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Management-Based Regulation

Cary Coglianese* and Shana Starobin**

Abstract

Environmental regulators have embraced management-based regulation as a flexible instrument for addressing a range of important problems often poorly addressed by other types of regulations. Under management-based regulation, regulated firms must engage in management-related activities oriented toward addressing targeted problems—such as planning and analysis to mitigate risk and the implementation of internal management systems geared towards continuous improvement. In contrast with more restrictive forms of regulation which can impose one-size-fits-all solutions, management-based regulation offers firms greater operational choice about how to solve regulatory problems, leveraging firms' internal informational advantage to innovate and search for alternative measures to achieve the intended results more cost-effectively. Drawing on both illustrative cases of management-based regulation and on available empirical research, this chapter explains management-based regulation's relative advantages and disadvantages as well as the likely conditions for its effective use.

Keywords

Management systems; meta-means regulation; flexible regulatory instruments; mandated self-regulation; process standards; risk management

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Management-Based Regulation

Cary Coglianese and Shana Starobin

Management-based regulation has received greater use by regulators than it has systematic study by researchers. Yet experience with it to date—confirmed by the limited empirical study of it that does exist¹—indicates that management-based regulation can prove to be a viable instrument in the policymaker’s toolbox and one that may be most appropriate for addressing a non-trivial range of regulatory problems, such as pollution, catastrophic industrial accidents, and foodborne illnesses. But what exactly is management-based regulation? How and when does it work? And what are its limitations—especially given that it often seems to target problems that are poorly addressed by other available policy instruments?

I. What is Management-Based Regulation?

Management-based regulation, as the name implies, mandates that regulated firms’ managers engage in management activities, such as planning and analysis, oriented toward addressing the underlying problem motivating the regulation. This regulatory strategy has been defined as one that requires regulated entities:

to produce plans or adopt management systems that comply with criteria stated by the regulator, such as to identify hazards, develop 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.²

Management-based regulation often stands in contrast to traditional forms of regulation—or ‘command and control’ regulation. Stereotypically, these traditional forms of regulation are highly restrictive: they constrain firm choice not only about which problems to solve but also exactly how they must solve them. By imposing one-size fits all solutions on all firms, traditional regulation results in higher costs because firms have no flexibility to innovate or search for alternative measures to achieve the intended results. Moreover, traditional forms of regulation emanate from regulators

¹ Cary Coglianese and David Lazer, ‘Management-based Regulation: Prescribing Private Management to Achieve Public Goals’ (2003) 37(4) L & Soc’y Rev 691-730; Lori S. Benneer, ‘Evaluating Management-Based Regulation: A Valuable Tool in the Regulatory Toolbox?’ in Cary Coglianese and Jennifer Nash (eds), *Leveraging the Private Sector: Management-Based Strategies for Improving Environmental Performance* 51-86 (Resources for the Future Press 2006).

² Cary Coglianese, ‘Management-Based Regulation: Implications for Public Policy,’ in Gregory Bounds and Nikolai Malyshev (eds), *Risk and Regulatory Policy: Improving the Governance of Risk* 159-183 (OECD Publishing 2010).

who inherently have less access to information about regulated firms' internal operations than the firms do. In principle, management-based regulation overcomes these limitations of traditional regulation. Management-based regulation seeks to leverage the firms' informational advantage as well as provide flexibility to adapt solutions to each firm's circumstances so as to increase effectiveness and reduce compliance costs.³

Management-based regulation can be adopted by any kind of regulatory authority.⁴ What makes it distinctive is the nature of its command—that is, what it tells a regulated entity to do. Traditional regulatory commands take the form of either means or ends—instructing regulated firms to undertake (or avoid) certain actions (for example, install emissions control devices), or to achieve (or avoid) specific outcomes linked to regulatory goals (for example, keep concentrations of air pollutants below a designated level). By contrast, management-based regulation has been said to force regulated entities to 'think'—compelling efforts at planning and internal operational decision-making.⁵ Instead of telling a firm what action to take that will directly achieve a regulatory goal, such as installing pollution control equipment, a management-based rule tells firms to take actions that aim at achieving the regulatory goal by improving firms' management. Such a rule requires firms to analyze their operations and come up with their own internal plans and procedures aimed at making improvements that will advance the regulatory goal. What is required is management activity: planning, analysis, and the adoption of internal systems and procedures.⁶ Some management-based rules do not even require that regulated firms actually implement their internal plans and procedures, just that they develop them.

