When risk-based regulation aims low: Approaches and challenges

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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 regulators or activities tend to form the bulk of the regulated population. This article asks why regulators need to address low risks and it outlines the potential difficulties that such risks present. It then considers how regulators tend to deal with lower risks in practice. A body of literature and survey-based research is used to develop a taxonomy of intervention strategies that may be useful in relation to low-risk activities, and, indeed, more widely. In an article to be published in the subsequent issue of this journal, we will then develop a strategic framework for regulators to employ when choosing intervention strategies and we will assesses whether, and how, such a framework could be used by regulatory agencies in a manner that is operable, dynamic, transparent, and justifiable.

Keywords: risk, regulation, risk-based regulation, environmental regulation

1. Introduction

In a striking wave of regulatory homogenization, risk-based regulation is becoming widespread across the globe and in areas as diverse as environment, finance, food, and legal services (Black 2005a,b, 2006; Hampton Report 2005; Hutter 2005; Rothstein et al. 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, 2008; Black & Baldwin 2010). In such an approach, the tendency is for regulators’ gaze to be drawn to their highest risks and for regulators to be encouraged to pull back resources from lower risks. The bulk of regulated sites and operations, however, tend to present lower levels of risk and 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 hold 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 a second, “companion,” article (in the next issue of this journal) seeks to develop a strategic framework for regulators to use in determining how to regulate lower risk sites or activities (Black & Baldwin 2012). 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. The companion article 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 categorization, 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. The companion article assesses whether, and how, such a framework could be used by regulatory agencies in a manner that is operable, dynamic, transparent, and justifiable, and argues that coming to grips with the challenges presented by low risks compels us to rethink our conceptions of risk-based regulation more generally.

2. The challenges of low risks

There are a number of challenges involved in developing and implementing systems to manage risks (e.g. Renn 1992; Hood et al. 2001; Sunstein 2002; IRGC 2005) and, more specifically, in developing and implementing the particular strategy of risk-based regulation (Black 2005a,b, 2006, 2008; Hutter 2005; Rothstein et al. 2006; Hutter & Lloyd-Bostock 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 prioritize 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 distinguish between lower and higher categories of 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.

2.1. Distinguishing lower from higher risks

How risks are selected, framed, and categorized for attention is a complex process, involving a mosaic of technical, psychological, cultural, social, political, organizational, and economic concerns (e.g. German Advisory Council on Global Change 2000; Black 2005a; IRGC 2005). The categorization decisions made in risk-based regulation are no exception. There is, however, no single and uncontroversial way to define and “rate” many risks – what is a “low risk” or a “high risk” is a matter of construction – and risk categorization is an art rather than a science, notwithstanding the prevalence of quantitative risk models in much risk regulation. 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 such factors as differences in the overall risk profile of the regulated population.

A key use of risk categorizations is to determine, or at least facilitate, resource management and, whatever type of characterization is used, risk-based regulators need to prioritize the different risks that they have to manage (Black 2005a). “Low risk” means, in practice, “low priority” – it is not so much a characterization of the risk itself as a statement of a risk’s relative significance to the regulatory organization and, usually, its potential to attain its objectives or mandate.

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, and 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 other activities such as 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. Nor is our principal concern here to consider why regulators categorize risks in the way they do. What is addressed in this article is the set of problems that many regulators face in dealing with the risks that they have placed in their lower-risk categorizations. 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.

2.2. Distinguishing between types of low risks

Risks are conventionally categorized on the basis of two dimensions: probability and impact, with impact often defined as an adverse event of different degrees of tolerability. 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 irremediable, concentrated or diffused); and the socio-political contestability of the risk (e.g. IRGC 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 irremediable or irreversible (Wildavsky 1988; Klinke & Renn 2002; Majone 2002; O’Riordan & Cameron 1994).

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 (e.g. 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 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 would be the case if 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 fertilizer 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. If risks from individual sites are the focus, the actions from any single small farm present a very low risk. If risks are categorized according to activity, however, 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 straightforward 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, accord-
ingly, 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 regu-
lation 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
categorizations 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 environ-
mental 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. The Scottish Environmental
Protection Agency (SEPA) has, however, 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 categorizations 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.

Table 1 below therefore develops a typology of low risk-based on these dimensions.

2.3. Going low – the challenges
The common political and functional justification for risk-based regulation is that regu-
lators should prioritize their resources by targeting them on those firms, sites, or activities
which pose the highest risks to their objectives (Sparrow 2000; Hampton Report 2005). If,
however, resources are moved to one area, such as higher risks, they are necessarily
withdrawn from somewhere else – a facet of risk-based regulation that chimes well with
the mantra of “burden reduction” but is frequently underplayed in the policy literature
(Hampton Report 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, 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, a regulator’s giving a risk a low priority may be contested by consumers, local residents, politicians, NGOs, and industry. The result may be that the regulator loses public and political support. An example in the environmental sector is noise and odours. Actions to limit noise and odours are not always legally demanded of the regulator, and they pose modest risks to the environment (though the latter may be useful as risk indicators in some circumstances). 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.

