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When risk-based regulation aims low: approaches and challenges

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When Risk-Based Regulation Aims Low: Part I – Approaches and Challenges

Abstract

Risk based regulation is becoming a familiar regulatory strategy in a wide range of areas and countries. Regulatory attention tends to focus, at least initially, on high risks but low-risk regulatees or activities tend to form the bulk of the regulated population. In the context of expanding remits and shrinking budgets, regulators are turning their attention to how to manage such risks, and in short, asking ‘how low can they go’ in regulating them. The first part of this article examines the particular issues that arise with respect to selecting and managing low risks, and considers how regulators tend to deal with lower risks in practice. The second part, published in the subsequent issue of this journal, then develops a strategic framework for regulators to employ when choosing intervention strategies and it assesses whether, and how, such a framework could be used by regulatory agencies in a manner that is operable, dynamic, transparent and justifiable.

Introduction

In a striking wave of regulatory homogenisation, risk-based regulation is becoming widespread across the globe and in areas as diverse as environment, finance, food and legal services (Black 2005a; Hutter 2005; Hampton Report 2005; Rothstein et al. 2006; Black 2005b; Black 2006; Hutter & Lloyd Bostock 2008). Risk-based regulation is a particular strategy or set of strategies that regulators use to target their resources at those sites and activities that present threats to their ability to achieve their objectives (Black 2005a; Black 2008; Black & Baldwin 2010). In such an approach, the tendency is for regulators’ gaze to be drawn to their highest risks. High risks, however, tend to be concentrated in a relatively small proportion of firms or activities and the bulk of regulated sites and operations tend to present lower levels of risk. Risk-based regulation encourages regulators to pull back resources from these latter risks, but most regulators need to deal with lower risks in some way or other. Such risks have some capacity to produce both significant harms and political contention, and in many cases the law will demand that lower risks be attended to.

Regulators, therefore, cannot ignore low risks, but such risks pose a very real set of questions for them. How far can they pull back from actively intervening with respect to low risk sites or activities? Can they control low risks with strategies that are low resource, but also efficient, effective, transparent and justifiable to those both within and outside the agency? How do they ‘go low’, and indeed ‘how low can they go’, when addressing low risks?

This article examines the particular challenges that regulators have to face when overseeing low risks, and Part II seeks to develop a strategic framework for regulators to use in determining how to regulate lower risk sites or activities. The framework offered is

derived from a research project conducted for, and in conjunction with, the four environment regulators of England and Wales, Northern Ireland, Scotland and the Republic of Ireland.¹ The discussion commences by asking why regulators need to address low risks and it outlines the potential difficulties that such risks present. It then considers, in Section 2, how regulators tend to deal with lower risks in practice.² A body of literature and survey-based research is used, in Section 3, to develop a taxonomy of intervention strategies that may be potentially useful in relation to low-risk activities, and, indeed, more widely.

Identifying a range of possible intervention strategies does not in itself, however, provide a framework for strategic decisions. Part II Section 1, therefore, develops such a framework for regulators to employ when choosing low-risk intervention strategies and for reviewing such selection processes. It is important to stress that the framework is not proposed as a complete framework for risk governance. Rather it focuses principally on part of that process: the selection and implementation of regulatory strategies (or tools of risk management) and a framework for review. The intervention framework does not cover in detail the processes of goal setting, risk selection, assessment, and categorisation, though it does propose a secondary assessment process and it argues that the distinctions between these stages are in practice blurred for a number of reasons which are explained. Part II Section 2 then assesses whether, and how, such a framework could be used by regulatory agencies in a manner that is operable, dynamic, transparent and justifiable. Finally, Part II Section 3 argues that coming to grips with the challenges presented by low risks compels us to rethink our conceptions of risk-based regulation more generally.

1. The Challenges of Low Risks

There are a number of challenges involved in developing and implementing systems to manage risks (eg Renn 1992; Hood C et al. 2001; Sunstein, 2002; Kasperson et al. 2003; Renn 2005) and, more specifically, in developing and implementing the particular strategy of risk-based regulation (Black 2005a; Hutter 2005; Rothstein et al. 2006; Black 2005b; Black 2006; Hutter & Lloyd Bostock 2008; Black 2008; Black & Baldwin 2010). Each aspect of a risk-based framework involves a complex set of choices and risk-based regulators have to address a number of issues including: the risks they will identify as requiring attention; the indicators and methods they will use to assess those risks; where they will prioritise their attention and where they will not. They will also have to decide how the implementation of the risk-based framework will be managed; how it will be justified and communicated both internally and externally; how they will respond to changes and, ultimately, what level of risk or failure they are prepared to accept.

These challenges are well documented and will not be rehearsed here. Our present focus rests on the particular challenges of regulating those firms, sites or activities that fall at the lower end of a regulator's risk spectrum. 'Low' should, therefore, be read as synonymous with 'lower'. The main such challenges are: first, whether and how to fine-tune risk categorisations in a manner that distinguishes the very low from the low or medium-low risks; second, to determine what level of regulatory attention to give to lower risks; and third, to develop a justifiable strategy for intervention and review.

Distinguishing lower from higher risks

In conventional risk analyses, risks are distinguished from hazards. A hazard is the inherent potential for harm arising from a substance, structure or activity; risk is the potential effects of that hazard on a particular target and its related probabilities (Renn 2005 p. 19). In turn, 'risk' is distinguished from 'uncertainty': the former is used where probabilities are known, the latter where they are not (Knight 1921). Levels of risk are conventionally assessed as the product of the quantum of a potential harm and the probability that the harm will be realized (Renn 2005), an assessment also used in risk based regulation (Black 2005a).³

Just how risks are categorised is a matter of some debate both in academic and policy circles. In most of the risk based frameworks that are encountered across sectors and countries, risks are ranked in order of priority from 'low' to 'high' with various stages in between (most frameworks employ four or five categorisations or 'levels' of risk). Some may dispute the appropriateness of categorisation in terms of 'levels' of risk, arguing that it does not make sense to hold something to be a 'low' or 'high' risk and preferring instead to categorise risks on the basis of other dimensions including and simplicity, complexity, uncertainty of estimates of probability and / or impact, and socio-political contestability (eg Renn 2005; WBGU 2000). Whatever type of characterisation is used, though, regulatory agencies still need to prioritise the different risks that they have to manage and, in practice, categorisations of 'low' or 'medium-low' or 'high' operate as prioritisation categories. 'Low risk' means 'low priority' – it is not so much a characterisation of the risk itself as a statement of a risk's relative significance for the organisation (which may or may not equate to its risk to the environment, food safety, financial stability or other matter that the agency is charged with ensuring, protecting, contributing to).

As is well recognised in the risk literature, how risks are selected, framed and categorised for attention is a complex process, involving a mosaic of technical, psychological, cultural, social, political, organisational and economic concerns. The categorisation decisions made in risk-based regulation are no exception. Distinguishing 'low' from 'high' risks is therefore an art rather than a science, notwithstanding the prevalence of scientific analysis and quantitative risk models in much risk regulation. Most importantly, there is no single and uncontentious way to define and 'rate' many

risks – what is a ‘low risk’ or a ‘high risk’ is a matter of construction. Risk assessments, moreover, are usually relative – what counts as a ‘low’ risk for one regulator may be seen as a ‘high’ risk by another because of differences in the overall risk profile of the regulated population.

In addition, what constitutes ‘low’ and ‘high’ in risk-based regulation is usually defined in terms of the risks to the agency not attaining its objectives or mandate. Risk-based regulation is a strategy of institutional risk management, and like many risk assessments can be significantly affected by the socio-political context, organisational factors and the regulator’s own risk appetite. It is important to emphasise that in risk based regulation, organisational factors can be important in constructing and applying risk categorisations. A key use of the risk categorisations is to determine or at least facilitate resource management (Black 2005a). As noted above, categorising something as a ‘high’ risk means it is a ‘high priority’ risk to be addressed with a high level of resourcing. The link between risk categorisation and resources can, moreover, skew the risk assessment in a number of ways. Divisions within a regulatory agency can ‘bid up’ their risks to attract more resources. Alternatively (or additionally), a regulatory body may tend to define only as many ‘high’ risks as it knows it has resources to manage (Black 2005a). Conversely, if a charging scheme is linked to a risk categorisation (so that those firms categorised as ‘higher’ risks pay more fees, as is the case in the environmental regulators examined here), then the agency’s own need to gain resources can be an important factor in the categorisation process and may drive more firms into the higher risk categories.

Thus, for a number of reasons, what is a low risk to one regulator in one context might not be treated as such in another set of circumstances. In the environmental sector, the types of risks that we refer to as being ‘low’ risk include sites and activities such as point source discharges into water, waste transfer stations, small oil pumping and container sites, septic tanks, dry cleaners. However, as our research discovered, regulators may agree that such activities are ‘low’ risk, but they can still disagree quite significantly on whether diffuse pollution from agriculture, for example, or peat harvesting, or coal-fired power stations could also be considered ‘low’ risks.

Our concern here is not to seek to identify a precise point at which a risk *should* turn from ‘low’ to ‘medium-low’, ‘medium-high’, ‘high’ and so forth in the regulators’ classification scheme, nor would such a prescription necessarily be productive. What is addressed in this article is the set of problems that many regulators face in dealing with the risks *that they have put* in their lower risk categorisations. A first challenge is posed by the very numbers of sites or activities that give rise to lower risks. We, accordingly, ask, first, whether it is possible and / or useful to further break the ‘low risk’ category down in order to devise appropriate regulatory strategies for managing those risks.

Distinguishing between types of low risks

There are a number of different ways to categorise risks, as noted above. Risks are conventionally categorised on the basis of two dimensions: probability and impact, with impact often defined as an adverse event of different degrees of tolerability.⁴ In the activity of risk governance, however, other dimensions come into play, including the simplicity or complexity of the causal chain between hazard and harm, the degree to which probability and / or impact are known or uncertain, the nature and distribution of the impacts (remediable or irreducible, concentrated or diffused) and the socio-political contestability of the risk (eg Renn 2005). Different strategies may be appropriate for risks which are known and simple and whose impacts are remediable or reversible than for those which are uncertain and / or highly contestable whose impacts are irreducible or irreversible (Wildavsky 1988; O’Riordan & Cameron 2002; Majone 2002; Klink & Renn 2002).

It is suggested here that two further dimensions are important for regulators in managing all levels of risks, not only low risks. These are the extent to which a risk is stable or volatile, including the extent to which it may accumulate to present an overall higher risk, and whether what is being assessed is ‘intrinsic’ or ‘net’ risk. Thus, the risks presented by some activities may be ‘intrinsically’ low because the quantum of the potential harm that might ensue is not high even in the absence of any risk control measures. Others may be categorized for the purposes of risk governance as ‘net low risks’: where the potential harm is higher than for the intrinsically lower risks, but the probability and / or impact is reduced by risk management and other control measures, or by systems of resilience – such as capital requirements in financial institutions, or engineered safety controls in power stations, or by the possibility of remediation (eg compensation for financial loss, treatment for disease, or environmental ‘clean up’). Assessments of ‘net’ risk are common in risk based regulation in the financial sphere, for example (Black 2010).

With respect to the dynamic dimension (volatility and accumulation) of risk, an important issue for risk governance purposes is the time horizon over which control measures are being applied and assessed. A key issue for most regulators will be whether a given risk is liable to change materially in the period between their reviews of strategies for dealing with it. That ‘review period’ is, thus, the logical temporal scale to be used in assessing volatility. A risk may be relatively stable with respect to either quantum of potential harm or probability of occurrence over a defined period of time, or it may be subject to change. In the case of water pollution, for instance, the level of a potential harm may vary with climatic conditions or water levels. Alternatively, the managerial team that controls a risk may be liable to change, altering the probability of harm occurring, and constituting a matter of key concern for ‘net’ risk assessments.

It is also the case that, although individually a particular site or activity may pose a small risk, that risk may be generated by a large number of actors so that it accumulates to form higher, possibly systemic risks – as where thousands of farmers each discharge

small quantities of effluent into a water course as the result of a commonly adopted operation (e.g. the cleaning of milking parlours or fertiliser run-off from fields). This process of accumulation may, moreover, render an otherwise stable risk volatile: the risk becomes more substantial as accumulations cross thresholds of tolerance or create systemic problems.

