Risk and Regulatory Policy
Improving the Governance of Risk

Chapter 5

Management-based Regulation: Implications for Public Policy

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A common set of challenges faced by regulators is to achieve public risk management objectives at lower cost, often by giving greater flexibility to the private sector without sacrificing public health and welfare. In addition to improving existing regulation, challenges increasingly arise from new kinds of risks that seem to evade resolution through traditional forms of regulation. A potentially promising regulatory solution – management-based regulation – may help regulators better address both existing risks and new ones. The underlying concept is to deploy regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks. This flexibility also raises the question of whether this regulatory strategy can actually deliver value to society. Empirical evidence indicates that management-based regulations can lead firms to make risk-related behavioural changes and induce positive behavioural change within industry. The purpose of this chapter is to explain where management-based regulation fits within government's overall policy toolkit and examine the conditions under which management-based regulation is both a viable and superior policy strategy.

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Introduction

Regulators around the world face major challenges associated with risk management (OECD, 2006) and regulatory reform (OECD, 2005; OECD, 1997). One common set of challenges arises when trying to achieve public risk management objectives at lower cost, often by giving greater flexibility to the private sector without sacrificing public health and welfare. In addition to improving existing regulation, challenges increasingly arise from new kinds of risks that seem to evade resolution through traditional forms of regulation. The purpose of this chapter is to analyse a potentially promising regulatory solution – management-based regulation – that may help regulators better address both existing risks and new ones.

In different jurisdictions and across various policy areas, management-based regulation goes by other names, including process regulation, systems-based regulation, safety-case regulation, and enforced self-regulation. Whatever it is called, the underlying concept is to deploy regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks. Under management-based regulation, firms are not mandated to adopt specific risk protection technologies or practices, nor even necessarily to achieve specific limits on levels of risk or other measures of performance. Rather, firms are mandated to study their operations comprehensively and develop their own management strategies suited to the risks they identify in their operations.

Management-based regulation is increasingly used around the world to address risks as varied as environmental pollution, workplace hazards, food contamination, and terrorism (Coglianese and Lazer, 2003). Part of the attraction to management-based regulation is that it holds a number of potential advantages over traditional forms of regulation. By charging firms with responsibility for developing their own responses to public problems, management-based regulation takes advantage of firms' superior knowledge about the risks they generate and the potential methods of reducing those risks. As such, the means firms adopt in response to management-based mandates should presumably be less costly and more effective than means selected by a central government regulator. Firms may also be more likely under management-based regulation to innovate and seek out better solutions over time. Furthermore, since firms' managers make the key decisions in designing management systems, they may also be more likely to comply with their own rules and procedures than they would with ones imposed on them by government regulators.

On the other hand, the flexibility inherent in management-based regulation raises the question of whether this regulatory strategy can actually deliver value to society. Some might well worry that firms will easily game a management-based regulatory system, going through the motions of planning and filing required reports but not really doing anything to reduce underlying risks. Even if firms do reduce risks after a management-based regulation is adopted, perhaps they do so for reasons other than the imposition of management-based rules, such as to reduce costs or decrease liability risks.

After all, if a particular management-based regulation were to give firms complete flexibility to decide how to address the risks they create, then it presumably would have no independent affect whatsoever on firm behaviour.

Yet empirical evidence indicates that management-based regulations can lead firms to make risk-related behavioural changes (Bennear, 2007). This evidence, combined with the increasing use of management-based regulation, provides reason to consider management-based regulation as part of a larger "better regulation" strategy and as a potentially cost-effective approach to addressing risk regulatory problems. The purpose of this chapter is to explain what management-based regulation is, when to use it, how it should be implemented, and how it can achieve risk management goals. In the sections to follow, this chapter will explain where management-based regulation fits within government's overall policy toolkit and examine the conditions under which management-based regulation is both a viable and superior policy strategy. Reviewing the existing empirical evidence on the effects of management-based regulation, the chapter provides an account of why management-based regulation can succeed and merits consideration as a potential regulatory option when addressing risk problems. The chapter considers design characteristics that will likely affect management-based regulation's ultimate impact and addresses the challenges of estimating and assessing these impacts *ex ante* using benefit-cost analysis. Finally, the chapter concludes by discussing implications management-based regulation holds for the role of government as risk regulator.

5.1. Management-based regulation in the regulatory toolkit

Regulatory approaches vary greatly. Meeting the challenge to make regulation better requires, as a first step, understanding the differences among regulatory tools and then applying the appropriate mix of tools that will achieve the best results under the relevant circumstances. For many years, regulatory officials and analysts have faced varied but usually overlapping taxonomies of regulatory tools, which has sometimes clouded rather than advanced the clarity needed for regulatory analysis. For example, Richards (2000) summarises over a dozen different taxonomies of regulatory tools, each containing over about six or seven different labels used to describe discrete policy instruments in just one field of regulation. Although the array of instruments available to any decision maker may seem large, regulatory tools all share a common characteristic. By definition, all regulatory tools consist of a rule or rule-like statement having normative force and being backed up with some at least probable consequences. Despite this common characteristic, the myriad regulatory tools available to regulators vary in important ways along distinct dimensions. To understand how management-based regulation differs from other regulatory strategies, it helps to clarify the distinct aspects of regulatory tools and how they make up the regulatory toolkit.

Four dimensions of regulatory tools

Regulatory tools all share in common the following four major dimensions: regulator, target, command, and consequences. Each of these is briefly defined below in order to set the stage for understanding what makes management-based regulation distinctive.

- *Regulator.* The entity that creates the rule and dispenses the consequences is the regulator – typically a legislature or governmental agency. In principle, though, the regulator could also sometimes consist of a nongovernmental standard-setting body, non-profit organisation, industry trade association, or even business firms themselves – forms of what is commonly considered self-regulation (Sinclair, 1997).

- *Target*. The regulated entity is the individual or organisation to which the rule applies and upon whom or which the consequences can be imposed if the rule is not followed. However, the target – or frame of reference – of the regulation can be smaller or larger. For example, if an air pollution regulation prohibits industrial facilities from emitting pollution from any smokestack above a specified level, the target is the individual smokestack even though the facility (or its corporate parent) will suffer the consequences if the smokestack's levels exceed those in the regulation.
- *Command*. A rule directed at a target can specify means or ends. It can direct the target to engage in (or avoid) a specific action designed to advance the regulatory goal, such as a command to install ventilation systems or provide employees with protective equipment would aim to protect worker health and safety. It can direct the target to achieve (or avoid) a specified outcome related to the regulatory goal, such as a rule stating that workplaces shall not have levels of contaminants in the air exceeding a specified concentration level. A further elaboration on commands is provided in the next sub-section.
- *Consequences*. The normative force of a rule is reinforced with consequences. Negative consequences take the form of penalties such as fines or loss of a licence for a regulated entity's failure to comply with the rule. But consequences can also be positive, such as when subsidies, product approvals, regulatory exemptions, or other "rewards" are provided whenever the predicate conditions in a rule (or set of rules) are met.

Four types of regulatory commands

Of these four dimensions, the one central to management-based regulation is the *command*. This is because management-based regulation can be imposed by any type of regulator on any type of target, and it can be reinforced by a host of different kinds of consequences. What distinguishes management-based regulation from other types of regulation is the nature of what it obligates regulated entities to do.

