waste treatment. This was because the Ministry and the firm had agreed, when the licence was first issued, that the method it was using was the best way to ensure destruction of DNA. This was also supported by the scientific literature. The firm conceded, nevertheless, that there had been at least 8 accidental releases of incompletely inactivated GMOs out of a total of 142 releases that year, and that there had also been 5 releases where antibiotic resistance genes had not been properly fragmented. A copy of the protocol showing these results was enclosed.

The firm went on to explain that the reason the regulators had not been informed of the releases was 'an uncertainty over when the Institute should be informed'. Remedial action was, however, being taken: '… in the last few months we have developed new documents to, among other things, ensure that accidents, such as the release of the production organism, are immediately reported to the Institute of Public Health.' It was also remarked that the released organism had poor survival abilities outside the production environment, and that it would probably have disintegrated by the time it reached the communal cleaning system. The letter

[6] Letter to biotech firm from the Ministry of Health and Social Affairs, dated 9 July 1998.
[7] All translations in the paper are my own.
[8] Letter to biotech firm from the Institute of Public Health, dated 25 August 2000.
[9] Letter to the Institute of Public Health from the biotech firm, dated 31 August 2000.

ended by stating that there had been no productions since mid-July, and that before any new production would start, the firm would improve its waste treatment.

The regulators informed the firm that the situation indicated significant deviations from the terms stipulated by the Ministry in its approval for the production of shikimic acid[10]. Not only had the Institute not been informed of the releases, the firm had disposed of the production waste *before* obtaining the viability test results. As the inactivation of bacterial waste did not work as expected, the Institute considered disposal without obtaining test results in breach of the approval requirements that all waste and environmental releases should only contain inactivated GMOs and fragmented antibiotic resistance genes. The Institute instructed the firm not to start production until the Institute had received satisfactory documentation of measures: 1) to improve bacterial inactivation and tests for viability, 2) to ensure that incompletely inactivated waste was not released, and 3) to inform the authorities when deviations occur.

Soon after – on 4 October 2000 – the regulators visited the firm. On the basis of the visit and supplementary information the Institute developed a report[11]. The following is an excerpt from the report's 'general impressions':

> The firm seems to have interpreted the Ministry's approval requirements for the production of shikimic acid in a way that makes it possible to keep a high level of production despite having too small a capacity in the biowaste storage tank. A thorough examination of the biowaste storage tank log indicates, firstly, that there have been close to 30 incidents of GMO releases in the period 1 June 1999 – 19 July 2000. The firm has not made any effective attempts to improve the procedures even though one must have been aware that GMO releases had occurred. Further, the log has been inadequately completed. In spite of the approval requirements, the firm has changed the procedures for treating waste and has not validated this new procedure either. The cultivation and plasmid analyses have not been carried out regularly, or appropriately. The analyses lack quality assurance, including positive and negative controls. The procedures (the SOPs) are very inadequate as they do not describe in a satisfactory manner how the steps should be completed. They do not describe which measures should be implemented in unforeseen circumstances, nor who has the responsibility in such circumstances.

The report also stated that during the visit the firm informed the authorities that its contract to produce shikimic acid had not been renewed, and that this had led to the dismissal of most employees and the termination of all production. Even though the firm had the possibility to make a batch of xylanase in the autumn, it could not maintain production for just one batch. The firm hoped for new projects and was working on a collaboration project with two Norwegian universities for the large-scale production of various GMOs. Its goal was therefore to prepare the ground for a new production start and to continue with the xylanase application.

Later that month the Ministry withdrew the firm's three-year licence to produce shikimic acid – this had no effect in practice on the firm as production had already ceased[12]. It noted that although the releases probably did not pose a danger to humans, the firm had deviated significantly from the requirements and the Ministry decided to revoke the licence until the firm could document that they would be fulfilled.

[10] Letter to the biotech firm from the Institute of Public Health, dated 7 September 2000.
[11] Letter to the director of the Institute of Public Health from the field inspectors, dated 8 November 2000.
[12] Letter from the Ministry of Health and Social Affairs to the biotech firm, dated 20 October 2000.