A key related issue here is how risks are defined or ‘bundled’ by the regulator in its analytical and monitoring processes, for that bundling can reveal or obscure risks, depending on how it is done. If risks are assessed in terms of risks arising from individual *sites*, the actions from any single small farm present a very low risk. However if risks are categorised according to *activity*, the widely practiced operation presents a huge risk. Parallels can be drawn with other regulatory domains: in the food sector, meat from one contaminated source can quickly be distributed into thousands of meat products sold through further thousands of venues, often in different countries. In the financial sector, such accumulations may involve a systemic threat in so far as they prejudice overall stability of the financial system or investor confidence.

A fundamental difficulty in scoring low-risks with any precision is that the evaluation process can consume considerable agency resources. It may be justifiable to engage in close-grained analysis of higher risks, but it will be less easy to justify the devotion of higher resource levels to evaluating risks that are at the lower end of the agency’s risk spectrum. Any categorization for firms in the low-risk category is, accordingly, likely to have to be broad brush. It can similarly be difficult to justify higher levels of monitoring activity with respect to lower risks. A central message of risk-based regulation is, after all, to pull back from spending resources on the lower risks. A core challenge for any risk-based regulator is thus to deploy low cost approaches to lower risks and yet be able to pick up accumulations of such risks when they become an issue without expending significant amounts of resources, a matter to which we return below.

Within any regulatory agency, moreover, there may be a number of different risk categorisations in operation (these are often driven by the legal frameworks which the agencies have to apply). This is particularly the case in the environmental sector, where regulators in the UK and Ireland have to implement separate legal frameworks for waste management, water quality, emissions to air and a number of other discrete environmental risks. The risk-based framework can be more developed for some activities (e.g. pollution control) than others (e.g. waste or water quality).⁶ Developing a single, unified method of assessing and scoring risks across the whole of the agency’s remit can be challenging as the risks can be difficult to compare and render commensurable, though not impossible: SEPA (the Scottish Environmental Protection Agency) has recently developed such a unified approach, an essential first step in developing a coherent framework for establishing priorities for action.

Even a unified framework can leave a large ‘bulge’ in the low risk category. This prompts the question whether it is possible to develop a typology of low risks which can

be applied across the agencies' different legal mandates, which can help regulators to disaggregate the large numbers of firms, sites or activities which fall into this category, and which captures some of these complexities, but is still practical? It is suggested here that this can be done. If it is assumed that the broad category of low risks contains those which are relatively simple, the main characteristics are relatively well-known, the harm is relatively remediable or reversible, and the risk is relatively uncontested, then we can differentiate this broad category by focusing primarily on two dimensions: the volatility and propensity to accumulate of the risks, and the degree to which the categorisations of those risks as low or high is dependent on the application of risk control measures. The reason for focussing on these two dimensions is that this allows regulators to tailor their strategic interventions to their major concerns about lower risks: whether they are stable or likely to change into higher risks and whether their lower risk status is dependent on effective risk management by the regulatee.

The types of risk that an agency is likely to have categorised as 'low risk' (ie low priority) are usually relatively simple in that the properties of the risk, ie, its probability, impact and causal relationships are relatively well known, and there is relatively little socio-political contestability as to the nature of the risk (though there may be as to its relative prioritisation for attention). Those dimensions are therefore fairly constant (and indeed are likely to be within any one risk 'band' or category, though this is not an issue which we can explore further here). Where risks within the 'lower risk' category differ relative to one another is with respect to the role of risk controls in bringing any particular risk down into the lower risk categorisation, and in terms of their potential to change, which can bring them up relative to more stable risks.

The following table therefore develops a typology of low risks based on these dimensions.

Table 1: Types of low risks

<i>Inherent low risk – stable</i>	The activity is not capable of producing intolerable harms/impacts and operations are not likely to change in the periods between regulators' strategy reviews.
<i>Net low risk - stable</i>	The activity is capable of producing intolerable harms/impacts in the periods between regulators' strategy reviews but risks are reduced by good management.
<i>Inherent low risk but may change or accumulate</i>	The activity is not capable (as presently organized) of producing intolerable harms/impacts in the periods between regulators' strategy reviews but

	operations (e.g. chemicals used) may change or there may be numbers of such risks being created that create a cumulative problem (e.g. because environmental absorption capacities are exceeded).
<i>Net low risk but may change or accumulate</i>	The activity is capable of producing intolerable harms/impacts in the periods between regulators' strategy reviews but, at present, risks are reduced by good management. That good management may, however, change or there may be numbers of such risks being created that create a cumulative problem.

Going low – how low to go?

As noted above, the political and functional justification for risk based regulation is that regulators should prioritise their resources by targetting them on those firms, sites or activities which pose the highest risks to their objectives (Hampton 2005; Sparrow 2000). Resource allocation, however, tends to be a zero-sum game. If resources are moved to one area – such as higher risks- they are necessarily withdrawn from somewhere else. This is a facet of risk-based regulation that chimes well with the mantra of 'burden reduction' but is frequently underplayed in the policy literature (Hampton 2005).

The difficulty for regulators is that there are a number of reasons why it may be dangerous for them to underplay lower risks by failing to control them or to keep them under review. First, as noted, risks, even low risks, are dynamic. Circumstances may change so that inherently low risks become higher risks because, for instance, a production process has changed or waste starts to accumulate at a site which previously had a high throughput. Low net risks may also mutate to higher risks as managers become complacent about, and less effective with, their risk controls, or indeed, if regulators reduce their inspection activities. If regulators do not operate systems that allow them to pick up and deal with such changes, they may fail to control very significant dangers.

Secondly, the categorisations the regulator uses may be contested by those outside the organisation, such as NGOs, consumers, local residents, politicians, and industry. The result of this disjuncture may be that the regulator loses public and political support for not aligning its priorities with those endorsed beyond its organization. A clear

example in the environmental sector is noise and odours. Actions to limit noise and odours may not be part of the legislative responsibilities of the environmental regulator, and, even if they are, they pose modest risks to the environment. Noises and odours are, however, matters that give rise to public concern and which the public expects the regulator to address. It is because of such sensitivities that, in practice, a regulator's risk tolerance is often materially driven by political considerations. However, similar political problems may arise from the way in which the regulator has bundled risks. As noted above, how a risk is bundled has implications for how it is assessed: a regulator may deem a risk to be low because it calculates risks with reference to individual *sites* or firms, but this evaluation is at odds with those that look at risks stemming from certain general *activities*.⁵

Thirdly, and related to the point above, risk-based regulation tends to expose a regulator's risk tolerance to problematic public scrutiny. With respect to low risks, a regulator has to decide 'how low it can go' – how far it can hold back from regulating lower risks, and conversely, how far it can divert resources from regulating higher risks in order to focus resources on less significant risks. It is not easy to defend a strategy of reducing regulatory attention when things go wrong. When a harm occurs at a low risk site, it may be difficult to explain why that site was a low priority for action, and *will continue to be* a low priority. This may be notwithstanding evidence that suggests that inspections can have little effect on compliance, and longer frequencies between inspections have very little or no impact on the rate of 'compliance decay' (SNIFFER 2009; Ko et al. 2010). Further, as noted, what a regulator considers low risk may not be what the public considers to be low risk.

Fourthly, the internal organisational context of the regulatory body itself is important. Reducing the resources devoted to lower risks is a managerial challenge as well as a political one. Reallocating resources inevitably means that there will be winners and losers within the organization. Difficult messages will therefore have to be communicated internally. Thus, field-officers may not be happy to be told that they can do their job just as effectively by inspecting once every three years as opposed to three times in one year. As noted, divisions can respond by bidding up risks in an attempt to gain resources; alternatively officials can reduce risk categorisations as they are reluctant to take a more interventionist approach (Black 2010). The case for reallocating resources, it should not be forgotten, has to convince those within the regulatory body as well as those outside it.

Finally, it should be noted that regulators are not always free to move resources away from lower risks. The legislative frameworks that regulators operate under will commonly require them to regulate activities that their own analyses would suggest should be allowed to fall out of the regulatory net altogether.

Such legal restrictions apart, it is likely that the higher the political salience of a sector or risk, the less will be the regulators' tolerance of failure in that particular area.

Regulatory effectiveness is affected by levels of political support (Haines 2011a; Turner 2009) and several regulators deliberately calibrate their risk models with reference, *inter alia*, to their ability to maintain public confidence in themselves and in the sector they are regulating (Black 2005a). The political context is often fickle, however, so that issues that were not salient suddenly become so, and vice versa. This has consequences for the allocation of resources, which may not always go where the risk model says they should. Rather they go to the area which is most politically sensitive (Black 2010, pp. 332-9).

Regulators' Responses to Low Risks

In Part II of this paper (Black and Baldwin forthcoming) we develop a framework for regulators to use in deciding how to address the challenges presented by lower risks. A necessary precursor to developing such a framework, however, is to understand how, in the environmental sector, regulators tend currently manage such risks. It is important to emphasise that the aim of the research project was not to assess what the *legislative* framework should be: the policy and legislative processes at the EU and national levels had already determined which risks the regulators had to address. Instead, it was to investigate how regulators managed the regulatory tasks they had been given with respect to risks which they categorised as being lower risks, and to develop a framework to help them to manage them better, assessed against a number of criteria.

In general terms, the environmental regulators in the UK and Eire aspire to regulate low risks in a manner that serves three core objectives. Their first stated aim is to use resources efficiently and effectively to control these risks in a manner that serves the regulator's given statutory aims. (These will generally include avoiding the imposition, or incurring of, disproportionate costs). Second, to operate systems that can be assessed and justified - whose performance can be measured and which satisfy 'representative' values such as those of transparency, fairness, and accountability. Third, to apply approaches that are dynamically efficient - that can cope with change, adjust to new challenges and improve over time (SNIFFER 2010a).

As part of the research for this project, a web-based survey⁷ was used to identify current practices and strategies relating to low risk sites.⁸ Notwithstanding the low risk categorisation, the survey results are consistent with many of the findings of previous studies into regulators' inspection and enforcement behavior, particularly in the UK and Australia (Gunningham 2010, Haines 2011b; Grabosky & Braithwaite 1986; Hawkins 2001). (Full details of the findings including detailed breakdowns of the responses can be found in SNIFFER 2011). Overall, the survey found that there were some regional differences in the strategies for regulating low risks. The Irish EPA relied heavily on operator self-assessments, the Environment Agency for England and Wales had introduced a scheme of third party audits for agricultural sites and activities, the Farm

Assurance Scheme, and the Scottish Environmental Protection Agency (SEPA) had introduced a system of audits rather than inspections (these are discussed in more depth in the next section). Subject to those exceptions, however, regulators generally used the same strategies for lower risks as were employed for higher risks, namely routine monitoring, audit or inspection, but with a lower frequency and / or intensity. Enforcement and intervention actions were conducted in accordance with their agency's existing enforcement policies, which emphasised the nature of the risk and the attitude and compliance history of the regulated operator as key factors shaping which enforcement and intervention tools should be adopted. A broadly 'compliance'-orientated approach was preferred (relying on informal warnings, advice and assistance), but although prosecution was not often used, it was seen as effective. In contrast, providing information and guidance to firms was often used, but not seen as particularly effective in improving compliance.

Inspection and monitoring

The central strategies employed for regulating low risks were inspection, monitoring and audit. These activities served a number of functions: they enabled the regulator to gain information about a regulatee, to identify potential risks or non-compliance (the two may not be the same), and to 'turn' the regulatee towards better risk management / compliance or provide a basis for doing so. Direct inspection and monitoring of sites / activities is costly, however. A critical question for regulators is what should they be looking at, and how often should they look. Inspection and monitoring strategies common to all the agencies included registration, regular reporting requirements, routine and random inspections and incident/complaint responding. In contrast, self-certification was not used frequently by the agencies in the areas surveyed, with the exception of the Irish Environmental Protection Agency (EPA), noted above, and to an extent the EA. Proxy measures (methods of gathering information on operators' performance other than going to the site directly) were cited as seldom used by any agency.

Common factors influencing the choice of inspection and information gathering methods were the compliance history and cooperation of the operator, the nature of the risk or level of the risk rating and resources. In addition, respondents listed deteriorating proxy indicators, a change in policy/legislation, and deviation from agreed self-monitoring schemes as influential factors.