As noted above, there are really only two basic types of commands available to regulators: means and ends. Means regulation mandates the use of technologies or behaviours; regulators tell targets to adopt a particular means, such as install a certain type of pollution control technology, maintain specified types of records, or ensure employees wash their hands or wear safety equipment, to give just a few examples. Alternatively, regulation can mandate the achievement or avoidance of ends; in other words, regulators direct targets to achieve or avoid certain outcomes, such as to keep concentrations of air pollutants below certain levels, ensure new drugs prove to be safe and effective, or avoid causing accidents (Coglianese *et al.*, 2003).

Both of these two types of commands can be distinguished along another dimension having to do with the scope of the command's focus: macro *versus* micro. In other words, both *means* and *ends* embedded in regulation can be either *specific* or *general*. As such, regulatory commands can be classified in four categories, as shown in Table 5.1. When regulation is focused at the micro-level, it requires either the adoption of specific means (such as with equipment standards) or the attainment of concrete outcomes that are proxies for the outcome of ultimate concern to the regulator (such as product testing standards). When regulation is focused at the macro-level, it requires either the adoption of very general means (such as to conduct planning or set up a management system), or the achievement (or avoidance) of the outcome of ultimate concern to the regulator (such as general duty clauses that direct employers to protect workers from harm but do not specify how to do so).

Table 5.1. **Typology of regulatory commands**

	Means	Ends
Macro	**Management-based** *Also sometimes referred to as:* Process or systems regulation; safety case regulation; risk-management requirements; enforced self-regulation; meta regulation. *Examples:* HAACP food safety regulations; workplace process safety; pollution prevention planning.	**Meta-performance** *Also sometimes referred to as:* *Ex post* liability; general duty clause. *Examples:* Tort liability for harm; compensatory and punitive damages for spills/accidents.
Micro	**Means-based** *Also sometimes referred to as:* Design standards; specification standards; technology-based regulation; command and control regulation. *Examples:* Safety equipment requirements; mandated use of pollution control devices.	**Performance-based** *Also sometimes referred to as:* Outcome-based regulation; market-based regulation (when non-uniform performance is permitted, such as with emissions trading). *Examples:* Effluent concentration standards; product testing protocols.

Management-based regulation, then, requires regulated entities to adopt only the most general type of means. Usually these means are defined in terms of internal planning and management practices that are to be aimed at achieving some improvement in achieving the social objectives underlying that regulation. Importantly, with a pure management-based regulation, the desired improvement in social objectives is not what the regulation mandates; if it did mandate achievement of the objective, that particular mandate would be either a performance-based or meta-performance standard. Instead, regulated firms subject to management-based regulation are expected to produce plans or adopt management systems that comply with criteria stated by the regulator, such as to identify hazards, develop a options for risk mitigation, establish procedures for monitoring and correcting problems, train employees in these procedures, and develop measures for evaluating and continuously improving the firm's management with respect to the stated social objective. Firms are sometimes expected to obtain approval or certification by government regulators or third-party auditors of their management practices and their compliance with their internally generated plans and procedures.

Examples of existing applications of management-based regulation

Regulators around the world have adopted management-based regulation in numerous regulatory settings. Often this regulation imposes on firms the obligation to "Plan-Do-Act-Check" with respect to addressing a public regulatory problem. Management-based regulation often requires firms begin by conducting an internal risk analysis. Then firms are expected to identify and evaluate various risk management options; implement some of the effective options; establish procedures, training, documentation, and monitoring functions; and engage in auditing and on-going efforts to improve the firms' management. Three examples illustrate this approach:

Industrial safety

Management-based regulation has been used to address mine safety in Queensland (Gunningham, 2006), rail safety in the United Kingdom (Hutter, 2001), and workplace safety throughout Europe, Canada, Australia, and the United States (Bluff, 2003). For example,

following the 1984 chemical faculty catastrophe in Bhopal, India, environmental and OSHA regulators in the United States adopted management-based regulation for what they called, respectively, "risk management planning" and "process safety management".

US OSHA and EPA regulations require firms to implement a multi-step management practice to assess risks of chemical accidents, develop procedures designed to reduce those risks, and take actions to ensure that procedures are carried out in practice. Firms must begin by conducting a "process hazard analysis" to identify what could potentially go wrong in their facilities' processes and what steps must be in place to prevent such accidents from occurring. Firms must rank their different processes according to factors such as how many workers could potentially be affected and the operating history of the process, including any previous incidents involving the process.

Firms must next identify both actual and potential interventions to reduce hazards associated with each process, including control technologies, monitoring devices, early warning systems, training, or safety equipment. Based on this analysis, firms must develop written operating procedures both for normal operating conditions and emergency situations. These procedures must be made available to employees who work with the chemical processes. In addition, firms must continuously review these procedures and update them as necessary to reflect process changes, new technologies, or new knowledge.

Firms are required to certify their operating procedures on an annual basis and to provide for compliance audits every three years. By tracking process and incident data in a systematic way through process safety management, firms are supposed to make modifications that can improve worker safety over time (Coglianese and Lazer, 2003; Chinander *et al.*, 1998; Kunreuther *et al.*, 2002).

Pollution prevention

For many years, conventional forms of environmental regulation have aimed to get firms to control their air and water emissions. In the United States, a number of states have gone further to impose requirements on firms to manage their operations in such a way as to achieve reductions in the use of the substances that cause polluting emissions. Rather than mandating pollution control, these pollution prevention regulations require businesses to engage in a management process aimed at preventing pollution from occurring in the first place.

The Massachusetts Toxic Use Reduction Act (TURA) represents one such effort at management-based regulation designed to promote pollution prevention rather than just pollution control. Under TURA, firms that use large quantities of toxic chemicals must analyse their use and flow of chemicals throughout their facilities, develop plans to reduce their use and emissions of toxic chemicals, and submit reports of their planning to state environmental agencies (Karkkainen, 2001). The state also requires that a state-authorised "pollution prevention planner" certify each plan as having met the law's criteria.

Interestingly, although firms are required to go through the planning process and develop a system for reducing the use and emissions of toxic substances, TURA does not require firms to comply with their own plans (Coglianese and Lazer, 2003). It is just a planning law. Since TURA was enacted in 1990, about a dozen other states have adopted similar pollution prevention planning laws (Bennear, 2006).

Food safety

The most prominent and globally extensive example of a management-based regulation is the food safety regulatory regime called HACCP – an acronym that stands for Hazards Analysis and Critical Control Points (Ropkins and Beck, 2000). HACCP requires firms to evaluate, monitor, and control potential dangers in the food-handling process. Under HACCP, firms must identify the potential hazards associated with all stages of food processing and assess the risks of these hazards occurring. Food processors are expected to use a flow chart to aid them in analysing the risks at every stage of production after the food enters the plant in question.

HACCP next requires firms to identify the best methods for addressing food safety hazards. The firm must identify all "critical control points" (CCPs), or points in the production process at which hazards can likely be eliminated, minimised, or reduced to an acceptable level. For each CCP, the firm must establish a minimum value at which the point must be controlled in order to eliminate or minimise the hazard. Having developed a methodology for dealing with hazards, the firm is required to ensure that it complies with that methodology. The firm must list the procedures that will be used to verify that each CCP does not exceed its critical limit, and must determine and indicate how frequently each procedure will be performed.