A process of improving the firm's SOPs ensued through dialogue between the Institute of Public Health and the firm[13]. At the end of February, the Institute completed its assessment for the Ministry of the firm's procedures for handling production waste[14]. The assessment was based on the firm's final draft of its SOPs and concluded:

> The enclosed firm documents indicate that the firm is making an effort to aspire to the Ministry's requirements. However, from the SOPs it seems to us that the firm still does not accept that changes in the production process require approval from the authorities, and that the production waste cannot be released before negative results [from tests of organism inactivation and DNA fragmentation] are shown. Further, we consider it uncertain whether the routines can satisfactorily be carried out in the way they are described in the SOPs… The Institute of Public Health cannot recommend approving the production of GMOs from the enclosed documentation, and without our remarks being complied with.

The Ministry notified the firm of the Institute's assessment and of the xylanase consultation responses, and asked for the firm's comments[15]. Two weeks later the firm withdrew its application or the production of xylanase, and informed the Ministry that it would not, at present, apply to restart production of shikimic acid[16].

> The basis for withdrawing the application at this point is that the firm has new owners, and they have started an extensive examination of the markets, products and processes the firm should focus on in the future. We believe this process could lead to significant alterations in our activities, and that it could involve changing the firm's focus, redesigning the premises and altering our quality assurance systems… These circumstances imply that the production of xylanase and shikimic acid are not relevant for the firm in the near future. The logical consequence is that we withdraw our application.

Considering the Firm's Response to the Regulatory Requirements Imposed on it

The biotech firm presented in the case study was in general a 'good apple', inclined to comply with the law. Indeed, one of the regulators I spoke with characterised the firm as 'very conscientious'[17]. It developed elaborate SOPs[18] detailing the firm's routines for handling its production waste; it engaged in dialogue with the regulators about the regulatory requirements both before and after non-compliance was uncovered; and it consistently communicated with the regulators about its production cycles: 'They sent in notices every

[13] Letter to the biotech firm from the Institute of Public Health, dated 8 November 2000; letter to the Institute of Public Health from the biotech firm, dated 19 December 2000; letter to the biotech firm from the Institute of Public Health, dated 10 January 2001; and letter to the Institute of Public Health from the biotech firm, dated 2 February 2001.

[14] Letter to the Ministry of Health and Social Affairs from the Institute of Public Health, dated 28 February 2001.

[15] Letter to the biotech firm from the Ministry of Health and Social Affairs, dated 15 March 2001.

[16] Letter to the Ministry of Health and Social Affairs from the biotech firm, dated 30 March 2001.

[17] Interview, 22 November 2001.

[18] The SOP 'Treating Production Waste' described steps to be taken to inactivate the organisms and fragment the antibiotic resistance genes. (PE-07: 2; enclosed in letter to the Institute of Public Health from the biotech firm, dated 31 August 2000) The SOP 'Taking and Analysing Samples from the Biowaste Tank' described the tests to be carried out on the samples to check for bacterial viability and DNA fragmentation (KP-04: 1, KE-04: 1; ibid). These involved spreading the samples on agar plates to see if the bacteria would grow, as well as running electrophoresis gels to estimate the size of the DNA fragments and transformation tests to check whether living bacteria, receptive to external DNA, would absorb antibiotic resistance genes in their genome and become resistant to antibiotics. The tests were to be used 'to control the status of the biowaste tank contents before it is released to the communal sewage' (KP-04: 1; ibid). The treated waste should not give positive test results. However, if such results were obtained management was to be alerted, the samples were to be saved, the analysis was to be repeated, and the results were to be logged.

time they started production and stopped production, and every time they went on holiday and everything like that. So we got reports the whole time and knew when they were producing… they were very good at notifying us'[19]. Accepting the firm's general inclination towards regulatory compliance, how can we account for the breaches described above?

The firm's behaviour can be interpreted in a number of ways. One explanation draws on the organisational failure model, where firms do not apply themselves to the regulatory objectives because they lack attention, ability, or knowledge. The firm's 'uncertainty over when the Institute should be informed' as an explanation of why it did not inform the regulators of the releases certainly provides this argument with some support. Yet, the development of the SOPs, the continuous dialogue with the regulators about the regulatory requirements, and the consistent notifications about production starts and stops suggest that the firm in practice paid a fair amount of attention to the regulatory requirements and that it was not chronically plagued by managerial incompetence. Workforce ignorance or concealment of 'short cuts', 'bad news', or 'illegal remedial action' from management (Stone, 1975) do not seem like persuasive explanations for the infringement either as the biotech firm – typical of firms comprised of professional and highly trained employees – did not experience the traditional divide between skilled managers and unskilled subordinates. The firm also seems too small – it had less than ten employees – to have communication problems between departments, or to be affected by the problems of specialisation and division of labour as have been the case in other studies (cf. Gross, 1980; Finney and Lesieur, 1982; Vaughan, 1983). So, although lack of attention, ability, or knowledge may account for the breaches to a certain extent, it does not provide an entirely satisfactory explanation.