One of the challenges of adopting risk-based approaches is coping with risk volatility or accumulation. Respondents indicated that their agencies were generally good at identifying changes in risk levels, mainly through inspections and information received through regular reporting requirements. The general drive to reduce 'regulatory burdens' across government was, however, hindering them in this respect. To this extent, the observations of the 'really responsive' framework are pertinent: that the institutional context and conflicting logics of different control instruments and regimes can impact on

an agency's behavior (Black & Baldwin 2010). Some used proxies such as sampling, but many noted that spotting dynamic changes in risk is very challenging and often happens in response to complaints.

All respondents identified limitations in the co-operation, knowledge and capacity of the regulated as significant challenges to monitoring and inspection, along with internal resources and data collection and management. The dispersion of activities across a large number of sites was also identified as a factor that could present difficulties. In order to address these challenges, many identified a need to improve systems of data management, in particular to consolidate record keeping systems for registration or licensing data and for compliance, creating an 'end to end' licensing and enforcement database, and improve data sharing with other agencies. A minority suggested a greater use of operator self-monitoring, though it should be noted that this is the dominant strategy used in Eire. One particular issue for all agencies was whether inspection and monitoring activities should be organized on an activity basis (e.g. emissions to air, water discharges, waste treatment) or on a site basis. The legislation and permitting system is organized on an activity basis, and most agencies used the legislative structure to organize their internal operational structures. As a result, one farm might be visited several times a year by different teams focusing on different types of activity. For lower risk activities this was potentially an over-use of resources.

Enforcement and intervention

A further question for the regulators of low risks is the level of resources that should be put into taking enforcement action in response to non-compliance with rules, particularly if that non-compliance does not in fact cause much, or any, environmental damage. Should enforcement focus on risks rather than rules, and how much time and resources should regulators devote to taking formal enforcement action with respect to low risk sites or operators?

The agencies possessed a familiar set of enforcement tools: prosecution; statutory notices; informal warning; advice/assistance; and information/education. In addition, the EA and EPA had the power to impose fines. Advice and assistance was by far the most commonly applied tool in all agencies, with informal warning, civil monetary penalties and financial/administrative incentives all coming a close respective second, third and fourth. Advice and assistance was identified by a significant majority as the most effective approach for gaining compliance and prosecutions (along with statutory notices) were viewed as quite effective although they were the least commonly used. In contrast, information/education directed at regulated operators was often used but was not regarded by field officers as very effective. There were some regional differences in approaches used. For example, the EPA and SEPA more commonly use interdict/injunctions; the EPA is less likely to provide advice and assistance to operators and to use public information campaigns. The use of public information campaign was

cited as being greater at the NIEA than at other regulators, whereas the EA and SEPA are more likely to use financial/administrative incentives than the other agencies, though the research also found that these had also been used by the NIEA with respect to landfill regulations.

For all respondents, their agency's own enforcement policy was the main factor influencing their approach.⁹ Other factors commonly cited across all agencies were the attitude/ intent of the operator, the relevant compliance history and the level of environmental damage/risk or the seriousness of the breach, all of which are reflected in the agencies' enforcement guidance (EA 2011). Additional considerations mentioned included the public / national interest, the cost-benefit analysis of the proposed remedies, the evidence available for demonstrating a breach, timeframes for achieving compliance, and the relevance of remedial action taken. Some respondents noted that they would escalate the severity of intervention or enforcement strategies up an 'enforcement pyramid' (Ayres & Braithwaite 1992).

The main challenge to low-risk enforcement and intervention was identified as a lack of capacity by operators to comply (due, for example to inadequate record keeping, and/or paucity of resourcing). The difficulties of relying on incident reporting or complaints were also noted, as reports by the public can be inaccurate or there is a difference in perception between the public and the regulators regarding the severity or importance of a risk or event. As for operational difficulties within the agencies, particular challenges cited were those presented by: the information and evidence gathering processes; limitations in enforcement resources; and sectors offering a large number of sites to inspect. Finally, some responses highlighted the challenges that flowed from nature of the risk itself – as was said to be the case with volatile or cumulative risks.

Quality of management and controls

Responses indicated that the strength of management and controls strongly affected the choice of methods for gathering information and deciding how to intervene with enforcement actions. In addition, all regulators believed that good management was a strong indication of a less problematic site with a lower likelihood of permit breach. It also indicated that issues would be identified early, and dealt with promptly. Less regulatory 'effort' was necessary with good managements and there was both a lower need for inspection or formal enforcement action, and a greater potential for self-monitoring strategies to be used in conjunction with external auditing and regulator-led inspections. Remedial action was also easier to plan with such managers. More flexibility and a less intensive intervention approach was therefore taken by all agencies whenever there was evidence of good management.

Agencies own assessment of their overall performance

The majority of respondents stated that their current approach to low-risk sites was structured by established standards and criteria, and that their methods were periodically checked for effectiveness. Overall, the respondents rated their agencies as performing well regarding effectiveness of resource use, justification to the public, targeting, consistency, ease of implementation and overall 'good practice'. There were, however, indications that they felt that performance in some areas was stronger than others, though exactly which areas differed across the agencies.

Summary

Overall, the survey revealed the relevance, in shaping agency strategies, of: the compliance history and cooperation of the operator; the nature of the risk or level of the risk rating; the organization and resourcing of the operator; and its capacity to comply. The responses indicated, moreover, that the legislative context, and the organization, systems, processes and interpretive approach of the agency itself had an impact on how regulation was performed.

The broad assessment given by officials was that field-level regulators were reasonably happy with the way that their agencies were regulating low-risk sites and activities. The detailed comments, though, revealed a more complex picture, with many suggesting that there were areas which could be improved, as discussed above. As for the possible deployment of unused but potential strategies for regulating low risks, a strong majority of respondents suggested that such opportunities were not being missed.

Such survey responses, however, focus on the levels of satisfaction of involved parties rather than provide an independent view of strategies and operations. High levels of satisfaction may indicate either those current approaches are successful or that those responding are failing to think critically or laterally about the ways in which their agencies deal with low risks. It is striking, moreover, that those further up the organization, in more strategic policy positions, evidenced lower levels of satisfaction than those at field officer level – regarding both the agency's current performance and the need for change.¹⁰ Whether it is possible to devise a general approach to low risks that will convince those inside and outside the regulatory bodies is a matter to which we now turn.

2. Intervention strategies for low risks – a broader perspective

The empirical research gave some broad indications of the types of approaches used with respect to low-risk sites or activities and of some of their strengths and weaknesses. More specific strategies for regulating low risk sites were gleaned both from a review of the primary and secondary literature of risk based regulatory strategies in five different domains (environment, fisheries, food safety, financial services and occupational health

and safety) in a number of countries (US, UK, the Netherlands, Canada, Australia, New Zealand and Sweden) and from the qualitative interviews with agency officials which supplemented the survey.¹¹ This research revealed that a wide range of tools is used to regulate low-risk sites, many of which will be familiar to regulators and used for regulating higher risk activities, but whose effectiveness is often contingent on specific sets of factors. These strategies can be divided into three main groups, which broadly align with the order in which regulatory tasks are performed (we have excluded formal enforcement strategies as the aim of the project was to devise regulatory strategies to use other than formal enforcement action, though some of these overlap with informal modes of gaining compliance, notably advice and assistance). These are screening and rule-based strategies, monitoring strategies and engagement and incentive strategies.

Screening and rule-based strategies

Regulatory regimes start from one of two default positions: an activity is allowed, but if carried out, becomes subject to regulation (as seen, for example, in much occupational health and safety regulation) or an activity is not allowed unless specifically authorized or exempt (for example, much financial services business, and much environment regulation). Screening and rule-based strategies are used initially to determine which default position is being adopted, who should fall within the regulatory regime and where their regulatory obligations are expressed. Broadly, there are four main strategies: exemptions without notification or registration; exemptions with notification or registration; application of general binding rules without notification/registration; and general binding rules, or standardized / bespoke permit and licensing systems with notification / registration. Clearly, complete exemptions are the least intensive, although some monitoring may still be necessary to ‘police the boundaries’ and ensure there are no illegal operators. Notification or registration has the advantage of enabling the regulator to identify and locate its regulated population, though requires both the agency and operators to keep records up to date if they are really to serve this function effectively. As for the instrument that contains the regulatory requirements to which the operator is subject, generally applicable binding rules are arguably a better instrument than licences for low risk activities, as tailored licences should not be necessary, and changes to provisions are easier to communicate via rules than changes to licence conditions.

Unfortunately for regulators, the choice of strategy is usually made by the legislator, leaving regulators to administer systems which can be out of kilter with their risk assessments. For lower risk activities, bespoke permitting or licensing systems are rare, and arguably not a good use of resources. Often, however, even very low risk activities have to have some form of licence or permit. Thus even though it may be more appropriate on a risk-basis to exempt a range of sites or activities completely, the regulator is stuck with a system which requires everyone to get a license which has to be renewed annually. However, the legislative framework can provide more flexibility in

some instances. There are examples of control of lower-risk activities by General Binding Rules (in Scottish water pollution) and General Mandatory Standards (in the Dutch environmental sector) (SEPA 2008). This involves the supervision of low risk activities by means of general rules that are applicable in the absence of any obligation to notify the regulator that an activity is being undertaken, quite common in health and safety but relatively rare in the rest of UK environmental regulation (IMPEL 2009, p. 12).

Monitoring tools

The second group of strategies comprises mechanisms that are used to gain information about a firm or sector's compliance and to verify that information. These can be categorized into four main types: those which involve direct contact between the regulator and regulatee; those which use proxy indicators; those which rely on the firm; and those using third party monitors.

Those which involve direct contact between regulator and regulatee are the most common. These include inspections and regulatory audits which may be performed on a routine, themed or random basis; advice and guidance visits and reactive investigations: responding to complaints, whistleblowing or post-incident investigations.

One frequently used strategy for dealing with low-risk sites in the environmental, food and other sectors in the UK and globally is to relate the frequency of inspections to the level of risk that the regulated activity presents.¹² Thus the low-risk site might be inspected every two years instead of six monthly for higher risk operations. A related approach is to limit the spread, rather than the frequency, of inspections by using sampling approaches in which certain sites are visited and those visits are used as indicators of more general practices and performance. In each case, all inspections cover the entirety of the firm's activities (EPA 2007; Minnow Environmental Inc. 2005; Food Standards Agency 2010; Food Safety Authority of Ireland 2006; NAO 2008c).

In many sectors, themed and special inspections have also been increasingly employed. Regulators identify particular themes or issues that they want to focus on, and inspect firm's activities in those areas alone. Which firms are to be inspected within the theme may be based on a prior risk assessment or may be decided randomly (Black 2008). In some jurisdictions, risks are prioritized within annual compliance and enforcement programs (AFMA 2010). The extent to which an agency can adopt a wide range of monitoring and intervention strategies may, however, be significantly hindered by legislation, often emanating from the EU. In the food sector, for example, themed inspections have only recently been included as one of the 'official controls' that the EU will recognize as constituting inspection and enforcement activity.

One challenge with themed inspections is to balance attention to thematic risks with attention to firm-specific risks. The Health and Safety Executive (HSE) moved to a topic based approach to inspections from 2002, as part of its 'revitalizing health and safety' approach and then its Fit 3 program (HSE 2011). A National Audit Office (NAO)

report, produced late in the transition, found that questions arose within the HSE as to the actions that inspectors should take in response to risks that they saw during an inspection but which were not part of the ‘topic pack’ that they were using to assess the generic risks. As a result, there was an under-utilization of firm specific information and, inspectors felt unable to use their discretion and judgment in response to observed problems (NAO 2008b).¹³

A second challenge in systems that operate to themes or periodic programs is establishing the efficient frequency and scope of these themes and programs. If, for example, annual reviews are used, as in Australian fisheries, this may demand the expenditure of excessive resources in analyzing and assessing activities whose risks are static but it may prove too unresponsive to volatile risks. In some sectors there may be a case for targeted reviews rather than periodic reappraisals. Other regulators, such as the Financial Services Authority, use statistical analysis to identify firms that should be prioritized for themed inspections, based on risk indicators (FSA 2006).