Each firm's HACCP plan should also indicate the actions the firm proposes to use to correct its operating procedures if a CCP is discovered to have exceeded its limit. As part of its corrective action, the firm must ensure that the cause of the deviation is identified and eliminated, that the CCP is "under control" after the corrective action is taken, that steps are taken to prevent recurrence, and that products adulterated by the deviation are not placed on the market. The firm is also expected to develop a methodology for monitoring and evaluating the effectiveness of its HACCP plan. Furthermore, in order to permit effective self-evaluation and government oversight, HACCP imposes extensive record-keeping requirements on firms (Coglianese and Lazer, 2003; Bennear, 2007).

Many countries have adopted HACCP as part of their domestic regulations (Lazer, 2001). In 1997, the Codex Alimentarius adopted HACCP standards and the European Commission subsequently required all member states to implement HACCP legislation by 2006. The European Commission has recognised that one of the advantages of HACCP is that it is "flexible by its very nature, being based on a limited set of principles and procedures supporting the objective of food safety, without compelling food businesses to comply with rules or to implement procedures which are not relevant or adapted to the specific context for their activity" (EC, 2005).

Summary

As these examples suggest, management-based regulation has already been used by regulators in advanced economies around the globe. These examples may also suggest certain similarities to other regulatory strategies. For example, management-based regulation would appear to be like self-regulation in that firms respond to management-based regulation by creating their own internal systems of "regulation". Moreover, like self-regulation, management-based regulation gives firms much flexibility to select the most cost-effective and innovative strategies for risk reduction (Unnevehr and Jensen, 1999). But unlike self-regulation, management-based regulation can be – and is – government-imposed regulation. It is not voluntary, but instead imposes actual legal obligations on firms to engage

in analysis, planning, and management practices. For this reason, scholars have sometimes called it "mandated self-regulation" (Bardach and Kagan, 1982; Rees, 1988) or "enforced self-regulation" (Braithwaite, 1982) to distinguish it from pure self-regulation.

Management-based regulation is also sometimes said to be "performance-based" (DHS, 007a; Chinander *et al.*, 1998). Indeed, it *is* performance-based in the sense that the required planning and management practices are supposed to aim to achieve a certain type of outcomes, such as reducing the use of toxic chemicals or preventing industrial accidents. Like performance-based regulation, and especially meta-performance standards, management-based regulation also gives much flexibility and discretion to firms themselves. But unlike performance-based regulation, which imposes an obligation to attain or avoid a certain *outcome* (Coglianese *et al.*, 2003), management-based regulation requires only that firms engage in certain *management practices* that are designed to achieve (or avoid) the outcome. The achievement or avoidance of the outcome is *not* what is mandatory under a pure management-based regulation; the establishment of management practices is.

Finally, management-based regulation should be distinguished from regulation that compels information disclosure. To be clear, management-based regulation often requires firms to collect and maintain considerable amounts of information. After all, the gathering of information is usually a first step in effective management. Yet management-based regulation is distinct from the most common kinds of information disclosure regulation (Sunstein, 1999; Karkkainen, 2001). The most common forms of information disclosure regulation are actually means-based regulation since the regulator commands the form of information dissemination (such as with labelling standards). Information disclosure could be performance-based if the mandate is output-oriented (such as to achieve a goal of a certain level of disclosure or knowledge by others). Only when the purpose of information collection and disclosure is to inform and affect management or planning decisions would it be proper to consider information disclosure a type of management-based regulation. While most instances of management-based regulation will necessarily have some time of informational component, management-based regulation typically requires firms to do much more than simply generate and disclose information – namely, it requires them to develop internal plans and procedures based on the information they gather.

5.2. Conditions for the use of management-based regulation

As noted at the outset of this chapter, management-based regulation holds advantages over traditional regulation, such as in providing firms flexibility to adopt more cost-effective solutions. However, this does not mean that it should be used to address every regulatory problem. After all, management-based regulation also holds potential disadvantages. The flexibility it gives to regulated firms may be used to the advantage of the firms more than to benefit the broader public. It may also be difficult for government or third-party auditors to determine whether management plans that look thorough and effective on paper are actually making a significant different in practice. Thus, in deciding whether to use management-based regulation, a regulator must compare this regulatory tool with its alternatives. Management-based regulation, like any regulatory option, should be selected only when it can be expected to lead to superior results, based on stated criteria, when compared with other available options.

The first question to ask, then, when considering management-based regulation is whether there is a need for regulation at all. The prevailing assumption is that competitive markets prove highly successful for producing and allocating society's resources, but that

conditions for socially optimal free market transactions do not always obtain (Stokey *et al.*, 1980; Viscusi *et al.*, 2005). Regulation is therefore generally justified when the market fails for reasons of externalities, information asymmetry, market power, or when other problems such as distributional inequities arise (OMB, 2003).

Assuming a need for regulation, how should a regulator choose between means-based, performance-based, or management-based regulation? The choice in any particular regulatory setting will depend on the circumstances and of course should be preceded by a regulatory impact analysis of each regulatory option (a topic addressed in more detail later in this chapter). That said, several general observations can be made at this point about the choice between three major categories of regulatory tools.

Means-based regulation will often provide reasonable certainty of effectiveness in addressing the regulatory problem, since the regulator will usually only mandate those means that have been shown to work in the past. Means-based regulation may also be easier for government to assess compliance, since presumably all an inspector needs to do is observe whether the specified means are in use. However, as already suggested, means-based regulation can be a blunt tool, sometimes requiring more costly behaviour for individual firms and discouraging innovation and the search for better or more cost-effective solutions. In some cases, the means that work well at some regulated firms may not work at all at other firms, given the particular circumstances of their operations. One size may simply not fit all.

In contrast to means standards, performance standards focus attention on desired outcomes and give firms flexibility to find less costly or better solutions. Rather than picking one means and requiring it for everyone, firms can choose how to address a problem as long as they meet the specified outcome. Furthermore, if performance standards are non-uniform, such as with market instruments like emissions trading, firms gain even greater flexibility. Non-uniform performance standards can yield still greater cost-effectiveness by allowing some firms to perform worse provided others perform better, as long as average performance meets the regulatory objective. Of course, making performance standards work depends on being able to measure and monitor firms' performance (Stavins, 1998). As noted at the outset of this chapter, though, sometimes it is difficult to operationalise the desired outcome into an enforceable regulatory standard, or sometimes it is prohibitively costly for the regulator to monitor outcomes.

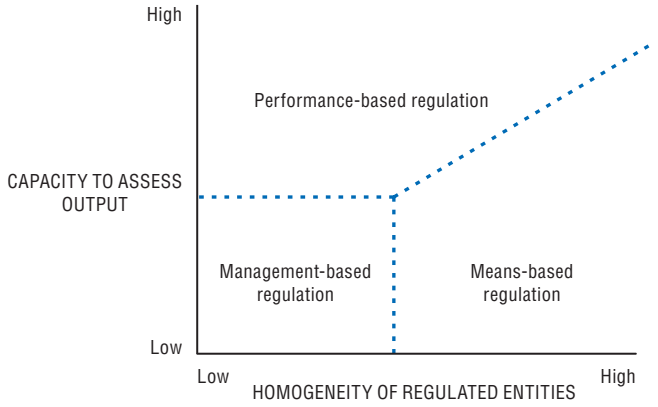
In a world with no administrative or transaction costs, governments could craft optimal regulatory instruments of any type. They could create infinitely specified and adaptable means standards that fit each firm's operations perfectly. For example, if a particular pollution control technology works well for all but a few firms, an environmental regulator would be able easily to identify those few firms and issue alternative means standards applicable to them. Or if the regulator chose a performance-based approach, they could create optimally calibrated performance standards that were fully monitored. But the reality is that regulators do face significant transaction costs in selecting and implementing regulatory standards. They can neither adapt means standards to every firm's circumstances nor costlessly monitor every possible measure of performance. As such, administrative costs to the regulator become a key consideration in choosing among regulatory instruments.