Thirdly, and related to the point above, risk-based regulation tends to expose a regulator’s risk tolerance to problematic public scrutiny. It is not easy to defend a strategy of reducing regulatory attention when things go wrong. When 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, and the frequencies of these, can have little effect on compliance levels (SNIFFER 2009; Ko et al. 2010).

Fourthly, reducing the resources devoted to lower risks is a managerial challenge as well as a political one. Reallocation of resources inevitably means that there will be winners

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**Table 1** Types of low risks

<table>
<thead>
<tr>
<th>Type of Low Risk</th>
<th>Description</th>
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<tr>
<td>Inherent low risk – stable</td>
<td>The activity is not capable of producing intolerable harms/impacts and operations are not likely to change in the periods between regulators’ strategy reviews.</td>
</tr>
<tr>
<td>Net low risk – stable</td>
<td>The activity is capable of producing intolerable harms/impacts in the periods between regulators’ strategy reviews but risks are reduced by good management.</td>
</tr>
<tr>
<td>Inherent low risk but may change or accumulate</td>
<td>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).</td>
</tr>
<tr>
<td>Net low risk but may change or accumulate</td>
<td>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.</td>
</tr>
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and losers within the organization and this may create problems. 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. 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 (Turner 2009; Haines 2011a) 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. 332–339).

3. Regulators’ responses to low risks

In (Black & Baldwin 2012) 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 to manage such risks.

In general terms, the environmental regulators in the UK and Ireland 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 survey was used to identify current practices and strategies relating to low-risk sites. Notwithstanding the low-risk categorizations, 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 (Grabosky & Braithwaite 1986; Hawkins 2003; Gunningham 2010; Haines 2011b). (Full details of the findings, including detailed breakdowns of the responses, can be found in SNIFFER 2011a.) Overall, the survey found that there were some regional differences in the strategies for regulating low risks. The Irish Environmental Protection Agency (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 SEPA had introduced a system of audits rather than inspections (these are discussed in more depth in the next
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 emphasized 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.

3.1. 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 toward 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 EPA, noted above, and to an extent the Environment Agency (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 cooperation, 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 Ireland. 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 overuse of resources.

3.2. 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 has 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 a public information campaign was cited as being greater at the Northern Ireland Environment Agency (NIEA) than at other regulators, whereas the EA and SEPA used financial/administrative incentives more 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. 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 2010). Additional considerations mentioned included the public/national interest, the cost–benefit analysis of the proposed remedies, the evidence available for demonstrating a breach, time frames 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.

3.3. 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.

3.4. 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.

3.5. 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 with respect to both the agency’s current performance and the need for change. 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.

4. Intervention strategies for low risks – a broader perspective

The empirical research gave some broad indications(8,9),(991,986) 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. 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. It should be noted that there is often some confusion in terminology in the way strategies are described – what are termed here “intervention” strategies are described by some agencies as “enforcement” strategies. We reserve the use of the term “enforcement” for formal processes and sanctions such as prosecution, notices, or fines.

4.1. 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, in 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 licenses for low risk activities, as tailored licenses should not be necessary, and changes to provisions are easier to communicate via rules than changes to license 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 license 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 obtain a license which has to be renewed annually. The legislative framework can, however, 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) (Scottish Environmental Protection Agency 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 (The European Union Network for the Implementation and Enforcement of Environmental Law 2009, p. 12).

4.2. Monitoring tools
The second group of strategies comprises mechanisms that are used to gain and verify information about a firm or sector’s compliance. Four main types are encountered: 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 that 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. 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 (MEI 2005; FSAI 2006; EPA 2007; NAO 2008c; FSA 2010).

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 initiative” (HSE 2008).
safety” approach and then its Fit 3 program (HSE 2011). A National Audit Office (NAO) report, produced late in the transition, found that using a “topic pack” to assess generic risks had led to under-responsiveness to firm-specific risks because inspectors had felt unable to use their discretion and judgment in response to observed problems (NAO 2008b).

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) (FSA 2006; EPA 2010). A publicity strategy can, moreover, make random inspections an effective deterrent.

Some regulators, for example, the 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 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 & Lazer 2003; Coglianese & Mendelson 2010). 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. Such processes allow regulators to operate at low cost by overseeing the regulatee’s work in controlling a risk rather than monitoring compliance directly. 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 (FSA 2006; EPA 2010).

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 assess 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 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 costs to themselves and businesses by avoiding duplications of effort. In Scotland, for example, the Environmental and Rural Services initiative brought together the regulatory activities of nine bodies working with rural land managers and stimulated the coordination and sharing of inspection activities (IMPEL 2009, p. 19). The Food Standards Agency also engages in joint inspections and data sharing with other regulators (NAO 2008a, p. 6). Such approaches have been applied in the Czech Republic, Greece, The Netherlands, Sweden, and Turkey as well as in 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 and this limits the use of third parties 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.