Random inspections are also used in monitoring low risk sites. Random inspections differ from thematic or sampling strategies in so far as minimal resources are devoted in the former to the selection of sites for inspection. Random inspections, nevertheless, can be an effective way to detect some non-compliance and they can be said to involve no unfairness to those targeted (merely bad luck) (EPA 2010; FSA 2006). A publicity strategy can, moreover, make random inspections an effective deterrent.

Some regulators, e.g. the Scottish Environmental Protection Agency (SEPA), have moved away from inspections to audit based strategies. In an audit, the regulator reviews the systems and processes in place at a site for controlling the risks of an activity, rather than looking ‘on the spot’ at what activities are occurring.

Inspections and audits, whether they are routine, themed, random or triggered by complaints, all involve ‘footfall’ by the regulator, a visit of some kind to the site or premises itself. In an attempt to rationalize this relatively expensive use of agency resources, other agencies have either replaced or supplemented such direct agency monitoring of a firm or site’s activities by using proxy strategies, relying to a greater extent on management-based strategies including self-certification, and by using third party monitors. Proxy strategies can include water sampling, for example sampling a downstream watercourse to measure water quality and use this as an indicator of discharges; or scrutinize fish market sales as an indicator of compliance with fishing at sea regulations.

A further type of monitoring strategy involves controls that are management-based – versions of which are known in the literature as ‘enforced self-regulation’ or ‘meta-regulation’ (Coglianese & Mendelson 2010; Coglianese & Lazer 2003). The firm is required to put in place systems for managing its risks or complying with regulatory requirements. These systems are then approved by the regulator. The processes of auditing or ‘meta-regulation’ allow the regulator to oversee the regulatee’s work in

controlling a risk rather than to monitor compliance directly. This makes for a low cost regime in so far as the regulator can examine the regulatees' risk management systems (either on paper or in the field) rather than rely on inspections on the ground. This approach has been used in UK Health and Safety regulation since the 1970s. In the Netherlands, this mechanism, as used in the chemicals and other sectors, is referred to as 'self-management supervision' (IMPEL 2009, p. 20). In the same country, the 'audit by topic' strategy is another process that assesses the quality of the management's general approach to risks rather than attempts to check the individual details of compliance with permit conditions (IMPEL 2009, p. 21).

Self-assessments are also being increasingly used with respect to low risk sites. For example, the Food Standards Agency has recently introduced self-assessments for low risk establishments. Self-certification is also an important aspect of the environmental regulation of certain low risk sites in the US as part of the Environmental Results Program (ERP). The ERP program is supplemented by targeted and random inspections. This combination has been shown to have a positive effect on compliance in a number of US states against a range of performance criteria (EPA 2010; FSA 2006).

A final monitoring strategy involves the use of third party agents. In some regulatory regimes, for example environmental regulation in Portugal, the task of certifying compliance is given to commercial organizations (Black 2010). In England and Wales, the Environment Agency (EA) has recently adopted the Farm Assurance Scheme, in which it uses existing farm assurance companies (who are assessing farms for large retailers such as Tesco) to inspect pig and poultry farms against a set of criteria (EA 2010). It then uses that data to decide whether or not to take enforcement action. The EA has gone from inspecting such farms twice a year to inspecting them once every three years. The assurance company inspects the farm annually, sending the information to the EA. The EA analyses the information to see if action needs to be taken and evaluates whether or not the farm still meets the criteria for being assessed as low risk. In assessing whether a farm should be in the scheme at all, the EA assesses it against a set of risk-based criteria. These criteria do not include the size of the farm, on the basis that although a large farm may pose a higher inherent risk its net risk may be low due to strong management. The scheme has only been in place since the start of 2010, but interviews with EA officials indicated that it is working well. Regulators who act concurrently in relation to a given area of activity can reduce their costs and the costs imposed on businesses by avoiding duplications of effort. In Scotland, for example, the Environmental and Rural Services initiative brought together the regulatory activities of nine bodied working with rural land managers. This included co-ordination of inspection activity and included the staff of one authority undertaking inspections for others (IMPEL 2009, p. 19). The Food Standards Agency also engages in joint inspections and data sharing with other regulators (NAO 2008a, p.6). Such an approach can be seen as a proxy system from the perspective of those agencies who enjoy the benefits of other agencies'

inspections. They have been applied in the Czech Republic, Greece, The Netherlands, Sweden and Turkey as well as the UK (IMPEL 2009, pp. 19-20).

The legislative framework can inhibit the adoption of some of these strategies, however, so agencies have to be careful how they construct such regimes. In the EU, for example, competent authorities are not allowed to delegate their powers. The use of third parties therefore has to be constrained to certain activities. There may also be legal obstacles to information sharing, such as confidentiality and data protection obligations which may stand in the way of certain disclosures. In certain cases, legislation may therefore be required to permit regulatory agencies to share information about a regulated firm.

Engagement and incentive strategies

The third group of strategies consists of a broader set of 'engagement' and incentive intervention tools. These involve engagement with interested groups such as industry associations, NGOs, local communities and with other regulators to perform a range of functions, including giving information about how improve regulatory performance, designing products and processes that can be more effective at achieving regulatory objectives, and engaging with other agencies in performing a range of activities, including linking regimes so that, for example, one agency can provide or withhold a subsidy from a firm depending on its compliance with the requirements imposed by another regulator.

In some cases, the best way to mitigate low levels of risk is not through the agency pursuing greater levels of compliance as such, but through encouraging stakeholder or industry-led solutions. Focusing on the design of equipment and technology has long been a central part of environmental regulation. It can be an effective way of demonstrating clear engagement with stakeholders, limiting risks and of targeting specific risks or particular localities. In particular, it can be a cost effective way of dealing with low risk sites, at least for the agency, and can have pay-offs for industry. A dynamic advantage may sometimes be gleaned in so far as industry is often best placed to identify and (with encouragement) to address new risks.

There are examples of agencies developing stakeholder-led solutions of this type. One example, in the agricultural sector, is the EA's practice of working with the Odour Group, an industry group, to encourage them to develop technologies to reduce odors from poultry and piggery farms. With respect to small household wastewater discharges, the EA liaises with manufacturers on designs and operating systems for lavatories. As for potential weaknesses of such strategies, one is that the regulator may be open to criticism if engagement is seen to stand in the way of proper enforcement action. A second difficulty may be that industry may take some time to develop and adopt appropriate designs. This is an approach that works best where there is a clearly identifiable group of affected stakeholders and where contention is low or can be resolved.

Information and education strategies can also play an important role with respect to low risk sites (e.g. EPA 2010, p. 11). One of the functions of inspections or visits is to inform regulatees of their obligations and to advise them on how to comply. For low risk sites, this is a very costly activity in proportion to the risks posed. However, if inspections cease or are severely reduced for these firms, this source of information obviously disappears. One approach is to use NGOs to advise and assist firms to develop an understanding of their regulatory requirements and to help build the technical capacity to develop adequate management systems. For example, in Northern Ireland, the NIEA worked with an NGO to help SMEs develop EMS accredited management systems.

Campaign information and guidance can be published 'bare' on websites or, as is common, can be disseminated through workshops (EPA 2008, p. 11). In relation to lower risk operators this advantage may be significant. A report by the NAO found that campaigning activity 'plays a key role in risk-based systems of regulation in reaching low-risk businesses that might not otherwise come into contact with the regulators' (NAO 2008a). In Australia it has been argued that, although proactive strategies such as education can be more resource intensive than reactive alternatives such as post-accident investigations, they can still be more cost-effective. Broad education campaigns, the argument runs, can deliver higher compliance levels than under-resourced inspection regimes (Productivity Commission Australia 2009, p. 133). The HSE is at the forefront of this approach in the UK. The HSE faces significant resource constraints, and cannot inspect the bulk of its regulated population on a regular basis. A firm will on average be inspected once every 14.5 years (HCSCWP 2007). In addressing this problem, the HSE has shifted from an approach based mainly on risk, which produces a huge number of firms with similar risk profiles, to one based on achievability: what is the most effective type of intervention that it can effect with respect to different types of firms, other than an inspection. It has been working on a system of 'segmenting' its regulated population, in much the same way as advertisers segment their target audiences. It has been developing a number of different ways to inform and influence small and medium sized businesses in particular.¹⁴

Finally, incentive strategies can be used to great effect. In Northern Ireland, for example, until recently those complying with the waste requirements received a rebate on their landfill tax payments, which significantly increased rates of compliance in the sector. In Scotland, farmers will not receive their single farm payments if they are in breach of their obligations under the Water Framework Directive (Scottish Government, *Single Farm Payment Scheme Information Leaflet*).

Such schemes require significant inter-agency cooperation, but are clearly not impossible. However, again other aspects of the overall regulatory framework can cut across this approach. Regulators can be dissuaded from strategies of education and advice by the evaluation criteria used to audit their activities. In the food sector, EU regulations stipulate what is an accepted 'official control' for the purposes of auditing food

inspection authorities. Until recently these did not include offering education and advice (EC 882/2004).¹⁵ In the environmental sector in the UK, including Northern Ireland and Scotland, the system of linking charging regimes with inspections means that any reduction in inspection activity reduces the amount of resources that the agency has. Charging structures can thus tie agencies to traditional approaches (i.e. routine inspections) cutting across their ability to develop alternative strategies. Charging schemes can also incentivise regulators to keep firms or activities in higher risk categories, for which higher fees can be charged. Low risk regulation still requires some resources, but it is difficult to fund them on a cost-recovery basis.

Summary

In practice there is a wide range of intervention tools which can and are being used with respect to low risks. The range and variety of these tools is at odds with the prescriptions of a number of other risk governance frameworks, which suggest that low risks can be handled through simple routine monitoring (eg IRGC 2005; WBGU 2000). The intervention tools that have the major potential for use with low-risk sites can be summarised as in Table 2.

Table 2: Potential tools for Low-Risk Sites/Activities

<i>Screening and rule-based strategies</i>
<ol style="list-style-type: none"> 1. Exemptions without notification or registration 2. Exemptions with notification or registration 3. Registration plus conditions/rules; permit and licensing systems 4. Application of general binding rules without notification/registration
<i>Monitoring tools</i>
<ol style="list-style-type: none"> 5. Frequency adjusted inspections or monitoring 6. Regulatory audits 7. Themed inspections or monitoring 8. Random inspections or monitoring 9. Advice and assistance visits 10. Reactive investigations, responding to complaints, whistleblowing or post-incident investigations 11. Surveillance
<ol style="list-style-type: none"> 12. Benchmarking or ‘yardsticking’ strategies 13. Measuring indirect/proxy outcomes
<ol style="list-style-type: none"> 14. Self monitoring and self certification by regulated firms 15. Management based strategies including mandatory performance disclosure by regulated firms

16. Third-party monitoring 17. Information and inspection sharing regimes
<i>Engagement and incentive strategies</i>
18. Information campaigns; generic advice and recommendations (including codes and guidance) 19. Dialogue with interested parties 20. Industry or NGO / interested party-led solutions 21. Multi-agency approaches 22. Incentive strategies

The above strategies can be used in combination: they are not necessarily alternatives. For example, even within a statutory permitting regime, it is still possible to use engagement strategies, such as information campaigns, to inform regulatees of their obligations and give advice on how to comply. Third party monitoring can be combined with some random inspections / audits by the agency itself, to check both the regulatee and the third party auditor. Proxy monitoring, such as water sampling, can be combined with themed inspections, for examples of particular farming practices.

Each of the specific strategies within each group has different strengths and weaknesses, and each may differ in the extent to which it meets different criteria. The criteria used to assess each strategy in this project were a variant of the UK government's PACTT principles, notably (proportionality, accountability, consistency, transparency and targeting (Hampton 2005), with the added criterion of adaptability (ability to identify and respond to change in risk profiles). In many cases, the extent to which a strategy does or does not meet the criteria in practice will depend on the details of its design and implementation in specific circumstances. For example, third party monitoring requires close supervision of the third party monitors, may or may not be done transparently, and may or may not be able to respond to change, all depending on how the scheme is designed and implemented.

Further, none of these strategies is specific to low risk sites. Under a risk-based framework, their use in relation to lower, as opposed to higher, risk sites should be decided with reference to the amount of regulatory resourcing that is needed for their application and the particular nature of the risk and risk creator. It follows that certain strategies are more appropriate for certain lower risk sites and regulatees than others. Where risks are inherently low and static, there is normally less need for bespoke licenses, for extensive audits, or for management based controls. Tailored licensing or rules, audits and management based intervention strategies, for example, may however be appropriate where the risk is dynamic and a net low risk, in other words, the level of risk is contingent on the strength of management and other controls to reduce the inherent risk level.