Organisational failure is not the only reason, however, why a good apple might violate the law. Compliance often depends on firms perceiving the law to be necessary and fairly administered. In the case study, the firm deemed the regulations imposed by the Ministry of Health and Social Affairs to manage its production waste unreasonable. This perception of unreasonableness arose because the waste treatment requirements conflicted with accepted scientific practice.

When – as part of the consultation process to re-issue the biotech firm with its xylanase licence – the Institute of Public Health asked the firm for documentation on the effectiveness of its waste treatment, the firm defended its lack of analysis on three grounds. First, it argued that the treatment was well-established in the scientific literature: 'It is known from the literature that [treatment with low pH] causes fragmentation of DNA'[20]. Second, it argued that the firm, the regulators and an independent advisor had agreed this treatment was suitable: 'In discussions three years ago between representatives from the firm, the Ministry of Health and Social Affairs, and the University in Bergen it was established that treatment with low pH was the best way to ensure destruction of DNA'[21]. Finally, it argued that the suitability of the treatment was corroborated by the firm's number of negative test results after treatment: 'The number of negative results in the viability tests indicate that the firm's waste management results in effective destruction'[22]. On the basis of these arguments, the firm viewed additional analysis of effectiveness as unnecessary. As one of my informants explained: 'Usually [in scientific practice] if you have a good procedure that is well-established and validated etc, and you test it five to ten times and it appears to work when

[19] Interview, 22 Nov 2001.
[20] Letter to the Institute of Public Health from the biotech firm, dated 31 August 2000.
[21] Ibid.
[22] Ibid.

you observe certain parameters like heat, pH etc, then you say this process is acceptable'[23]. Treating the waste with low pH was deemed acceptable by the scientific community, and further analysis of effectiveness was therefore considered superfluous. Although the firm later changed part of its treatment procedures, this was not seen to require approval from the authorities or an analysis of effectiveness, because the new procedures were also scientifically well-established and validated, as well as corroborated by negative test results after treatment.

The Institute of Public Health claimed that because there had been releases of incompletely inactivated GMOs' and of improperly fragmented antibiotic resistance genes, the waste treatment did not work as expected. Disposal of waste *without first obtaining the test results* therefore breached the specified approval requirements that 'all waste and environmental releases should contain only inactivated GMOs and 'the waste should not contain any DNA fragments large enough to comprise intact antibiotic resistance genes'. The firm argued in its defence, however, that it had interpreted the requirement to test the treated waste before it was released as an *extra control* to ensure that the procedures worked, rather than as an *additional safety precaution* as maintained by the regulators. In scientific practice, when you use a well-established and validated procedure 'you don't test and wait for the result every time'[24], and although there was a requirement to test every time, the requirements did not explicitly state that the production waste should be stored until the test results were available. As its waste treatment was accepted by the scientific community and considered suitable by the firm, the regulators and an independent advisor, the firm argued that it was not necessary to wait for the test results before its waste was released.

The firm also argued that the risks posed by the release of non-pathogenic GMOs and intact antibiotic resistance genes did not warrant the kind of precautionary requirements set by the Ministry of Health and Social Affairs. The recombinant *E.coli* used by the firm was classified as a Class I organism, which *by definition* does not pose a danger to human health or the environment. Furthermore, the amount of intact antibiotic resistance genes released from gene technology must be viewed in comparison with, for example, the amount of antibiotic resistance genes released by hospitals or the amount of antibiotic resistance genes contained in the soil. As noted by the field inspectors (who were trained scientists, and spending roughly 50 per cent of their time doing research) to the Ministry (comprised primarily of non-scientists), the benefits of completely eliminating antibiotic resistance genes from fermentation releases do not justify the resources required: 'One must accept minimal releases from contained use that in all likelihood have insignificant effects for health and the environment'[25]. An informant also pointed out that it is not technically possible to document the *complete absence* of antibiotic resistance genes in releases, as it will always be dependent on the method used and how sensitive that method is, and the regulatory requirement that 'the waste should not contain *any* DNA fragments large enough to comprise intact antibiotic resistance genes' was thereby scientifically unattainable.