It follows that these administrative costs can be expected to vary depending on at least two general factors that bear on the choice of management-based regulation and its alternatives: *i)* the ease of assessing outputs; and *ii)* the degree of heterogeneity in

regulated firms. If government possesses an ability to assess social outputs cheaply and accurately, then performance standards are a viable (and presumably desirable) regulatory standard. If the regulated sector is homogeneous (*i.e.* most firms have similar operations that remain stable over time), then means standards are likely to be viable; a one-size-fits-all standard works well, obviously, when one size truly does fit all.

As Figure 5.1 shows, if regulatory problems can be arrayed on two axises, depending on the capacity of the regulator to assess outputs and the heterogeneity of the regulated community, the conditions favouring performance-based and means-based regulation are fairly clear. But what is the regulator to do when performance is hard to measure and firms are heterogeneous?

Figure 5.1. **Conditions for use of means-based, performance-based, and management-based regulation**



Consider, for the sake of illustration, three emerging risk regulation issues facing many economies around the world:

- *Nanotechnology.* One of the fastest growing areas of technological development holds both enormous potential for improving consumer products and medicines but also some potential – often yet unknown – for health and safety risks. Nanoparticles' size means that they may more easily lodge in the lungs, penetrate the skin, and even possibly pass through the blood-brain barrier.
- *Import safety.* Recent incidents of tainted consumer imports, ranging from pet food to toothpaste to children's toys, have highlighted the risks from global trade. In an increasingly globalised economy, import countries face an increasing challenge of ensuring that products not directly covered by their own consumer product rules and regulatory oversight will still be safe.
- *Security of hazardous facilities.* Terrorist attacks of chemical plants, nuclear facilities, petroleum refineries, and other industrial operations threaten more than the destruction of these facilities. They also pose grave risks of broad-scale public harm, throughout the surrounding community and even possibly region.

These three examples share two characteristics that make them difficult to address by traditional regulatory instruments. First, they are problems where it is difficult to prescribe a one-size-fits-all solution. Nanoparticles are incredible diverse and their properties vary considerably from one compound to another. Imports are also highly varied and they are

continually changing due to market demand and technological innovation. Industrial operations pose highly varied security risks depending on their location and type of process. As a result of the heterogeneity in these areas, imposing traditional regulatory specifications is difficult, if not impossible for a government regulator. When there is no common solution for all firms, imposing specific requirements will lead to costly, ineffectual, or even at times counterproductive results.

Second, all three problems are ones where it is difficult to specify desired outcomes in regulatory standards. In each, the regulator is unable to monitor or measure risk adequately in order to require that firms keep risks below some specified level. In the case of nanotechnology, the health risks are largely unknown at this time, but the properties of nanoparticles and their size make it plausible that at least some of these new materials will pose public health risks. In contrast, the risks associated with product imports may be better known (*e.g.* lead paint on toys, contaminated toothpaste) – but it is much harder to monitor the risks created by imports, given the vast number of different products and the large volume of imports received by developed economies. With respect to security risks t industrial operations, the consequences will be easy to spot only once it is too late – so while some kind of preventative regulation is needed, it is hard to measure risk when it is ultimately generated by creative agents who can deliberately seek to identify and exploit weaknesses in any firm's security.

Challenges like these defy the conditions where traditional regulatory tools will work. They would meet the conditions where regulators could consider management-based regulation to be a viable regulatory option, because they present problems for which regulators would face substantial difficulty measuring outputs and where the regulated firms or their processes are much too heterogeneous to make it feasible to mandate specific means.

The same is true for the examples of management-based regulation described in the previous section of this chapter: namely, HACCP, chemical accident avoidance planning, and pollution prevention. For obvious reasons, no simple laboratory test of any kind can measure the (generally low) risks of chemical accidents, making performance standards infeasible. In the food area, the traditional methods of sensory monitoring for contamination (such as the so-called "poke and sniff" method) are often unable to detect the presence of pathogens, and lab results from advanced microbial testing can sometimes take too long to generate before perishable products must be shipped out into the supply chain (National Academy of Sciences, 1998). Moreover, the large number of firms covered by all three examples of regulations suggests that that the regulated population is highly heterogeneous. The US Food and Drug Administration once noted, for example, that even in the relatively narrow fruit juice manufacturing sector "no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities" (FDA, 2001). Even more extensive variation in operating conditions can be found across the firms addressed by chemical accident prevention and pollution prevention regulations.

Management-based regulation is worth considering any time the government confronts hard-to-assess risks generated by many diverse firms. Inevitably the firms and their managers will tend to have better information about the risks associated with their operations and the possible ways to reduce or manage those risks cost-effectively (Coglianese *et al.*, 2004). Management-based regulation recognises and seeks to leverage

industry's informational advantages. Unlike traditional forms of government regulation that treat the regulated firm as something of a "black box" – with the regulator not particularly caring what goes on inside companies as long as they used the prescribed means or achieve the outcomes desired by the regulator – management-based regulation explicitly seeks to shape the actual operations of a firm, imposing requirements for systematic planning with respect to public risks and the adoption of internal procedures, training, and management practices.

5.3. Does management-based regulation work – and why?

Can management-based regulation actually work? At least at first glance, a sceptical response to this question might appear warranted. After all, by definition management-based regulation does not require that regulated entities actually make any improvements in their outcomes. Instead it requires them to engage in analysis, planning, and the creation of internal processes. And sometimes, as with the pollution prevention planning laws in various states in the US, management-based regulation does not even require firms to implement their plans. As such, some observers might view with suspicion the flexibility management-based regulation gives to firms to select their own means of fixing the regulatory problem. That discretion could be used by firms to game regulators, perhaps simply by making it look like the firms are managing their operations responsibly by creating documents and procedures that look good on paper but do not reflect the reality of the firms' day-to-day operations.

These are not unreasonable concerns. Ultimately, though, the question of whether management-based regulation works is an empirical one. So far, data on the use of management-based regulation suggests that it can indeed make a difference, at least in some cases. If we look at the three areas where management-based regulation has been used in the United States, there is evidence suggesting it can indeed be effective in addressing important regulatory problems. For example, foodborne illnesses from E. coli O157:H7, a serious pathogen that prompted the mandating of HACCP in the beef industry, have decreased 42% in the United States following HACCP's introduction (CDC, 2006). Insurance claims in chemical industry declined by 40% in the decade after the introduction of federal risk management planning requirements (Coglianese and Lazer, 2003). In the state of Massachusetts – the first state to adopt mandatory pollution prevention planning laws – the use of toxic chemicals declined by 41% in the decade following the law's adoption, with a decline of 88% in the emissions of toxic chemicals (Coglianese and Nash, 2004).