3. Summary

There are, as discussed, a number of specific issues that arise with respect to selecting and managing low risks, and regulators have developed a number of different strategies to address them. Providing a review of strategies only takes us so far, however. The pressing question is which of the available strategies are the ones to use to control a given risk use. There are a number of different ways of devising a framework for guiding such choices of intervention methods, and it is to this task that we turn in Part II of this article (Black and Baldwin 2011 forthcoming).

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Notes

¹ Respectively: the Environment Agency (EA), Northern Ireland Environment Agency (NIEA), Scottish Environmental Protection Agency (SEPA) and the Environmental Protection Agency (EPA) of the Republic of Ireland. The research project consisted of three main stages: first, a desk-based review of the approaches adopted by regulators in the areas of environment, fisheries, food, financial services and occupational health and safety in the US, UK, Netherlands, Canada, Australia and New Zealand, and Sweden, together with a web-based survey of field officers (detailed at n.2) and semi-structured interviews with two policy officials at each agency responsible for different low risks (April-September 2010). Second, the framework was developed and then reviewed and revised in an iterative process which involved a series of meetings run to a common agenda with inspectors, programme or regional managers, representatives of the regulated sector, representatives of any relevant NGOs and a representative from the relevant government department where possible at each of the four agencies. Theselected areas were low-risk agricultural discharges, peat harvesting, low-risk industrial discharges, septic tanks and other domestic waste, and waste transfer stations. (February-March 2011) (a total of 14 interviewees), followed by a further series of meetings with a

wider range of senior policy officials within the agencies (May 2011) (a total of 38 officials across the 4 agencies). The final Framework was then tested in intensive case-study based workshops with the EA and SEPA in October 2011. Full details of the methodology and findings of each stage of the research are in SNIFFER 2010a, 2010b and 2011.

² The findings of this part of the research are based on a desk-based review of practices of regulators in five domains in six countries (conducted from May-September 2010), on a web-based survey of 102 field-level officers in the four agencies (conducted from July-September 2010); and semi-structured interviews with program managers and directors in each of the four agencies, representatives from regulated firms, the relevant government departments and NGOs (conducted between July 2010-May 2011).

³ It should be noted that it is often the *nature* of the impact (which may turn on the sensitivity of an impact site) and not just its quantum that is relevant - see e.g. the Environment Agency's OPRA framework outlined at EA *Operational Risk Appraisal*.

⁴ Extensive work on perceptions of risk indicates that that the assessment of either element is rarely as objective as risk models and risk management processes may assume (Royal Society 1992; Slovic 2000; Renn 1992).

⁵ As noted, a general activity (such as a commonly adopted practice in a sector) may give rise to a high cumulative risk in spite of the presentation of low risks at particular sites.

⁶ Regulators can be hampered by legislative frameworks that operate on a pollutant by pollutant basis and lead agencies to focus on specific activities that occur on different sites rather than to develop a site-based approach (which would often make more sense for the operator / firm and enable interactions between risks to be observed, assessed and addressed).

⁷ The survey covered the areas of: Agriculture (poultry and piggeries); Chemicals; Power stations; Waste (e.g. civic amenity sites, landfill sites (small non-hazardous), transfer stations (dry recyclables)); Scrap metal including ELV, shredder sites and metal recycling; Low effluent wastewater sewage treatment activities; and Industrial point source discharges to watercourses.

⁸ The survey was conducted between July and September 2010 using software provided by SurveyMonkey. Of the 111 respondents, 64 were from the EA, 6 from the EPA, 20 from NIEA and 21 from SEPA. The responses were analyzed by regulatory agency as well as by overall response, as the analysis would otherwise be skewed by the EA response. Most of the respondents identified the sites they surveyed as 'net low-risk'

rather than ‘intrinsic low-risk’ and most believed their sites were of ‘medium’ or ‘high’ social/political importance. Full details are set out in SNIFFER 2010b.

⁹ The large majority of field officers responded that they did not distinguish between low- and high-risk sites in their enforcement strategy. However, enforcement at low risk sites was frequently reactive, following a complaint.

¹⁰ A number of commentators have drawn attention to the ‘multiple selves’ of regulated organizations and the gulf between management and field-level operators (Ayres & Braithwaite 1992; Braithwaite 2001; Baldwin 1990, p. 332-3; Barrett & Fudge 1981).

¹¹ Semi-structured interviews were conducted with senior officials in each of the sectors that were the subject of the survey in each of the agencies. The project also involved a desk-based review of the approaches adopted by regulators in the areas of environment, fisheries, food, financial services and occupational health and safety in the US, UK, Netherlands, Canada, Australia and New Zealand, and Sweden. The full findings are available at SNIFFER 2011.

¹² This option was suggested in the IMPEL 2008, p.43. See also Black 2008.

¹³ Clearer communications within the HSE have since gone some way to alleviating this problem.

¹⁴ The HSE has sought to reach agricultural workers by attending agricultural shows, farmers markets, and by targeting information at farmers’ wives. It even used the BBC Radio 4 program, *The Archers*, to publicize the dangers of tractors through a storyline about a tractor fatality. It has, similarly targeted construction workers with radio and TV campaigns, celebrity endorsements, and shock campaigns. In a further initiative, it has co-operated with hire shops and builders merchants who have run equipment replacement schemes for builders.

¹⁵ Recent changes to EU requirements have, however, enabled the Food Standards Agency, to adopt such approaches and following research which showed the effectiveness of such strategies, the FSA has relaxed its own criteria for auditing local authorities to include education and advice in the intervention strategies that it will ‘count’ in assessing their enforcement activities (Fairman & Yapp 2005, p. 491).

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When Risk-Based Regulation Aims Low: Part II - A Strategic Framework

Abstract

This part of the article builds on the analysis of the first part (published in the previous issue) and it develops a strategic framework for regulators to employ when choosing intervention strategies. The framework offered derives from a research project conducted for, and in conjunction with, the four environment regulators of England and Wales, Northern Ireland, Scotland and the Republic of Ireland. The elements of the framework are presented and the discussion considers whether, and how, such a framework could be used by regulatory agencies in a manner that is operable, dynamic, transparent and justifiable. It is argued that coming to grips with the challenges presented by low risks compels us to rethink our conceptions of risk-based regulation more generally.

Introduction

The first part of this article (Black and Baldwin 2011) examined the particular issues that arise with respect to selecting and managing low risks, and it considered how regulators tend to deal with lower risks in practice. Providing a review of strategies only takes us so far, however. The key issue is how to select the strategies to use in any given context. In this respect, other risk governance frameworks tend to gloss over the difficulties involved in making a selection, and where the matter is addressed in any detail, they are inclined to restrict the range of strategies to routine monitoring. Much of their attention, is focussed, instead, on methods of risk assessment and on engagement with the wider community (eg IRGC 2005; WBGU 2000; Cabinet Office 2002; Codex Alimentarius 2003; FERMA 2003). There are, however, a number of possible ways to devise a framework for intervention strategies.

A simple approach would be to select one strategy of the many that are possible and apply this to all lower risk sites or activities. A modified version of the US Environmental Protection Agency's Environmental Results Programme could be used, for example, to require all those operating low-risk sites or activities to adopt a program or self-certification supplemented by periodic inspections (EPA 2010). Requiring regulators to adopt only a single strategy, however, may be unnecessarily constraining, and, in some instances, may lead to ineffectiveness (Simon 2010).

An alternative option would be to focus on the nature of the risk alone and to select intervention strategies with reference to the amount of regulatory resources that each involves. We have argued that low risks can take a number of forms: they may be inherent or net, static or dynamic, systemic or non-systemic. So even within the low-risk category, some low risks are lower than others. Based on this breakdown, an intervention 'pyramid' could be constructed with the least intensive regulatory strategies at the base used for inherent and stable low risks, and the more intensive used for net, dynamic low risks. For example, for inherent low risks which are stable, general binding rules, shared monitoring with other agencies where possible or by third party auditors over a relatively long cycle, for example once every five years, and / or using NGOs or others to develop and deliver education and advice programs). For net, dynamic low-risks more intensive strategies

would be appropriate, such as bespoke licensing, self-certification verified by third party auditors with full regulatory audit supplementing periodically, but with a shorter monitoring cycle, for example once every three years.

Such an approach would be consistent with the main thrust of most risk-based assessment frameworks which direct resources to the highest risks. Using the nature of the risk to drive the intervention strategy, however, focuses on just one aspect of the task in hand and is largely divorced from the enforcement approach that most regulators take (and the literature urges them to take), which is to tailor their response to the attitude of the regulatee and their capacity to comply (Ayres & Braithwaite 1992; Braithwaite 2001; Baldwin 1990; Barrett & Fudge 1981; Neilsen & Parker 2009). It could be argued that a 'pyramid' approach, which adjusted the intervention strategy simply to the firm's risk score, would capture both elements since compliance history forms part of that score. Most risk scoring systems, however, do not capture the reasons why regulatees fail to comply, despite research showing the need for regulators to take account the reasons for non-compliance as well as the fact of non-compliance.

The extensive literature on literature on regulatory enforcement and its counterpart literature on business responses to regulation suggest that both compliance-orientated and enforcement activities (including for these purposes advice and assist visits, or education campaigns as well as formal enforcement action) should vary with the behaviour and compliance motivations of the regulatee (eg Kagan & Scholz 1984; Kagan 1994; Scholz 1991; Ayres & Braithwaite 1992; Gunningham & Sinclair 2009; Parker and Neilsen 2011). In practice, as the research for this project and the literature on inspections and compliance shows, regulators do adjust their strategies on a firm by firm basis, often with reference to the compliance history of the particular firm or site operator. Indeed, some regulators have gone a step further and grouped their regulated population according to their propensity to comply. For example, Her Majesty's Revenue and Customs (HMRC) characterizes those who pay VAT on the basis of their predicted response to tax laws.¹ As noted above, a similar approach is used by the Australian Tax Office, which uses categorizations of people's propensity to pay tax as the basis for structuring its interactions with them, an approach also adopted by the Australian Fisheries Management Authority

Such targeting can enable the type of intervention to be tailored most appropriately to the type of regulatee (e.g. advice for those who are well-intentioned but ill-informed; strong enforcement action against those who are ill-intentioned).² It is a focus, however, that does not deal with the nature of risks as such, other than risks of non-compliance. Not all instances of non-compliance pose the same level of environmental risks.

A disconnect thus exists between the risk-based categorization of sites and activities, which drives permitting and is meant to drive resource allocation, and the predominantly behaviour-based approach of the enforcement manuals, and indeed of the preponderance of the literature on compliance and enforcement.

Furthermore, there is a strategic gap between the risk-based assessment process and the enforcement process, with very little sense of an approach to using, not simply inspections, but a broader range of screening, monitoring, engagement and incentive strategies – all of which fall short of formal enforcement action.

Can a general strategic framework be developed for dealing with low-risk sites/activities which can bridge these two gaps? In this and the following section, we develop a framework for strategic decision making that integrates risk and behavior, and which is based on a ‘really responsive’ approach to regulation (Baldwin & Black 2008; Black & Baldwin 2010, p. 181-213).

The ‘really responsive’ approach suggests that there are five sets of factors which should, and often do, influence how regulators behave and the effectiveness of regulation. Thus, once regulators are clear about their regulatory objectives, they should devise their strategies with an eye not merely to the kind of low risk at issue and the *suitability of different tools* for intervention, but to the relevant characteristics of the regulated concerns that are involved. These characteristics should include, notably, their *cultures* - the attitudes, motivational postures and cognitive frameworks of regulated firms that influence regulatory relationships and the regulator’s capacity to influence behavior. Other factors to be considered are the *organizational settings* - the institutional locations of the regulator that have a critical effect regulation. This includes not only the regulators’ resource positions but the systems of accountability and political sensitivities that (actually or potentially) impact on low-risk regulation. A further matter to take on board is performance *assessment* and the need for processes that allow the regulator to judge whether their efforts (and budgets) are having any positive effect in furthering their objectives and whether there is a need to adjust approaches. Finally, as noted, it is necessary to establish systems that are marked by *sensitivity to changes* in risks as these may flow from new operations, processes and technologies and which need to be responded if confidence in the regulator is to be sustained. We expand on each of these in turn in the context of regulating low risks.