The firm's perception of the regulatory requirements as unreasonable suggests that its violation of the law can also be interpreted to stem from a principled disagreement with the regulations (Kagan and Scholz, 1984). Yet, principled non-compliance is typically accompanied by openness about the non-compliance, and although the firm in the case study

[23] Interview, 22 November 2001.
[24] Ibid.
[25] Letter to the Ministry of Health and Social Affairs from the Institute of Public Health, dated 8 January 2001.

was fairly open about the releases once prompted by the regulators, it was not *proactive* in making its stance known.

But, perhaps the firm's behaviour stemmed from a more subtle form of principled disagreement. The conflict between the waste treatment requirements and accepted scientific practice can be conceptualised as a struggle between different institutional environments impacting on the firm. Organisational theory holds that in most situations, multiple environmentally prescribed models of behaviour exist, and that these may offer competing, or even conflicting, alternative formulations and prescriptions for organisational forms[26] (Scott, 1991, 2001). Heimer elaborates:

> … organizational participants adopt institutionalized practices in order to send messages to particular audiences. Generally they will try to send those signals without substantially altering the character of existing organizational processes. But if organizations have multiple audiences, a critic might object, the adoption of a policy or practice that sends a favourable message to one audience may simultaneously send an offensive message to another. Institutions (and the portions of an organization's environment that would support them) should therefore be conceived as competing for the chance to influence the organization.
>
> (1999: 18)

Heimer (1996, 1999) illustrates the competing nature of institutions in her work on neonatal intensive care units, or NICUs. She observes that legitimacy plays a significant role in pressuring NICUs to adopt practices that make them look reputable to key elements of their environments. Yet, 'what makes a NICU appear legitimate to the state government that regulates NICU professionals or to the federal government that supplies some of its funds may be very different from what makes the same unit look legitimate to families who entrust their infants to the staff. And that may in turn be quite different from what makes a NICU seem reputable to the American Academy of Pediatrics' (1999: 60-1). In her work, Heimer explores how medical decision-making procedures are influenced by these legal, familial and medical institutions.

In the case study, the firm was presented with two models of behaviour: one prescribed by the regulators (or, more specifically, the Ministry of Health and Social Affairs), and one prescribed by biological scientists. The former was explicitly imposed through the approval requirements, the latter implicitly learned through professional training. These two models sent different signals to the firm as to what constituted appropriate precautionary measures. The firm could have responded to this confusion by negotiating between the two models, and adopting certain elements from each in its waste management routines. This may have allowed it to balance the two divergent environmentally prescribed models to achieve what it considered *adequate compliance*. The firm's violation of the law can thus be explained to stem from an interpretation of satisfactory precaution in line with professional belief and accepted scientific practices. Of course the firm could also have responded to the different signals by being plain confused, in which case the violation can be explained to stem from an organisational failure to grasp its different institutional environments.

The firm's breach of the regulatory requirements despite its general inclination towards compliance can, in addition to the interpretations presented above, also be interpreted through

[26] The existence of competing or conflicting institutions potentially undermines the facility or 'taken-for-granted' quality that is seen as a defining property of institutions. But, as Heimer (1999) notes drawing on Jepperson (1991), there are degrees of institutionalisation. Where several institutions might govern and legitimate organisational activities, no one institution can be taken for granted.

the amoral calculator model of firm behaviour. The presence of market pressure on the firm is apparent from the limited number of contracts secured, the dismissal of most employees after one of the contracts failed to be renewed, and the shift in focus following the change of ownership. The tension between the regulatory requirements and production pressure was also observed by the regulators in their inspection report: 'The firm seems to have interpreted the Ministry's approval requirements… in a way that makes it possible to keep a high level of production despite having too small a capacity in the biowaste storage tank.' The biotech firm can therefore be portrayed as an amoral profit-seeker, who, driven by market pressures, violated the law because 'the anticipated fine and probability of being caught [were] small in relation to the profits to be garnered through disobedience' (Kagan and Scholz, 1984: 67).