These data need to be approached with some caution, though. In the area of food safety, despite the decline in foodborne illnesses related to E. coli and other pathogens in the US, illnesses related to a small number of other foodborne pathogens have actually increased (CDC, 2006). In addition, other factors unrelated to the introduction of management-based regulation may explain at least some of the changes in reported outcomes, whether for the worse or the better. For example, foodborne illnesses constitute a broad proxy for the impact of HACCP in reducing pathogens during the processing of food. Illnesses can be caused by the spread of pathogens in the handling or preparing food – not just the processing of food in plants covered by the HACCP regulation. Changes in these other pathways leading to the ultimate outcome (illness) could well mask the true effects associated with HACCP in addressing pathogen introduction during the processing of food. Illnesses could rise even if HACCP resulted in pathogen reductions in food processing, and they could drop even if HACCP caused no change in pathogen reductions in food processing.

In addition to confounding effects from other contributing causes, the introduction of management-based regulation does not always occur in isolation of other regulatory changes. For example, the reported declines in toxic emissions in Massachusetts might have been affected by changes in conventional regulations, such as the new performance-based hazardous air pollutant requirements adopted by the federal government around the same time as the passage of the TURA law. The likelihood that broader legal factors explain some of the decline in toxic chemicals is suggested by the fact that overall toxic emissions declined 46% across the United States during the same period (Coglianese and Nash, 2004). Moreover, compared with neighboring states in New England, where toxic emissions also declined an average of 87% during the same period (Coglianese and Nash, 2004), the 88% decline in toxic emissions in Massachusetts does not look nearly as striking (Karkkainen, 2001). The declines reported during the same period in New Hampshire (93%), Connecticut (92%), and Rhode Island (91%) were somewhat larger than experienced in Massachusetts, even though none of these other states had adopted a management-based pollution prevention law (Coglianese and Nash, 2004).

Given the potential for confounding effects, it is necessary to turn to statistical analysis to untangle the precise effects of management-based regulation. Bennear (2007) has tested the effects of the pollution prevention planning laws using longitudinal data on toxic emissions from more than 30 000 facilities throughout the United States, both from the fourteen states that had adopted pollution prevention planning laws similar to TURA as well as those that had not. These laws, recall, only require that firms plan – not necessarily that they implement their plans. Using a differences-in-differences statistical strategy, Bennear compared the trends in toxic emissions across both the "experimental" group of states with management-based regulation and the "control" group of states without management-based regulation. Emissions declined everywhere, but to determine whether changes came about due to the introduction of management-based regulation, Bennear analysed how the trends in management-based regulation states fared against other states, when controlling for a variety of other factors correlated with toxic emissions. She found that the presence of a management-based regulation in the jurisdiction within which facilities were located was associated with about a 30% decrease in toxic emissions – over and above what otherwise would have occurred in the absence of the management-based law. Bennear's (2007) study is the strongest evidence that management-based laws like TURA can contribute positively to their intended results.

This research isolating positive effects of management-based regulation raises the question of how exactly it is that management-based regulation works. If laws like TURA only require firms to engage in planning but do not even require them to follow their internal plans, it may be wondered why firms would ever invest in the additional costs that would be involved in implementing their plans. Is positive social change in the wake of management-based regulation consistent with rational economic behaviour?

It has sometimes been argued that, even in the absence of regulation, socially responsible behaviour yields bottom line results for businesses (Porter and van de Linde, 1995) – what has come to be known as "win-win theory". For example, Reinhardt (2000) shows that making investments in social goals can advance a company's profits if doing so enables the company to lower production costs, differentiate its products from competitors, or manage liability risks better. Yet despite these reasons for businesses to act in socially responsible ways, the continued need for regulation would indicate that firms do not find

enough private benefits to act in ways that are privately costly but socially optimal. As Palmer *et al.* (1995) caution, if there was money simply lying on the floor in terms of profits from corporate responsibility, companies would have picked it up already.

The scholarly debate over win-win theory is relevant to management-based regulation. Although management-based regulation compels firms to engage in planning, it still gives firms considerable discretion to decide what these plans should contain. In the exercise of this discretion, firms may simply engage in the required planning instead of actually undertaking the costly, follow-through action needed to implement their plans and achieve improvements in the outcomes addressed by the regulation. The evidence of the positive effects of management-based regulation suggests that firms do indeed respond to management-based regulation by making at least some investments that they otherwise would not make. Yet these effects cannot stem from win-win theory by itself. After all, if there were private gains to be had from the investments taken after the introduction of management-based regulation, would not firms already have reaped these gains even without the imposition of management-based regulation? Three complementary accounts explain why management-based regulation can be expected to work, even when regulation simply mandates that firms engage in planning and analysis.

The first explanation might be called a theory of "sunk search costs". This account, like win-win theory, recognises that firms can reap private rewards from investing in actions that deliver positive social outcomes. But it also recognises that firms face costs associated with identifying socially beneficial actions that also yield private actions. In other words, to extend Palmer *et al.*'s analogy, firms do not find money simply lying on the floor waiting to be picked up by taking socially responsible action. Rather, such money lies hidden underneath the floor tiles and behind the shop equipment – if only they can find it. Since finding cost savings and competitive advantages from socially responsible behaviour is costly, rational firms will only expend the necessary search costs when the expected net benefits exceed the search costs. Since firms have not found these cost savings yet, they may well view the expected net benefits as small, discounted by a low probability estimate of finding anything. If nothing else, firms' managers may "expect there would be more value in devoting their management resources to some other area" (Bennear, 2006). For this reason, firms might be said to be rationally ignorant of potential win-win opportunities. However, when a management-based regulation mandates firms to engage in planning and analysis, firms must engage in search costs that they otherwise would have avoided. Search costs become sunk costs to the firm, and any cost-saving or profit-enhancing actions firms identify along the way of complying with management-based regulation will be adopted as long as they prove net beneficial.

A second explanatory account focuses on the complementarity between planning and the achievement of social goals. Bennear (2006) argues that for mandated management activities to deliver social benefits, there must be a direct connection between the mandated activities and the desired social outcomes. This complementarity is most readily apparent with problems that arise due to poor management. Accidents in chemical plants, for example, could be expected to occur more frequently in facilities with poor oversight and co-ordination. At the limit, entirely untrained workers who mix chemicals on their own accord, without supervision, would clearly be expected to be more likely to cause an accident. To the extent that there are management-based *problems*, then management-based regulation is clearly complementary. For these types of problems,

management-based regulation would yield results if firms are not already engaging in a socially optimal level or quality of analysis, planning, and other management activities. In other words, the lack of good planning is itself a type of market failure.

Finally, management-based regulation may work because of a background threat of liability under a meta-performance standard (such as tort liability) or other regulatory threats (such as the risk of increased regulatory scrutiny under other laws). If firms face the risk of liability if they discover problems but do nothing to solve them, then once problems are discovered in response to a management-based mandate, firms have a background incentive to take action to solve them. On this account, it is not solely the management-based regulation that operates to induce firms to make costly investments that follow-on management-based regulation, but the interaction between such regulatory commands and other legal norms.

At present, researchers have yet to distinguish which of the three accounts best explains the impact of management-based regulation. It remains possible that a combination of some or all of the three explanations could be operating at the same time. However, the existence of these reasons for expecting management-based regulation to work combined with the available data showing that management-based regulation can indeed work, suggests that management-based regulation should be considered a viable option when regulators consider options for addressing public risks.