Key elements of a ‘really responsive’ framework

The suitability of different tools

In choosing different strategies and tools for use with respect to lower risks, attention should be paid to two central issues: the potential of particular intervention mechanisms and the ways in which different tools will interact. On the first matter, it has been seen above that some strategies relate to the discharge of detection and monitoring functions and others are concerned with impacting on the behavior of regulatees more directly through enforcement and related actions. The different tools, as seen, have divergent strengths and weaknesses when judged according to the factors considered above (targeting, costs and efficiency; transparency, justification and representative values; and dynamic efficiency) and it is necessary to link these different capacities to the particular risk and regulatory sector.

In general terms, regulators should develop mixes of strategies that are suitable for discharging the main tasks of regulation (notably of detection, enforcement, performance assessment and strategic adjustment) (Baldwin & Black 2008). In particular, in relation to low risks, they should also be aware of the potential of the variety of non-routine inspection strategies discussed in Part 3 and should weigh up their respective strengths and weaknesses. Regulators should also strive to minimize the costs of their detection work and, to this end, they should consider using the different proxy strategies reviewed above. They should, in addition, consider using generic (across the board) responses (e.g. screening and rule-based

strategies or engagement strategies) where this would be more cost-effective than enforcing against particular sites. They should, moreover, be able to identify common (or ‘cumulative’) risks that are best regulated generically and, if they are applying a general strategy across risks, they should be aware of the special challenges that are presented by low-risk sites. Finally, they should consider how intensively to apply their chosen tools.³

As for interactions of regulatory tools, challenges arise because different such tools often have divergent logics – they embody different regulator to regulatee relationships and they assume different ways of interacting. It is, accordingly, essential for a low-risk regulator to consider how numbers of tools are mixed, when there will be compatibilities of tool use and when there will be tensions or underminings (For similar reviews of compatibilities in intervention methods see Gunningham & Grabosky 1998; Gunningham 2007). Of the tools discussed above, for instance, it can be foreseen that exemptions without registration are difficult to use in combination with systems of self-monitoring and self-certification by regulated firms. Similarly, stakeholder dialogues cannot easily be combined with the use of third party surveillance and monitoring processes. In contrast, there may be no reason why whistle-blowing strategies cannot be combined with licensing and permitting systems or why themed inspections cannot be used alongside requirements of mandatory performance disclosure by firms. The search for the optimal mix of strategy will, moreover, have to be conducted with the particular type of low risk site or activity in mind.

Cultures

Many of the intervention tools described above will work best when applied to certain kinds of regulated concern. Some will tend to work especially badly when the regulatee’s attitude is inappropriate. Thus, the use of General Binding Rules to non-notifiable activities is liable to produce problems with organizations that are ill informed about their legal requirements and ill disposed to secure information on their obligations. Reduced frequency inspections will tend to be problematic when regulatees are ill disposed to voluntary compliance and liable to game the system. Themed, or *ad hoc*, investigations may, however, have considerable potential where there are particularly difficult regulatees who are engaged in an activity. Visits to assist with compliance will work reasonably effectively with well-intentioned regulatees (as will rules requiring performance disclosures by firms) but may prove to be a waste of resource with ‘amoral calculators’ who will not be inclined towards voluntary compliance (Kagan & Scholz 1984). In some areas of industry (as where risks are numerous and complex) it may be more necessary than in others to consider regulatees’ cultures and, in such instances, behaviour-targetted inspections will prove especially useful.

Organizational settings

In using its regulatory toolkit to control low risks, it is important for the regulator to be aware of the risk tolerance that it embraces and of the political risks that it is running. The regulator should consider such matters as the probability that a given tool will not detect or influence certain conduct and how it can cope with criticism when a harm occurs or its inactions are exposed. Matters to be taken in here include special ministerial, media, parliamentary or public sensitivities concerning particular risks and any inter-institutional factors that should be taken on board. The special propensity of some tools to expose the regulator to such

institutional and political risks will accordingly be a matter to be adverted to in using these. The use of General Binding Rules without notification, for instance, means that there are high risks that some undesirable activities will escape attention and this may be particularly embarrassing for the regulator in some sectors or in relation to some activities. Another potentially difficult tool is the third party inspection system - which may present particular problems of accountability, for example.

Resourcing issues also have to be taken on board in looking at the regulator's organizational position. The resource available for controlling low risks will generally be restricted by general budgetary constraints and by the regulator's balancing of higher and lower risk priorities. These budgetary limitations should be considered in selecting intervention tools and strategies. Some mechanisms may be especially useful when resources are very thin (e.g. reactive, complaints-driven and whistle-blowing systems) others may only become live options when higher levels of resource are available (e.g. licensing and registration mechanisms).

Assessment

The testing of performance is, as noted, vital if approaches to low risks are to be evaluated, adjusted or justified. Different intervention approaches, however, vary in their conduciveness to such testing (as do different mixes of these). Themed inspections, for instance, tend to be useful for measuring both compliance levels and regulatory performance in a specified area but exemptions without registration can be expected to be far less conducive to testing and assessment. As for other indicators of performance, quite different challenges are posed by such devices as: mandatory disclosure requirements, third party monitoring systems, complaints-driven mechanisms and procedures for measuring indirect or proxy outcomes. Thus, measuring a proxy outcome, such as water quality, can, in some circumstances offer a very useful guide to the performance of the regulatory system whereas regimes of mandatory disclosure can constitute highly dubious assessment procedures where the regulated concerns are ill disposed to compliance or lack the capacity to comply. Reactive / complaint-driven mechanisms are useful for visible effects of non-compliance (eg where the water has turned purple), but are largely useless for diffuse pollution, which by its nature is difficult to detect.

Sensitivity to changes

It is important that low-risk regulators can both detect shifts in challenges or risks and that they have the capacity and commitment to respond to such changes by adapting and developing their approaches to low-risk sites or activities. The various intervention strategies and tools that were discussed in Part 3 do, however, vary in the extent to which they can foster responsiveness. Some tend to be attuned to static risks (notably exemptions without registration and General Binding Rules covering non-notifiable activities) but others will provide much stronger responsiveness to changes (notably reactive investigations, random inspections, and measures of proxy outcomes). In circumstances where regulators are not fully confident that risks and political expectations are fixed, a best practice approach would demand that they use a mix of intervention methods that allows them to cope with the shifts described.

Regulating Low Risk Sites - A Proposed Framework

Our argument is that, in developing and deploying strategies for dealing with low-risks, regulators should be responsive to these five key factors. We suggest, furthermore, that there are strong arguments, noted above, for basing a regulatory strategy not just on the nature of the risks of the activities, but on the attitude of the firm and the likelihood of compliance, either by particular operators or across a particular sector or activity as a whole. How, though, is a regulator to determine which strategies to use in which circumstances, and what level of regulatory resources to apply in using them? A ‘best practice’ framework cannot neatly reconcile public expectations of universal protection with the regulatory reality of prioritization and rationing. It can, however, help regulators to identify those intervention tools that are likely to have the most potential in relation to different risks and contexts. Such a framework can also provide a rational and defensible basis for decisions and can be referred to when strategic choices are subjected to public and political challenge.

The framework we propose has at its core a matrix which we call the GRID – the Good Regulatory Intervention Design. The aim of the GRID is to provide a framework for deciding systematically which strategies should be used for which types of risk and which type of regulatee. It operates on the basis that two key factors should guide decisions on the intervention tools to use.

The first is the nature of the risk. If an activity is inherently low-risk and liable to remain so during the period between strategic reviews, it can be dealt with by means of a strategy that might not be appropriate in the case of a net low-risk (i.e. an inherently higher risk that is reduced by good management) – especially a net low-risk that is not stable – because there is evidence that management may change between strategic reviews.

The second key factor is the nature of the regulatee. Some low-risk intervention strategies work well with well-motivated and high capacity⁴ firms (e.g. self-certification systems) but would not prove successful where firms are ill-motivated and have a low capacity to comply. Some low-risk intervention strategies work well with well-motivated firms who have a high capacity to comply (e.g. self-certification systems) but would not prove successful where firms are less motivated to comply, and have a low capacity to comply because of limitations in such matters as information about regulatory requirements, resources, systems and personnel (On capacity see Kagan & Scholz 1984; Baldwin 1990; Haines 2011a; Black 2003). On compliance motivations see Braithwaite et al. 2007). Moreover, the attitude and capacity of the regulatee is particularly critical for determining whether a higher risk can be in fact classified as a lower ‘net’ risk and for the intervention strategy that should be used.

The breakdown of regulatee types set out in Table 2 below involves a downward progression from those liable to demand low levels of intervention to those who need to be controlled by more robust methods. It is worth noting that the order in which they lie in the GRID was the subject of considerable discussion during the project; the rationale for having those with low capacity and lower motivation at the bottom of the GRID, and thus as requiring the more intensive intervention, is that even if the regulator manages to ‘turn’ them to be more motivated, there is still the difficult problem of capacity to address.

Table 1: Characterizing Regulatees

Type of Regulatee	Characteristics
<i>Well- motivated with high capacity to comply</i>	Regulatees are willing to comply (judged on their records and/or officers' estimations) and are sufficiently well informed, resourced, and organized to allow compliance.
<i>Well- motivated with low capacity to comply</i>	Regulatees are willing to comply but are not sufficiently well informed, resourced, and organized to foster compliance.
<i>Less motivated with high capacity to comply</i>	Regulatees are less willing to comply but they are sufficiently well informed, resourced and organized to allow compliance if their motivation is improved.
<i>Less motivated with low capacity to comply</i>	Regulatees are less willing to comply and are not sufficiently well informed, resourced and organized to foster compliance even if their motivation is improved.

In combining types of risk and types of regulatee, the GRID offers a framework for identifying potentially useful regulatory tools. The horizontal axis involves a progression in types of low-risk activity – from inherent and stable low risks that require the least intensive interventions on the left, to net low risks that are unstable and which call for more urgent attention on the right. The vertical axis involves a similar ‘progression of intensity’ from those who are well motivated with a higher capacity to comply at the top to those who are less well motivated with a lower capacity to comply at the base.⁵

The bare GRID matrix is thus:

Intensity of intervention increases according to risk type



Intensity of intervention increases according to regulatee type



Nature of the Regulatee	Nature of the low-risk site/activity				Regulatory Activity & Intensity
	<i>Inherent lower-risk – stable</i>	<i>Net lower-risk – stable</i>	<i>Inherent lower-risk – but may change or accumulate</i>	<i>Net lower-risk – but may change or accumulate</i>	
<i>Regulatees are well-motivated with high capacity to comply</i>					<i>Screening tools</i>
					<i>Monitoring tools</i>
					<i>Engagement & incentive mechanisms</i>
	Low	Low	Low	Low	<i>Regulatory intensity</i>
<i>Regulatees are well-motivated with low capacity to comply</i>					<i>Screening tools</i>
					<i>Monitoring tools</i>
					<i>Engagement & incentive mechanisms</i>
	Low	Low	Medium-Low	Medium-Low	<i>Regulatory intensity</i>
<i>Regulatees are less motivated with high capacity to comply</i>					<i>Screening tools</i>
					<i>Monitoring tools</i>
					<i>Engagement & incentives</i>
	Medium	Medium	Medium	High	<i>Regulatory intensity</i>
<i>Regulatees are less motivated with low capacity to comply</i>					<i>Screening tools</i>
					<i>Monitoring tools</i>
					<i>Engagement & incentive mechanisms</i>

	Medium	Medium	High	High	<i>Regulatory intensity</i>
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The right hand column of the GRID divides intervention tools into three types (in the ordering used in Section 2 and Table 2 above) and it also suggests a level of regulatory intensity that might be appropriate in the case of a particular combination of risk and regulatee type. Suggested regulatory intensity refers to the amount of regulatory resources to be applied to a site or activity and to the severity with which any sanctions are applied. Intensity is expressed relatively and is rated ‘high’, ‘medium’ ‘medium-low’ or ‘low’.