Although it may at first seem contradictory to simultaneously depict the firm as an amoral calculator and as a good apple, the two portrayals are compatible. The firm may have a general inclination towards regulatory compliance, but choose to let market pressures direct its behaviour in particular instances. In these instances, it is important for the firm to uphold an outward appearance of compliance to maintain legitimacy in the eyes of participants and constituents. As Meyer and Rowan (1977) observe, maintaining legitimacy by conforming with 'rationalised myths', or models of behaviour prescribed by their institutional environment, allows organisations to strengthen their support and secure their survival. If the institutionalised models conflict with organisational efficiency, they often become decoupled, or buffered, from organisational activities. In Meyer and Rowan's own words:

> Institutionalized products, services, techniques, policies and programs function as powerful myths, and many organizations adopt them ceremonially. But conformity to institutionalized rules often conflicts sharply with efficiency criteria; conversely, to coordinate and control activity in order to promote efficiency undermines an organization's ceremonial conformity and sacrifices its support and legitimacy. To maintain ceremonial conformity, organizations that reflect institutional rules tend to buffer their formal structures from uncertainties of technical activities by becoming loosely coupled, building gaps between their formal structures and actual work activities.
>
> (1977: 340-1)

Research by Edelman and colleagues (Edelman, 1990, 1992; Edelman et al, 1991; Edelman et al, 1999) examining the response of a diverse sample of US organisations to the equal opportunity/affirmative action laws passed in the early 1960s, supported the theoretical framework outlined by Meyer and Rowan (see also Hutter, 2001). It showed that the organisations responded to the introduction of the legislation by creating structures, such as new offices, positions, rules and procedures, and enhancing the symbolic value of those structures by incorporating legal language like 'Affirmative Action offices' and 'EEO policies'. The equal opportunity/affirmative action structures were, however, to varying extents, decoupled from other personnel and governance activities, like hiring and promotion. Edelman concludes that organisations:

> … elaborate their formal structures to create visible symbols of their attention to law. Structural elaboration helps to alleviate the conflict between legal norms and managerial interests by helping organisations to secure legitimacy as well as more tangible environmental resources while at the same time allowing administrators to preserve at least some managerial discretion.
>
> (1992: 1567)

Like the 'Affirmative Action offices' and the 'EEO policies' in Edelman's study, the incorporation of the regulatory requirements into the biotech firm's SOPs provided a visible symbol of the firm's attention to the regulations, as did the firm's dialogue with the regulators

about the regulatory requirements and its consistent communication regarding production cycles. Gaining legitimacy and increasing public confidence in the technology is particularly important for biotech firms as they ultimately depend on social support for the creation of new markets. The SOPs and the interactions with the regulators could therefore have been a response designed to signal conformity to the externally legitimated requirements. There were, however, instances where tensions arose between the regulatory obligations on the one hand, and firm efficiency and production output on the other. Following Meyer and Rowan (1977), the firm could have accommodated this tension by selectively decoupling its formal waste management procedures from its actual waste treatment routines, permitting the firm to maintain both ceremonial conformity and production efficiency.

Concluding Remarks

The case study presented in this paper outlines the requirements imposed on a Norwegian biotech firm to regulate its large-scale contained use of GMOs, and the firm's breach of those requirements. The case study also describes the subsequent interactions that took place between the firm and the regulatory authority, and the views the two parties expressed regarding the breach.

To explore the firm's behaviour I drew on models of the firm recognised in the regulatory literature as providing rich heuristics for understanding responses to regulation. These models, or variants thereof, all provided plausible interpretations to account for the breaches. Yet, rather than supporting any one particular interpretation, the aim of the case study is to highlight that the justification behind the firm's behaviour may encompass a mixture of explanatory realms. The firm may have 'multiple selves' (Ayres and Braithwaite, 1992); it may have violated the law both because it found the requirements unreasonable and because it calculated that the anticipated costs and probability of being caught were small in relation to the profits to be made. Indeed, as Hutter (1997) points out, different parts of an organisation may be differently categorised. Perhaps some of the employees violated the law because they found the requirements unreasonable, others might have violated the law because they calculated that the anticipated costs and probability of being caught were small in relation to the profits to be made, and others again might have violated the law because they lacked attention, ability, or knowledge. Finally, the influence of any one realm on firm behaviour may also vary over time. The firm may have initially violated the law because it lacked attention, ability, or knowledge, but violated the law later on because it found the regulatory requirements unreasonable. Or it may have generally violated the law because it found the requirements unreasonable, but then violated the law in particular instances on the basis of maximising profits. However the firm justified its non-compliance, the case study has illustrated the very complex, messy and 'un-boxable' nature of firm behaviour.