That said, it is one thing for a regulatory tool to achieve improvements in the near term, shortly following its introduction. It is another for that tool to sustain long term and continual improvements over time. Since sometimes management-based regulations explicitly seek to encourage businesses to make continuous improvements in their facilities' operations, it is worth asking whether a management-based approach can continue to encourage firms to make investments over time. Interestingly, Bennear (2006) tested for the effects of management-based regulation on facilities over time. The most statistically significant effects (at the 5% level) occurred within two to four years after the imposition of a planning mandate. However, the statistical significance dropped for years five and six (10% level). After year six years, mandatory planning requirements showed no statistically significant effect on toxic emissions.

These declines in statistical significance could simply result from the decrease in the number of states with older management-based regulations related to pollution planning – making statistical analysis difficult due to the small sample size. But it could also indicate that management-based mandates yield diminishing effects over time. According to interviews reported by Coglianese and Nash (2004), facility managers in one state with toxic planning laws generally indicated that they achieved most gains from the required management exercises in the first few years after passage of the management-based regulation. There is reason to wonder, then, whether some businesses tend to view required planning, over time, as little more than a paperwork exercise. After managers identify and respond to the low hanging fruit soon after the introduction of management-based regulation, they may be able to find fewer opportunities (or fewer low-cost opportunities) to make further improvements. This remains an important consideration for both researchers and policy makers.

5.4. Designing effective management-based regulation

Even though research shows that management-based regulation can yield positive social benefits, this does not mean that all types of planning requirements will be equally successful. Policy makers need to consider how best to design management-based regulation. As with other regulatory instruments, the effectiveness of management-based regulation almost certainly depends on how they are designed and used. Management-based regulations vary in terms of at least four major characteristics, each of which may affect the ultimate impact that the regulation achieves.

The first characteristic centres on the nature of the mandate. Management-based regulation can require planning only or it can require planning plus implementation of firms' plans. As noted, the pollution prevention laws studied by Bennear (2007) only required that firms engage in planning, not that they implement their plans. In contrast, HACCP requires that firms not only engage in hazard analysis and internal planning, but that they adhere to the plans and procedures developed under HACCP. Regulatory decision makers should consider the incentive effects that each option may have. "Planning only" requirements can work when firms will find it cost-effective to implement their plans once they have sunk costs into planning. But if firms have no other incentive to implement their plans, either because they are unlikely either to find win-win gains or face background liability, then requiring implementation should be considered because otherwise planning would be an empty gesture. However, regulators also need to be cognizant of the impact an implementation mandate may have on the quality and rigor of the planning firms engage in. If firms know they will be required to implement the plans they develop under a management-based regulation, they may develop plans that identify fewer problems or that only consider the least costly (and perhaps least effective) solutions. In deciding whether to require implementation, then, regulators need to consider whether they have the governmental resources to review the adequacy of firms' internal management plans and monitor firms' diligence in implementing them.

The second characteristic focuses on how prescriptive management directives should be. Some management-based regulations impose only broad standards for planning, while others are quite detailed. Under the Massachusetts Toxic Use Reduction Act, for example, plans must simply contain "a comprehensive economic and technical evaluation of appropriate technologies, procedures and training programmes for potentially achieving toxics use reduction". In contrast, the US Environmental Protection Agency's chemical risk management regulations call for firms plans to address:

- initial start-up;
- normal operations;
- temporary operations;
- emergency shutdown and operations;
- normal shutdown;
- start-up following a normal or emergency shutdown or a major change that requires a hazard review;
- consequences of deviations and steps required to correct or avoid deviations; and
- equipment inspections.

The degree of specificity selected will likely depend in part on the degree to which the regulator already understands the important parameters in managing certain kinds of problems.

A third characteristic centres on whether firms should be required to submit their plans for prior approval from regulators. Actual management-based regulations vary on this dimension in several ways. For example, in Canada the government must review in advance all HACCP food safety plans submitted by seafood processors and must give approval before firms can proceed to implement their food processing. In the United States, chemical companies must submit their risk management plans to the government in advance, but the government does not need to approve them. Finally, some management-based regulations (such as the US Food and Drug Administration's HACCP rules) simply require firms to keep their management plans on file and make them available on request to government inspectors. The regulator's capacity to review firms' plans in advance is likely to affect which of these options gets selected.

A final characteristic of management-based regulation focuses on their associated paperwork and auditing requirements. When management-based regulation is needed to get firms to plan and act to reduce risks, this means that firms' incentives are not aligned to conduct such planning and action on their own, and hence some firms in such situations have incentives to try to resist complying with the letter and spirit of the management-based requirements imposed on them. Some firms can be expected to devote as little effort as possible to their planning and to create plans that simply try to minimise their private implementation costs. When management-based regulation requires both planning and implementation, firms may have the incentive to cut corners on implementation. Regulators therefore need to be able to assess whether firms' planning has been adequate and monitor whether firms are following their plans. The way regulators do this is by imposing suitably detailed record-keeping requirements and instituting inspections or third party audits. Many management-based regulations are enforced by documentation reviews. For example, HACCP includes requirements that food processors regularly check temperatures and the cleanliness of surfaces that come in contact with food – and that they keep meticulous records of both temperatures and surface cleanings.

Management-based regulations vary in terms of the frequency of inspections, from continuous inspections for certain firms in the food industry to annual (or even less frequent) visits for other firms. In addition, under some management-based regulations, third parties are given responsibility for auditing compliance, which may reduce government inspection costs. Massachusetts' TURA, for example, requires that each facility have a certified "pollution prevention planner" review their plans for compliance with the planning criteria in the law. Such third party auditing is also increasingly part of private management-based codes, such as ISO 14000 (Prakash and Potoski, 2006). Whether the auditors are third parties or employed by the government, they nevertheless face common and significant challenges in overseeing management-based regulation. Even when the law contains highly specific planning criteria, what constitute "good" management effort may still be at least somewhat open-ended or case specific, especially since ultimately management-based regulation gives firms discretion in deciding how to address their own risks.

In addition to the characteristics of management-based regulation, an additional design issue is whether other regulatory instruments should be combined with management-based regulation. For analytic purposes in this chapter, management-based regulation has been

treated in isolation – but in practice, it can be combined with some limited forms of means-based or performance-based regulation. For example, even though food processors are now subject to HACCP requirements, they can (and are) still subject to other regulatory commands, such as that they use specific means such as refrigeration or that food handlers wash their hands. When regulators can be confident that a particular means – such as refrigeration and hand-washing – works effectively across all regulated firms to address part of a regulatory problem, or when they know that a particular method of measuring performance can partially addresses a regulatory problem, then it will be appropriate to combine these limited means or performance standards with management-based regulation.

Management-based regulation is sometimes combined with performance measurement, even though the performance measures do not form the basis of the regulation's command. For example, in the area of food safety, the US Department of Agriculture has combined its HACCP requirements with requirements that firms sample products and test for levels of E. coli and salmonella (USDA, 1996). These performance requirements are inadequate by themselves as a basis for the regulatory command, since testing regimens necessarily rely on a relatively small number of samples and since perishable food products must be shipped into distribution before testing results can be confirmed. For reasons like these, regulators often cannot rely on performance measures as the obligatory command in a regulation. Yet even in such circumstances, a performance testing regimen can still be used to aid firms and regulators in assessing the quality and efficacy of firms' management plans and implementation. Regulators can also use such "backdrop" performance measures as a way of determining which firms' plans and record-keeping to scrutinise more closely.