Accompanying the GRID (but not set out here) is an Intervention Guide: a list of the Table 2 tools or strategies and an indication of the time frame required for their development in order to aid planning. Each tool is assessed in the Guide against three criteria: its relative effectiveness in different situations and contexts; the manner and degree to which it could be rendered transparent and justifiable; and the degree to which it could be dynamic, or able to identify and / or respond to change. The Guide provides a short description of the intervention strategy, some of the risks of using it and how these might be addressed. It also indicates which other strategies any particular strategy is likely to be compatible with, and which it is not (see SNIFFER 2011).

In some cases, notably for screening and rule-based strategies, the agency may not have any discretion as to the strategy that it is to adopt, as this is prescribed by legislation. In certain instances, however, the agency may be able to decide, for example, to exempt low risk sites completely without the need for registration. With respect to monitoring and proxy, and engagement and incentive strategies, however, the agency is likely to have greater ability to exercise a choice regarding the strategies that it will adopt. The Intervention Guide does not include formal enforcement tools, though some of the strategies included may also be used as informal enforcement tools, for example advice and assistance. It would, therefore, be important in implementing the Framework to ensure consistency between the agencies’ enforcement guides and the intervention strategies selected using the GRID, particularly where the same strategies are covered by both.

In order to use the GRID, however, regulators have to be able to characterize risk-types and regulatee-types accurately. Here regulators face a trade-off between accuracy and resources: given that these risks are already categorised as being at the lower end of the regulators’ risk spectrum, the amount of resources spent in analysing which ‘box’ each site or activity should be put has to be less than would be the case if a similar framework was used for high risks. For low risks, we suggest that agencies apply a sector-based approach, but they could give discretion to regional managers or field officers to deviate from the ‘default’ categorisation (subject to justification). Such managers or officers might also be given the tasks of setting ‘review periods’ - the frequencies with which they plan to conduct reviews of strategies for dealing with risks and their categorisations in the particular targeted area. Agencies and relevant staff will then be positioned to think methodically about the intervention tools that they will use in the coming period and to ‘populate’ the GRID’s boxes

with the tools that are considered to have potential in relation to different combinations of risk and regulatee type.

An example can help to illustrate the process. The regulation of septic tanks has proved a particularly difficult issue for a number of the regulators. Septic tanks are used for small scale, on-site sewage treatment for domestic waste water for households not connected to the main sewer system. Most consist principally of a collection tank and an underground disposal field or percolation area. They are high in number (over 350,000 in each of England & Wales and over 300,000 Eire, for example), but most users are domestic households or small organisations such as hotels, residential care homes, or schools. Many are sited in areas of natural beauty and near watercourses (eg in the English Lake District). Domestic wastewater contains many substances that are potentially harmful to human health and the environment and in recent years there has been an increase in the contamination of groundwater, lakes, rivers and streams as a result of lack of understanding of the treatment and disposal processes required for small scale domestic wastewater, which has led to poor design, siting and installation of septic tanks (EPA 2007). At present, permits are required for those over a prescribed waste limit.

How should regulators manage the risks that they pose? Using the GRID, regulators would first characterise the regulatees and the risks on a sector basis. In a workshop run as part of the research project this example was employed as a GRID case study and regulators concluded that most regulatees could be characterised as having low motivation (out of sight, out of mind) with low capacity to comply (small scale users with no relevant expertise). The risk could be characterised as a net low risk which may change or accumulate. Regulators then considered which strategy to use from each set of strategies. (In this case, the screening / rule-based strategy was mandated by the legislature, but it was noted that using the GRID provided an opportunity for agency strategists to identify any strategic deficiencies and a basis for raising these with the relevant government / EU officials.) Each of the monitoring strategies was considered in turn. Some were quickly discarded: routine monitoring was too resource intensive: there are simply too many individual sites to be inspected on a regular basis. Themed monitoring which focused on an activity or control system was not appropriate for a simple activity such as this, though it could be used on a geographical basis as a follow up to findings from proxy strategies such as water sampling. Some low frequency random monitoring could be done, but again it might be more fruitful to use proxy strategies such as water sampling first to decide where closer investigation is needed. Self monitoring and certification could be adopted; this might help to raise

awareness and improve motivation. Such a strategy could be combined with information campaigns, information sharing with local authorities (who give licences for abstraction of drinking water), and working with interested parties such as parish councils or other local community groups to raise awareness, and with industry to improve the design and installation of the septic tank systems.

The GRID, as applied to the case study, might be summarized as below and would suggest that certain intervention tools merit special consideration by strategists. (The tools are numbered as in Table 2 above). Note that although the regulatory intensity is marked as 'high', it should be remembered that this means 'high relative to other low risks'.

Applying GRID – Septic tank case study

Nature of the Regulatee	Nature of the low-risk site/activity	Regulatory Activity & Intensity
	<i>Net low-risk – but may change or accumulate</i>	
<i>Regulatees are less motivated with low capacity to comply</i>	Permitting regime now required by law where prescribed waste limit exceeded	<i>Screening tools</i>
	8. Low frequency random monitoring 13. Proxy strategies (water sampling) 14. Self monitoring and certification 17. Information and inspection sharing	<i>Monitoring tools</i>
	18. Information campaigns 19. Dialogues with interested parties 20. Industry led (design / installation) solutions 21. Multi-agency approaches	<i>Engagement & incentive mechanisms</i>
	High	<i>Regulatory intensity</i>

The case study supported the view that GRID can provide a systematic framework for considering which strategies are most appropriate for different types of risk and regulatees. But, as noted above, it is important that regulators should also be able to assess their performance in an ongoing manner and to modify their approaches where necessary. We therefore developed a Good Regulatory Assessment Framework (GRAF) to provide a step by step process for enabling ‘double loop learning’ (Argyris & Schon 1978).

GRAF operates on the basis of the same logical framework as the GRID. It asks regulators a series of questions that are designed to evaluate whether the GRID has been used appropriately in their agencies (the full GRAF is set out in SNIFFER 2011). Those completing the GRAF are thus asked to score, on a points scale, their agency’s performance on such matters as characterising accurately the types of low risks and regulatees involved in a given low-risk area; in considering the strengths and weaknesses of the different intervention tools; in surveying the complete array of intervention options; in allowing tools to be used with appropriate intensity; and in assessing and modifying (where appropriate) their agency’s overall performance regarding low-risk sites/activities.

The GRAF's scoring system is designed to allow managers quickly to pinpoint their areas of strength and weaknesses in selecting strategies for dealing with low-risk sites and activities. It also asks regulators to consider reasons for poor performance, and offers strategic managers the chance to identify possible improvements and to link reforms to feedback from field level officers.

The GRAF requires quite subjective assessments: as such it is prey to abuse in a number of ways, for example routinisation, mechanistic decision making, gaming by those completing the assessment so that scores are just below the required thresholds for action, or simply ignoring it altogether. We consider these challenges further in the next section. It should be recognised, however, that any framework is prey to the same key vulnerability: it is not self-executing, rather its success depends on the willingness and ability of those using it to engage fully with the process.

Challenging the Framework – will it work?

As outlined above, the regulators of low risks face a number of challenges. They have to be clear about the risks they are prepared to tolerate if they are to secure desired outcomes and to preserve public confidence in their regimes. They have to evaluate low-risks with modest levels of resources. They have to deal with low-risks in a consistent manner and have to be able not only to assess their performance in relation to low-risks but to be prepared and able to justify this performance. In addition, they must be capable of responding to changes in the nature of risks without investing a disproportionate amount of resources on monitoring and analysis.

The task of the project was to develop a framework for regulating low-risk sites that could be adopted by all four of the environmental agencies. One of the challenges in developing such a framework is that it has to be applicable to a wide range of different sectors and activities, and to the very different task environments of each of the agencies. It, furthermore, has to link to four very different sets of existing practices regarding risk analysis, risk scoring and enforcement.

We therefore designed the GRID with the aim of creating a flexible decision-making tool which could be the operational 'middle ground' between risk analysis and formal enforcement action. The broad implication of the GRID, nevertheless, is that, as risk-types move east on the GRID and firm-types move south, it is likely to be appropriate to apply enforcement strategies with increasing regulatory intensity. The agencies' risk analysis processes provide the categorizations of the risk level of a site or activity, but do not provide a plan for intervention. The agencies' enforcement guides provide guidance on when to use formal as opposed to informal enforcement actions, but do not provide a guide on what broader intervention strategies may be used as part of the regulatory process. Both the risk assessment frameworks and the enforcement guides emphasize risk and behavioural characteristics in their analytical frameworks, though with more weight given to risk characteristics than behaviour in the former and slightly more weight given to behavioural characteristics in the latter. In providing for a wide range of intervention strategies, and a matrix which combines risk and behavioural characteristics, the Framework is designed to

incorporate these two sets of driving factors in a way which enables regulators to develop strategies within a framework of 'structured flexibility'.

Will such a framework prove to be operable, dynamic, transparent and justifiable? The results of the Project's third phase of research suggested that the GRID/GRAF system offered considerable potential if used astutely by regulators.⁶ The view from the regulatory practitioners was that, in integrating the two elements of risk and behavior, and in providing a broad range of intervention tools that could be used with respect to those in each category, the GRID provided an innovative matrix and a framework for structuring decision making about strategies for low-risk sites. It also allowed the regulators the flexibility to customize the GRID to reflect the particular expectations, costs and challenges encountered in specific sectors.

The GRID/GRAF system, it was concluded, offered greatest potential as a strategic planning tool, primarily at the sector level. Agencies could identify which sets of strategies were to be used in particular sectors, and then allow field officers to adjust strategic choices to some degree. The GRID, for example, could be used to design a sector intervention plan with concise guidance and a summary of main options for field officers to implement at the sub-sector level. Most interviewees thought that GRID could be used as part of an annual planning cycle, or a 2-3 year planning cycle over time, or as part of a periodic strategic review. They suggested, moreover, that although the GRID/GRAF framework was designed with low risks in mind, it could be adapted to be used across a range of risks and at a number of different levels of decision making.

A further conclusion was that agencies should populate the GRID themselves, rather than work to a set of strategies prescribed by others. It was agreed that it would not be feasible or useful to provide a 'master GRID' that which was populated with different strategies for each box, as it would not be applicable in all contexts and sectors. There were two main reasons for this view. Intervention tools vary in character according to their context – a surveillance intervention in the chemicals industry (or a sub-sector thereof) might operate quite differently from one in farming. Further, the resource implications of using tools may also vary dramatically from context to context. In some sectors there may be sets of existing arrangements (e.g. reporting systems, existing third party monitors or cooperation with other regulators) that would render the marginal costs of using these tools with respect to a particular type of risk quite small, whereas in another area these mechanisms might have to be established anew, making the strategy more costly and requiring a longer planning time.

Similar reasoning led to the widely supported conclusion that a single strategy for low risk sites would not be advisable.⁷ The range of sites, sectors, agency practices and the task environments of the agencies is such that a 'single strategy' approach would be unlikely to be suitable to all circumstances. Instead, the combination of the 'structured flexibility' of the GRID and accompanying Intervention Guide was preferred.

The key question, however, is whether the GRID/GRAF approach would work. One risk in using the GRID is that too many types of intervention tools will be suggested for a given combination of risk and regulatee type. A response to this challenge would be for each agency to consider develop a resourcing index tool to accompany the GRID. The GRID tool list might, thus, be coded by agencies to indicate whether tools are high, medium or low cost and a way to manage the allocation of resources would be to give regional managers a budget

so that this can be used as a basis for determining which strategies to use within the given constraints, and using the resourcing index as a guide.

A further risk of the GRID is that its use would prove too costly and too complex, particularly for low risk sites or activities. In response, it can be argued that the combination of behavioral and risk characteristics in the GRID framework provides a structured approach that will help agencies to target their resources and intervention strategies appropriately. As noted above, there is a tension, however, between accuracy in mapping the regulated sites or activities onto the GRID, and the resources that are needed to do so. In the logic of a risk-based framework, the amount of resources put into analyzing behavior has to be proportionate to the risks. For lower risks the mapping would, therefore, have to be 'broad brush' in nature and, for example, conducted on the basis of particular sectors rather than individual sites.⁸

One way of refining the broad-brush approach to categorization would be to allow sector-level categorizations to be fine-tuned by field level officers if necessary. Field officers could be allocated a prescribed set of tools but could be authorized to escalate their interventions if risks are not controlled acceptably - though they would have to justify this decision. GRID could also be the basis for useful discussions between field level officers and those in policy making roles within agencies regarding the types of intervention strategies that could best be adopted in different circumstances. This would address one of the findings discussed above: that those in different positions within the agencies have a very different view of its activities.⁹

Is there a danger that, in enabling such a flexible approach, the GRID/GRAF framework could lead to inconsistent and non-transparent decision making? On this point it can be argued that the framework offers regulators a means of fostering a consistent approach to regulating low risk sites or activities across the agency. As other organizations have found, peer panels can have a role in this respect when strategies are just being introduced - they are a way for the agency to develop a common language about risk, and to facilitate learning. The framework could also provide a good audit trail for decision making internally, and brings potential improvements in the transparency of decision-making. It also allows agencies to explain their regulatory strategies more fully to those being regulated and to other interested parties. It could be published on the agencies' websites, for instance, and it could form part of a 'decision letter' or an open decision and decision communication tool.