4.3. 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 to 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. A dynamic advantage may sometimes be gleaned in as 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. The EA has worked with the Odour Group, an industry group, to encourage them to develop technologies to reduce odours 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 process is costly in proportion to the risks posed but if inspections are reduced a valuable informative role diminishes. One approach is to use NGOs to advise and assist firms to develop an understanding of their regulatory requirements and to build their capacities to develop adequate management systems. For example, in Northern Ireland, the NIEA worked with an NGO to help small and medium enterprises (SMEs) develop Environmental Management System (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). Such campaign activity can play a key role “in reaching low-risk businesses that might not otherwise come into contact with the regulators” (NAO 2008a). In Australia, indeed, it has been argued that broad education campaigns can deliver higher compliance levels than under-resourced inspection regimes (PCA 2009, p. 133). The HSE is at the forefront of this approach in the UK. The HSE 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). The HSE has, accordingly, shifted from an approach based mainly on risk, which produces a huge number of firms with similar risk profiles, to one based on achievability: searching out the most effective type of intervention (other than inspection) that it can employ on a given type of firm. It has been working on a system of “segmenting” its regulated population and 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, those complying with the waste requirements received, until recently, 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 2005).

It should be noted that a move away from inspections is not always easy or legally endorsed. Thus, EU regulations lay down acceptable “official controls” for the purposes of auditing food inspection authorities and, until recently, these did not include offering education and advice (Regulation (EC) no. 882/2004).15 In the context of UK and Irish environmental regulation the system of linking charging regimes with inspections means that any reduction in inspection activity reduces agency resources. Charging
structures can thus tie agencies to traditional approaches – most notably to routine inspections.

4.4. Summary

In practice there are a wide range of intervention tools which can be 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 (e.g. WBGU 2000; IRGC 2005). The intervention tools that have the major potential for use with low-risk sites can be summarized as in Table 2.

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

Table 2 Potential tools for low-risk sites/activities

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<thead>
<tr>
<th>Screening and rule-based strategies (can in principle apply to all categories, dependent on legislation)</th>
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<tr>
<td>1. Exemptions without notification or registration</td>
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<td>2. Exemptions with notification or registration</td>
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<td>3. Registration plus conditions/rules; permit and licensing systems</td>
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<td>4. Application of general binding rules without notification/registration</td>
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<tr>
<th>Inspection/monitoring and proxy strategies</th>
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<td>5. Frequency-adjusted inspections or monitoring</td>
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<td>6. Regulatory audits</td>
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<td>7. Themed inspections or monitoring</td>
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<td>8. Random inspections or monitoring</td>
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<tr>
<td>9. Advice and assistance visits</td>
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<tr>
<td>10. Reactive investigations, responding to complaints, whistle-blowing or post-incident investigations</td>
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<td>11. Surveillance</td>
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<th>Proxy measures</th>
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<tr>
<td>12. Benchmarking or &quot;yardsticking&quot; strategies</td>
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<td>13. Measuring indirect/proxy outcomes</td>
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<th>Firm-based measures</th>
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<tr>
<td>14. Self-monitoring and self-certification by regulated firms</td>
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<td>15. Management-based strategies including mandatory performance disclosure by regulated firms</td>
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<th>Using third-party monitors</th>
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<td>16. Third-party monitoring</td>
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<td>17. Information and inspection-sharing regimes</td>
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<tr>
<th>Engagement and incentive strategies</th>
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<tr>
<td>18. Information campaigns, generic advice, and recommendations (including codes and guidance)</td>
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<tr>
<td>19. Dialogue with interested parties</td>
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<td>20. Industry or NGO/interested party-led solutions</td>
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<td>21. Multi-agency approaches</td>
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<td>22. Incentive strategies</td>
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and give advice on how to comply. Third-party monitoring can be combined with 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 example, 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 targeting and cost effectiveness; transparency and accountability; and dynamic 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 cost of 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.

5. 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 should be used to control a given risk. The companion paper (Black & Baldwin 2012), accordingly, considers different ways of devising a framework to guide such choices of intervention methods.

Acknowledgments

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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 main purposes of the project were to investigate how
regulators managed “lower” risks, and to develop a framework to help them to manage such risks more effectively and economically. 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. The selected 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). This was 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 four 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 (2009, 2011a, b).

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 between May and September 2010), on a web-based survey of 102 field-level officers in the four agencies (conducted between July and 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 and 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, for example, 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 (Renn 1992; RS 1992; Slovic 2000).

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, six 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 (2011a).

9 The large majority of field officers responded that they did not distinguish between low-risk and high-risk sites in their enforcement strategy. However, enforcement at low risk sites was frequently reactive, following a complaint.
A number of commentators have drawn attention to the “multiple selves” of regulated organizations and the gulf between management and field-level operators (Barrett & Fudge 1981; Baldwin 1990, pp. 332–333; Ayres & Braithwaite 1992; Braithwaite 2001).

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 SNIFTER (2011b).

This option was suggested in The European Union Network for the IMPEL (2008, p. 43). See also Black (2008).

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

The HSE has sought to reach agricultural workers by attending agricultural shows and farmers’ markets, and by targeting information at farmers’ wives. It even used a storyline in the BBC Radio 4 program, The Archers, to publicize the dangers of tractors. It has, similarly, targeted construction workers with radio and TV campaigns, celebrity endorsements, and shock campaigns. It has also cooperated with hire shops and builders merchants who have run equipment replacement schemes for builders.

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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