5.5. Regulatory impact analysis and management-based regulation

In choosing between different design characteristics of management-based regulation – and even in deciding whether to use at all – regulators should engage in the same kind of regulatory impact analysis needed for any sound regulatory decision (OECD, 2005). Regulators need to gather discrete information about the nature of the specific problem management-based regulation would address, as well as the estimated costs and benefits of different solutions to that problem, including management-based regulation and its alternatives. In conducting a regulatory impact analysis of management-based regulation, analysts confront many of the same challenges that arise with analysing any proposed regulation, such as quantifying and monetising the anticipated benefits and costs of the regulation (Hahn and Dudley, 2007) and assessing the uncertainties associated with different choices (Jaffe and Stavins, 2007).

The very flexibility inherent in management-based regulation does present some qualitatively distinct challenges for regulatory analysis. Since different firms can be expected to plan for and implement different techniques and technologies, there will be varying costs and benefits associated with each of these approaches. The US Department of Homeland Security (DHS) recognised this challenge when it recently imposed management-based antiterrorism standards on the chemical industry:

> As this regulation is not a "command and control" regulation, owners and/or operators will have considerable flexibility in how they choose to comply with its requirements.[M]any facility owners and/or operators will choose such measures as building fences, enhancing perimeter lighting, and hiring additional security guards in order to comply with the risk-based performance standards.

> We expect that chemical facility owners and/or operators will take full advantage of the flexibility that these risk-based performance standards will provide and will conduct facility-specific and company-specific analyses to determine the most cost-effective method to comply with the requirements of this interim final regulation. However, because process changes are so facility- and business-specific, DHS has no way of estimating how many facilities may ultimately implement such measures for the purpose of estimating compliance costs (DHS, 2007a).

Ideally, the regulatory analyst would want to know which methods which firms will use, and what level of effectiveness these various methods will have in terms of delivering social benefits and at what cost. However, since management-based regulation will tend to be used in situations where the regulated industry is highly heterogeneous, it will be quite difficult to assess these costs and benefits a high level of precision, since what firms will do will vary.

Still, regulators can and must make estimates – even if they are sometimes "simply [the government's] best guess based on currently available information", as the DHS acknowledged in issuing its recent antiterrorism rule (DHS, 2007a). If nothing else, it should be possible to place upper bounds on the predicted costs and benefits of management-based regulation. The cost of a management-based regulation should not be expected ever to exceed the product of the number of regulated firms and the marginal cost of the most expensive intervention possible.

Since all proposed regulations in the US expected to have an annual impact of USD 100 million on the economy must undergo careful economic analysis by the implementing agency and a review of that analysis by the White House Office of Management and Budget (OMB) (Graham, 2007), management-based regulations that meet this threshold have been subjected to extensive benefit-cost analysis and provide instructive examples of some of the distinctive analytical challenges associated with management-based regulation can be addressed.

For example, in the 1990s, the US Occupational Safety and Health Administration (OSHA) developed a major regulatory proposal to address muscular-skeletal disorders (MSDs) caused by repetitive motions in the workplace. OSHA's "ergonomics rule" required employers that had workers experiencing MSDs to create ergonomics management programmes within their workplace. The rule was a classic management-based regulation in that it required employers:

> … to implement a programme that includes the elements of any sound safety and health (ergonomics) programme. These include management leadership and employee participation, job hazard analysis to identify musculoskeletal hazards, the implementation of controls to reduce the hazards identified, training for employees and their supervisors or team leaders in jobs that have MSD hazards, management of musculoskeletal disorders when they occur, and regular evaluation of the programme to ensure that it is functioning as intended (OSHA, 2000a, Fed Register No. 65:68762-68763).

OSHA touted the flexibility the rule provided because it "requires employers to establish a basic framework with widely agreed-upon elements but leaves employers free to provide many of the establishment-specific details" (OSHA, 2000b). The ergonomics rule would protect millions of workers across all industries in the United States. OSHA reported that in 1996 about 625 000 workers experienced MSDs significant enough to lose one or more workdays (OSHA, 2000a). In some industries, workers faced an 80% probability over their career of losing time at work due to a work-related MSD injury (OSHA, 2000a).

Matching the significance of the workplace MSD problem itself were the challenges facing the regulatory analysts. The resulting regulatory impact analysis for the ergonomics rule ran over 700 pages in length – since the rule covered every sector of the economy. Overall, OSHA predicted that "employers will be required to fix almost 7 million jobs in the first year the standard is in place, and a diminishing number every year thereafter" (OSHA, 2000a). Based on an effectiveness analysis in OSHA's risk assessment, the agency estimated that employer fixes would reduce musculoskeletal injuries by 50% annually. The agency then used standard techniques to monetise the benefits of the avoided injuries, yielding an estimated annual benefit of USD 9.1 billion (OSHA, 2000a).

In terms of assessing costs, OSHA distinguished between programmatic costs (administrative, training, paperwork, etc.) and the costs of controlling jobs posing unacceptable MSD risks. To estimate these costs, OSHA studied workplaces that had voluntarily installed ergonomics programmes similar to those called for in the management-based regulation. The agency also "relied on responses to a 1993 ergonomics survey [...] of thousands of general industry employers to estimate the extent to which establishments within the scope of the standard already have implemented ergonomics programmes involving the control of jobs" (OSHA, 2000b). For each provision in the management-based rule, OSHA estimated the number of hours associated with paperwork burdens or the amount of costs needed to comply. For example, the agency estimated that per job it would take one hour of managerial time to engage in a hazard analysis of its MSD risks, and 2-16 hours of employee time and 2-32 hours of managerial time per job to evaluate and implement job controls (OSHA, 2000b). Overall, OSHA estimated that nationwide the rule would impose USD 8.4 billion annually in costs to society and to employers, of which USD 2.2 billion annually were programmatic costs (OSHA, 2000b).

The US Department of Homeland Security (DHS) made similar use of estimates in developing its recent management-based antiterrorism security rule for chemical facilities. That rule, promulgated in 2007, requires covered firms to develop vulnerability assessments and security plans, and to submit both the assessments and the plans to DHS for approval. DHS also required regular auditing by the firms in consultation with DHS, and clarified that DHS would assume a strong inspection authority to assess firms' implementation of their plans. Of course, some firms already had security measures in place, so DHS was careful to note that its estimates were only "intended to represent the marginal cost incurred by owner and/or operators as a result of the [agency's] rule" (DHS, 2007a). These marginal costs included the costs of security measures and equipment, such as fencing and lighting, as well as labour costs associated with security guards, training, and auditing. DHS also estimated the costs of developing and preparing the security plan required under the regulation, including the costs associated with "the expertise of various technical staff which may include engineers, EHS professionals, management, in some cases, lawyers and others" (DHS, 2007b). The agency grouped facilities into different categories and estimated the likely cost for a "model" facility in each category. DHS then multiplied the model facility cost estimate times the number of regulated facilities in each category (a total of about 5 000 facilities), and then summed to reach an estimate of USD 3.6 billion in total costs over a three-year period (DHS, 2007a). About 60% of these costs were for equipment (such as fencing, lighting, locks, and electronic surveillance equipment) and another 30% for security guards and officers (DHS, 2007b). DHS estimated that the costs for preparing the required vulnerability assessment and security plan amounted to only about 3% of the total costs (DHS, 2007b).