Will the GRID/GRAF system produce excessively complex sets of decision frameworks, with one for lower risks and another for higher risks? This is a possibility, but the initial findings of the research described here suggests, however, that, although it was designed with lower risks in mind, GRID/GRAF offers potential as a strategic planning tool at all levels of risks. Agencies suggested that it could be extended beyond low risk sites into higher risks areas and applied as appropriate at the sector, sub-sector, or site level for all categories of risk. It could also be used at a pre-regulatory stage when discussing strategies with policy makers, or when discussing possible changes to existing legislation. In particular, the Framework could help to highlight the impacts of legislative decisions on regulators by making the regulators' intervention choices clearer to policy makers in government.

Furthermore, the assessment element of the framework, GRAF, could be challenged on the basis that it is too subjective and could fall prey to mechanical box-ticking. This is a

danger to be recognized, but much depends on how it is perceived and adopted within the agencies. Initial findings suggest that GRAF could provide a useful way to reflect on whether GRID had been used appropriately and that it could form part of a broader strategic review, at annual intervals or even longer. Agencies were positive about GRAF, and recognized that it was a framework for assessing the quality of consideration that was being given to different tools and strategies and their appropriateness in different cases. It was not a tool for evaluating the quality of front line regulation. A consensus was that it was important that GRAF was not a ‘tick box’ exercise. It would not have to be performed frequently but could be undertaken as part of a strategic review within the agency. GRAF could also be part of a cross-sector peer review or cross-agency peer review process to help establish a consistent view of risk within and across sectors and develop consistent strategy. In particular, peer panels could play a valuable role in developing a consistency of approach.

The optimistic view is that agencies will use the GRID/GRAF framework to foster a wide-ranging conversation within the Agency regarding the strategies to be used with respect to different sectors – a conversation that will be fed into the decision and policy making processes that relate to lower risks. These conversations could occur within the agency both horizontally between sectors / regions and vertically, between officials at different levels within the organisation. Agencies could also consider introducing peer panels for both GRID and GRAF, as noted above, particularly in the early stages, to facilitate the development of a consistent approach to assessing risks across and within sectors and / or regions. In implementing GRID/GRAF, consideration could be given to developing a system which would facilitate the use of the GRID – for example by containing links to the specific tools, resourcing index, and any ‘best practice’ comments that accumulate across the agency over time.

GRID and GRAF could also be used as a basis for structuring conversations between agencies themselves, for example using inter-agency peer panels to work through case studies using GRID, or using GRAF as part of an intra- or inter-agency peer review process.¹⁰ They could also be used to structure discussions both with policy officials in government or the Commission, and with regulated operators and other interested parties regarding the strategies that regulators should adopt to manage low risks. By making the options clearer and the decisions more transparent, agencies could improve both their decision processes and what could be termed their ‘dynamic accountability’ - their engagement of a wider range of actors in decision-making. Using GRID/GRAF would also allow them to justify their chosen approaches more systematically than is currently possible within the normal ex post accountability processes to which they are subject.

Conclusions: Reframing Risk-Based Regulation

Risk-based regulation seeks to calculate the risks attached to certain behaviours, structures or states of the world so that resources can be allocated accordingly. Although it is sold as a rationalistic and technocratic solution to a host of complex technical, social and political problems, in practice it is no such thing. It can systemise decision making and render what is tacit explicit, but what it cannot in itself do, is provide a plan for what agencies should do. It does not determine how to construct discrete ‘risks’ or suggest how risk

creators are to be dealt with in order to increase compliance or the furthering of statutory objectives. Nor does it indicate the right balance between attention to lower and higher risks, or short and long term gains; or guide regulators on managing the political and institutional consequences of their intervention decisions. These are all matters of judgement which regulators have to make along the way.

The Framework proposed here is principally proposed as one aspect of a risk-based governance framework. As such, it runs with the grain of risk-based regulation strategies rather than call them fundamentally into question. The research process has, however, highlighted some of the complexities and tensions inherent in such strategies, and prompts some wider reflections on the project of risk-based regulation itself.

First, it is clear that how the risk is constructed and labelled by an agency is a highly complex process, in which, moreover, the scope for miscommunication is ripe. What is 'low risk' in an agency's risk-based framework, it should be remembered, is in fact code for what is 'low priority'. Criticising agency's characterisations of what constitutes a 'low risk' as technically unsound, or criticising as unsound the related assumption that low risks require low resources to be managed effectively, in effect misses the point and fails to understand the role that such risk categorisations play in an agency's operational framework. It fails, moreover, to recognise the reflexive relationship between the role that the risk categorisations play in an organisation's operations, and how risks are in fact constructed and assessed. It is commonplace in risk regulation to note the significance of how risks are configured and bundled for how they are managed, but the detailed intra-organisational research done for this project highlights the additional role of factors such as funding structures, legal mandates, and internal organisational politics in that risk construction and categorisation process. A perennially attractive assumption is that risks should be categorised before resource decisions are made, but, in practice, the two processes operate in tandem, with tensions surrounding decisions on how to organise risks (by site or activity) and whether to target biggest risks or those where there are the greatest possibilities for risk reduction at the lowest cost.

Second, although risk based regulation frameworks tend to impose unified sets of assessments which apply across risks in the regulator's remit, there is an argument for seeing low and high risk regulation as enterprises that differ in some important respects, rather than as the same game played with different stakes. It is true that, in some regards, low-risk regulation resembles higher risk regulation. Thus, in relation to all levels of risk, the regulators will have to be clear about their objectives and will have to come to grips with such familiar challenges as those of identifying and evaluating risks, of establishing priorities, dealing with potentially systemic issues, coping with change and evaluating and modifying performance. The above discussion, nevertheless, reveals that the conceptual, practical and political challenges of low-risk regulation are, at least in some significant ways, quite distinct from those that arise with respect to higher risks.

Third, these variations of challenge stem in no small way from a central difference between the processes of controlling lower and higher risks. High risk targeting is a 'mainstream' activity – this is what risk-based regulation is supposed to be about. Low risk regulation, in contrast, can be viewed as something close to an aberration: an activity that needs to be specially justified. It has, moreover, to be justified without devoting significant analytical resources to this task – since, by definition, the risks at issue do not merit the

application of material levels of resource. The product of these two factors is that the processes of justifying low-risk regulation can take on a different character from those encountered with higher risks. Most notably, the balance between different forms of justificatory argument can differ. Risk targeting appears to place considerable weight on rational-technical reasoning. Priorities are established with reference to the risk-scoring regime that underpins and drives the system. With low risks, however, the logical consequences of the risk scoring rationale are less acceptable to a public which expects to receive universal standard of protection of all risks, and may not accept that their particular concerns are not as a high a priority for the agency as they are for them. The game of justification and legitimation therefore changes in character. Rather than being rationalistic, it has to become more of an exercise in managing expectations and creating assurance – most notably that low levels of regulatory intervention are not allowing excessive risks to be run or to develop. The balance favors political deliberations rather than technical ones - and this point applies to the agency's internal as well as its external politics. This finding is in contrast to other risk governance frameworks which suggest that such dialogic processes should be reserved for complex and uncertain risks (eg IRGC 2005). The research here has emphasised that it is necessary even for simpler risks. The particular challenges of playing the low-risk, as opposed to the high-risk game mean that, in the former, it may be equally, if not more, appropriate to pay attention to the more political aspects of strategic choices.

Finally, the nature of the challenges of justifying regulation can change across levels of risks. As argued, it may be that the balance between rational-technical and political deliberations is quite different in higher and lower risk regulation, and in ways which are not commonly assumed. Regulatory conversations, as a result, may display different characteristics across risk levels. It follows that, since most regulators will have to control risks of many different kinds and severities, they will have to justify their actions, not by engaging in a single rationalistic conversation or game with respect to all their activities, but by playing a cluster of games that are contentious, dynamic and which impact on each other in often unpredictable ways, but which ultimately have to be funded from the same pool of resources.

Thus, although the exercise engaged in during this research project was a technical, prescriptive one, an awareness of the particular issues that arise in the regulation of low risks compels us to reassess attitudes to risk-based regulation more broadly. It does so, not least, by emphasizing that risk-based regulation cannot be viewed in any way as a mechanical and uncontentious approach that targets the highest risks and allocates priorities accordingly. Decisions regarding the balance of priorities between higher and lower risks are both contentious and shaped by particular conceptualizations of risk. The bad news, for those who are attracted to modes of numerical quantification, is that these matters are largely insusceptible of such determination and require the exercise of managerial and political judgments, and are shaped by considerations that range well beyond the technocratic.

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¹ The HMRC's Compliance Continuum seeks to capture the behavioral characteristics of all traders, from the compliant to the fraudulent, and to categorize each trader into one of seven categories: deliberate evader, avoider, chancer, failure, new business, trier and compliant. Each firm is assigned to a category, and that categorization in turn is used to order the HMRC's inspection and enforcement policy (Black 2008; HMRC 2009). The Australian Tax Office has adopted a similar approach. It commissioned research to find out why people did and did not pay tax. Based on this analysis, it then adjusted its practices for communicating with tax payers and its intervention strategies to fit the 'motivational posture' or attitude of the different groups of tax payers (Braithwaite et al. 2007; Leviner 2008).

² A critical issue, however, is whether regulators should expend resources on those operators that are likely to be most responsive to their attentions (the 'easy wins') or on those most likely not to comply (the 'hard cases'). A focus on easy wins can mean that the more intractable operators are effectively unregulated and those who are inclined to comply may perceive the strategy to be unfair if they are targeted more than the most recalcitrant and irresponsible.

³ The intensity issue concerns the levels of resources put into enforcement, the severity of the sanctions pursued and the enforcement strategies favored – be these escalatory, behavior-targeted, risk-based or other systems.

⁴ 'High capacity' to comply is used as shorthand and refers to a business that is well informed, well resourced, and well organized to foster compliance. For a similar definition see Renn 2005.

⁵ The ranking of both of risk and regulatee types was a matter of some debate in the course of the project. It was concluded that those who were less motivated and had a low capacity to comply required regulating at a greater intensity than those who were less motivated but possessed a higher capacity to comply. The reason was that, with respect to those who had an existing capacity to comply, the agencies' main challenge was to make them motivated, whereas those with a lower motivation combined with a lower capacity required the agency to address both motivation and capacity (for example through technical capacity building) and that this would demand more resources. Reversing the bottom two categories may be appropriate in different sectors, e.g. where there is a high potential for 'gaming' the rules.

⁶ This stage of the research consisted of qualitative interviews with senior officials from the four environmental regulators, regulatees, government officials and NGOs in England & Wales, Northern Ireland, Scotland and Eire. Main issues explored were concerns were

whether the framework was too complex, too resource intensive, whether it could be adapted to fit the very different operational systems and environmental contexts of the different regulators, and whether (as we hoped) it could extend beyond low risks to be used across all the agencies' activities.

⁷ Some US agencies have adopted a particular strategy for all low risk sites (e.g. the ERP).

⁸ Categorizations, moreover, would have to be reviewed as regulatees can move between boxes. Indeed, it may be that changes in strategy (such as reductions in inspections) may cause such movements. These shifts pose resourcing challenges of their own.

⁹ It was also noted by the agencies that policy level determination of the strategies that should be used, and of the appropriate regulatory intensity to be adopted, could give protection to field officers if they were to be criticized for changes in regulatory action and priority.

¹⁰ The Agencies involved could, for example, extend GRID/GRAF beyond the SNIFFER agencies to include those active in IMPEL or other networks.

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