References

Ayres, I. and Braithwaite, J. (1992) *Responsive Regulation: Transcending the Deregulation Debate*. Oxford: Oxford University Press.

Bardach, E. and Kagan, R. (1982) *Going by the Book: The Problem of Regulatory Unreasonableness*. Philadelphia, Penn: Temple University Press.

Braithwaite, J. (1985) *To Punish or Persuade: Enforcement of Coal Mine Safety*. Albany: New York Press.

Braithwaite, J. (1984) *Corporate Crime in the Pharmaceutical Industry*. London: Routledge.

Braithwaite, V., Braithwaite, J., Gibson, D. and Makkai, T. (1994) 'Regulatory Styles, Motivational Postures and Nursing Home Compliance', *Law and Policy*, 16 (4): 63-94.

Braithwaite, J. and Makkai, T. (1991) 'Testing an Expected Utility Model of Corporate Deterrence', *Law and Society Review*, 25 (1): 7-39.

Braithwaite, J., Makkai, T., Braithwaite, V., Gibson, D. and Ermann, D. (1990) *The Contribution of the Standards Monitoring Process to the Quality of Nursing Home Life: A Preliminary Report*. Canberra: Department of Community Services and Health.

Brittan, Y. (1984) *The Impact of Water Pollution Control on Industry: A Case Study of Fifty Dischargers*. Oxford: Centre for Socio-Legal Studies.

Burby, R.J. and Paterson, R.G. (1993) 'Improving Compliance with State Environmental Regulations', *Journal of Policy Analysis and Management*, 12: 753-772.

Cranston, R. (1979) *Regulatory Business: Law and Consumer Agencies*. London: Macmillan.

Cullen, F.T., Maakestad, W.J., and Cavender, G. (1987) *Corporate Crime Under Attack: The Ford Pinto Case and Beyond*. Cincinnati: Anderson.

Di Mento, J.F. (1986) *Environmental Law and American Business: Dilemmas of Compliance*. New York: Plenum Press.

Edelman, L.B. (1992) 'Legal Ambiguity and Symbolic Structures: Organizational Mediation of Civil Rights Law', *American Journal of Sociology*, 97 (6): 1531-1576.

Edelman, L.B. (1990) 'Legal Environments and Organizational Governance: The Expansion of Due Process in the American Workplace', *American Journal of Sociology*, 95 (6): 1401-1440.

Edelman, L.B., Uggen, C. and Erlanger, H.S. (1999) 'The Endogeneity of Legal Regulation: Grievance Procedures as Rational Myth', *American Journal of Sociology*, 105 (2): 406-454.

Edelman, L.B., Petterson, S., Chambliss, E. and Erlanger, H.S. (1991) 'Legal Ambiguity and the Politics of Compliance: Affirmative Action Officers' Dilemma', *Law and Policy*, 13: 73-97.

Finney, H. and Lesieur, H.R. (1982) 'A Contingency Theory of Organizational Crime' in Bacharach, S.B. and Lawler, E. (Eds.) *The Social Psychological Process* (Research in the Sociology of Organizations, 3). Greenwich, CT: Jai Press.

Fisse, W.B. and Braithwaite, J. (1983) *The Impact of Publicity on Corporate Offenses.* Albany, NY: State University of New York.

Geis, G. (1994) 'The Heavy Electrical Equipment Antitrust Cases of 1961' in Clinard, M.B. and Quinney, R. *Criminal Behavior Systems: A Typology 3rd Ed*. Cincinnati: Anderson.

Genn, H. (1993) 'Business Responses to the Regulation of Health and Safety in England', *Law and Policy*, 15 (3): 219-33.

Gray, W.B. and Scholz, J. (1993) 'Does Regulatory Enforcement Work? A Panel Analysis of OSHA Enforcement', *Law and Society Review*, 27 (1): 177-213.

Gross, E. (1980) 'Organizational Structure and Organizational Crime' in Geis, G. and Stotland, E. (Eds.) *White-Collar Crime: Theory and Research*. Beverly Hills, CA: Sage Publications.