As both the ergonomics and chemical security rules illustrate, the cost estimates for major management-based regulations can be significant. They include the costs of planning and, when firms are required to carry out those plans, the implementation costs as well. The planning costs include paperwork burdens on firms, since management-based regulation calls for firms to engage in planning activities (such as hazards and risk analysis) as well as to document their findings and report on their implementation of their management programmes. In an era when regulators around the world are seeking to simplify reporting requirements and lower the administrative costs associated with regulatory compliance (OECD, 2007), the administrative burdens associated with management-based regulation undoubtedly will spark close attention. In the United States, agencies are required under the Paperwork Reduction Act to estimate both the hour burden on regulated entities and their costs of processing the required paperwork. The DHS estimated the paperwork burdens on the private sector from its chemical facility security planning rule to be about USD 110 million over a three year period (DHS, 2007a), while OSHA estimated the annual paperwork costs associated with its ergonomics rule at USD 61 million (OSHA, 2007a).

Although the paperwork burdens of management-based regulation may appear substantial considered all on their own, they may from another vantage point be fully justified. At least in the OSHA and DHS rules, paperwork burdens amounted to only a small fraction of the total costs associated with the rules. Even though they may seem considerable, paperwork costs can be justified if they, plus any implementation costs, are still smaller than the benefits the regulation delivers. Furthermore, it should be kept in mind that if management-based regulation enables firms to implement more effective or cost-effective regulatory measures, any increase in paperwork costs management-based regulation creates will probably be more than offset by implementation cost-savings or an increase in benefits due to the more effective solutions adopted by firms. In its regulatory impact analysis of the chemical security rule, DHS explained that it had adopted a management-based approach for precisely this reason:

> [W]e believe for this rulemaking that any design standard would have been inherently higher cost and lower benefit. The inherent vulnerability of each facility to a terrorist incident is a function of their unique public health and safety risk, economic impact, and the mission critical aspects of the given chemicals and the Threshold Quantities (TQ) of the chemicals the facility processes. Any reasonable design standard the Department would have considered would have likely included provisions not useful for some facilities, and would have likely not included other provisions essential to reducing the risk in other facilities. On the other hand, if a design standard were proscriptive enough to include all of the essential provisions for every facility, it would have likely been much higher cost than this rulemaking (DHS, 2007b).

In the final analysis, paperwork burdens – however substantial they may seem – should be considered as part of an overall assessment of the regulatory impacts of management-based regulation and its alternatives.

5.6. Implementing management-based regulation: a changing government role?

For the same reasons that management-based regulation can be an attractive regulatory alternative – namely, heterogeneous businesses where performance measurement is costly or problematic – the role the government plays as a regulator and inspector may change

under management-based regimes. Instead of inspectors who assess whether one-size-fits-all means are in place at a facility, management-based inspectors have to make highly context specific judgments about management issues. The array of firms covered by management-based regulation will likely employ many different combinations of technologies and processes, and as a result these firms will possess the advantage over government in terms of the knowledge of how these processes could go wrong and how they can be fixed. Firms' managers are likely to understand their own processes in ways that allow them to foresee risks that a regulator would otherwise miss, as well as to anticipate and identify changes in operating conditions that may affect the underlying problem of concern to the regulator.

A critical question for management-based regulation, then, is how regulators can overcome their informational disadvantage to ensure that firms are planning effectively and implementing those plans if required. The tools available to regulators include audits and inspections (Power, 1997). For example, HACCP regulations grant inspectors access to firms' records, analyses, plans, and internal testing results. In addition, on-site inspectors can observe processes during site visits. But do regulators have the capacity to evaluate planning and implementation?

The experience with HACCP implementation in the United States highlights the need, at a minimum, for regulators to have sufficient resources to inspect and audit regulated facilities on a frequent basis (GAO, 2001, p. 17). But even inspections cannot easily reveal whether the firm carries out its plan when an inspector is not there. Instead, inspectors must rely on the firm's records of what occurred, raising the question of whether firms will maintain an accurate record of their actions under incriminating circumstances (Lassiter, 1997, pp. 444-456). Even if firms are not outright untruthful, they may conclude that they would do themselves little good by including in the plan any hazards that government inspectors are unlikely to spot on their own, particularly if these cannot be remedied cheaply. Since management-based regulatory strategies are designed to incorporate a firm's specialised expertise in its product and processes into its safety practices, the very instances in which a firm's expertise would help it to identify hidden hazards may well be some of the same ones in which the firm has the opportunity and incentive to keep its hazards hidden.

In this way, management-based regulation requires a very different profile of governmental capacities than other types of regulation. The very challenges that can make management-based regulation attractive over other regulatory options can also present challenges in government's enforcement role, as there is the inevitable question of how to determine what constitutes sufficiently good management. Ultimately, it is wise to be aware that the nature of the government regulator's role can shift with management-based regulation. Instead of conducting performance tests or observing whether firms have installed proper equipment, inspectors under management-based regulation need to assess the adequacy of a firm's planning and the documentation of its implementation. This can amount to a considerable new burden on certain regulatory agencies, which will need adequate resources to meet the challenges.

Conclusion

Management-based regulation has recently emerged as a regulatory strategy of interest to both researchers and regulators, as it appears likely to be an appropriate instrument for an important, and possibly growing, set of regulatory problems. In a

growing number of important policy areas – from food safety to domestic security – regulators around the world are turning to management-based regulation as a solution for otherwise vexing public problems.

As this chapter has shown, management-based regulation may work well where other regulatory approaches fail, particularly under circumstances of highly heterogeneous regulated firms and in the face of the regulator's inability to assess easily or effectively firms' true performance. Management-based regulation also promises important advantages over conventional regulatory tools. Because it gives firms flexibility to find their own ways to reduce or mitigate risks, management-based regulation may lead to better and less costly solutions to regulatory problems. Empirical research is beginning to show that management-based regulation can induce positive behavioural change within industry.

But management-based regulation is certainly no panacea. How it is designed and implemented will undoubtedly affect its ultimate effectiveness in practice. The same flexibility that generates its advantages also presents its potential sources of policy failure. To prevent shirking by regulated firms, regulators need to design management-based regulation carefully, paying attention to factors such as the degree of specificity in planning criteria and the resources needed to monitor and enforce compliance with management mandates.

Ultimately, determining whether to adopt management-based regulation in the face of any specific set of public risks will call for the same kind of regulatory analysis that should under-gird any regulatory decision making. Regulatory officials should consider not just the costs of the required planning, but also the costs and the benefits of the means firms are likely to adopt to implement their plans. Although there are reasonable concerns about the burdens management-based regulation places on industry in terms of preparing plans and filing reports, these planning and paperwork requirements can be justified in areas where the private sector undersupplies effective risk management practices from the standpoint of overall social welfare.

To understand better when and how to use management-based regulation, additional *ex post* evaluations will be needed. There remains a need for further empirical research on the impacts of management-based regulation, both to learn whether they are achieving meaningful benefits as well as whether their costs turn out as projected. Even though existing research shows that management-based regulation can prove successful under circumstances, clearly an additional open question remains whether such positive effects can be sustained over time – or whether the effects of management-based regulation wear off after the low-hanging fruit has been picked. Finally, management-based regulation poses new challenges for governmental authorities, so additional research is needed to illuminate ways for regulatory personnel to make the transition to what appears increasingly to be a more management-focused regulatory environment.

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