Gunningham, N., Kagan, R.A. and Thornton, D. (2003) *Shades of Green: Business, Regulation and Environment*, Stanford: Stanford Law and Politics

Hawkins, K. (1984) *Environment and Enforcement: Regulation and Social Definition of Pollution*. Oxford: Clarendon Press.

Hawkins, K. and Hutter, B.M. (1993) 'The Response of Business to Social Regulation in England and Wales: An Enforcement Perspective', *Law and Policy*, 15 (3): 199-217.

Heimer, C. (1999) 'Competing Institutions: Law, Medicine, and Family in Neonatal Intensive Care', *Law and Society Review*, 33 (1): 17-66.

Heimer, C. (1996) 'Explaining Variation in the Impact of Law: Organizations, Institutions, and Professions', *Studies in Law, Politics and Society*, 15: 29-59.

Helland, E. (1998) 'The Enforcement of Pollution Control Laws: Inspections, Violations, and Self-Reporting', *The Review of Economics and Statistics*,80 (1): 141-153.

Hutter, B.M. (1997) *Compliance: Regulation and Environment*. Oxford: Clarendon Press.

Hutter, B.M. (1988) *The Reasonable Arm of the Law?: The Law Enforcement Procedures of Environmental Health Officers*. Oxford: Clarendon Press.

Jepperson, R.L. (1991) 'Institutions, Institutional Effects, and Institutionalism', in Powell, W.W. and DiMaggio, P.J. (Eds.) *The New Institutionalism in Organisational Analysis*. Chicago: University of Chicago Press.

Kagan, R.A. and Scholz, J.T. (1984) 'The Criminology of the Corporation and Regulatory Enforcement Strategies' in Hawkins, K. and Thomas, J.M. (Eds.) *Enforcing Regulation*. Boston: Kluwer-Nijhoff.

Levi, M. (1997) *Consent, Dissent, and Patriotism*. Cambridge: Cambridge University Press.

Levi, M. (1988) *Of Rule and Revenue*. Berkeley: University of California Press.

May, P.J. and Wood, R.S. (2003) 'At the Regulatory Frontlines: Inspectors' Enforcement Styles and Regulatory Compliance', *Journal of Public Administration Research and Theory*, 13 (2): 117-139.

May, P.J. and Winter, S. (1999) 'Regulatory Enforcement and Compliance: Examining Danish Agro-Environmental Policy', *Journal of Policy Analysis and Management*, 18: 625-51.

Meyer, J.W. and Rowan, B. (1977) 'Institutionalized Organizations: Formal Structure as Myth and Ceremony', *American Journal of Sociology*, 83(2): 340-363. Also in Powell.
W.W. and DiMaggio, P.J. (1991) *The New Institutionalism in Organisational Analysis*. Chicago, Illinois: University of Chicago Press.

Scholz, J.T. (1984) 'Voluntary Compliance and Regulatory Policy', *Law and Policy*, 6: 385-404.

Scholz, J.T. and Pinney, N. (1995) 'Duty, Fear, and Tax Compliance: The Heuristic Basis of Citizenship Behaviour', *American Journal of Political Science*, 39: 490-512.

Scott, W.R. (2001) *Institutions and Organizations 2nd Ed*. Thousand Oaks, California: Sage.

Scott, W.R. (1991) 'Unpacking Institutional Arguments' in Powell, W.W. and DiMaggio, P.J. (1991) *The New Institutionalism in Organisational Analysis*. Chicago, Illinois: University of Chicago Press.

Stone, C.D. (1975) *Where the Law Ends: The Social Control of Corporate Behaviour*. New York: Harper and Row.

Tyler, T.R. (1990) *Why People Obey the Law*. New Haven: Yale University Press.

Vaughan, D. (1996) *The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA*. Chicago: University of Chicago Press.

Vaughan, D. (1992) 'The Macro-Micro Connection in White-Collar Crime Theory' in Schlegel, K. and Weisburd, D. (Eds.) *White-Collar Crime Reconsidered*. Boston: Northwestern University Press.

Vaughan, D. (1983) *Controlling Unlawful Organisational Behaviour*. Chicago: Chicago University Press.

Winter, S. and May, P.J. (2001) 'Motivation for Compliance with Environmental Regulations', *Journal of Policy Analysis and Management*, 20 (4): 675- 698.

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