With management-based regulation, firms retain what has been called the 'locus of discretion.'⁷ In other words, firms can still decide what direct or immediate actions to take to solve the regulatory problem. For this reason, management-based regulation is sometimes confused with other regulatory strategies that similarly leave regulated firms with discretion, such as performance-based regulation, voluntary programs, or self-regulation.⁸ Management-based regulation does share some affinities with self-regulation because, under management-based rules, firms do develop their

³ Ibid.

⁴ Ibid.

⁵ Serge Taylor, *Making Bureaucracies Think: The Environmental Impact Statement Strategy of Administrative Reform* (SUP 1984).

⁶ These activities are a type of required means, but they are managerial means aimed at the ultimate (or macro-level) outcome of concern. This is why a recent National Academy of Sciences committee (on which one of the authors of this chapter served) has opted to characterize management-based regulation as 'macro-means' regulation. National Academies of Sciences, Engineering, and Medicine, *Designing Safety Regulations for High-Hazard Industries* (National Academies Press 2018).

⁷ Kenneth R Richards, 'Framing Environmental Policy Instrument Choice' (2000) 10 Duke Envtl L & Policy F 221, 237.

⁸ Cary Coglianese, 'Performance-Based Regulation: Concepts and Challenges,' in Francesca Bignami and David Zaring (eds), *Comparative Law and Regulation: Understanding the Global Regulatory Process* 403-429 (Edward Elgar 2016).

own internal procedures and implementation plans to remedy problems.⁹ Since firms themselves decide what internal procedures to adopt and direct actions to take, management-based regulation can be more cost-effective than other strategies and may promote firm compliance in addition to reducing government resources dedicated to inspections and compliance. Yet, unlike self-regulation, management-based regulation is indeed a form of mandatory regulation—placing obligations upon firms to undertake analysis, planning, and management practices. Self-regulation in its various forms typically lacks monitoring and enforcement, beyond internal measures undertaken within the firm; it is purely voluntary. Management-based regulation, by contrast, is mandatory, just like other forms of regulation. For this reason, it has sometimes been referred to as enforced or mandated self-regulation.¹⁰

II. Examples of Management-Based Regulation

Most management-based regulations require that regulated entities follow a common management formula known as ‘plan-do-check-act’ which requires an ongoing cycle of attention and continuous improvement.¹¹ These regulations often share key components, including requirements for risk analysis, evaluation of management options, establishment of standard operating procedures, training in internal operating procedures, documentation of adherence to procedures, and monitoring and auditing. We offer examples of management-based regulation to show the diverse policy domains within which management-based regulation has become an important instrument for tackling public policy problems.

A. Preventing pollution

To reduce chemical emissions from power plants and manufacturing facilities, regulation has traditionally focused on mandating pollution control technologies or meeting emissions limits.¹² It has focused on halting the release of pollution, not explicitly discouraging facilities from *using* the very chemicals that create pollution in the first place. In contrast, management-based regulation has sought to encourage

⁹ Darren Sinclair, ‘Self-Regulation versus Command and Control? Beyond False Dichotomies’ (1997) 19 L & Policy 529-559.

¹⁰ John Braithwaite, ‘Enforced Self-Regulation: A New Strategy for Corporate Crime Control’ (1982) 80(7) Mich L Rev 1466-1507; Eugene Bardach and Robert A. Kagan, *Going by the Book: The Problem of Regulatory Unreasonableness* (Temple University Press 1982); Joseph Rees, ‘Self -Regulation: An Effective Alternative to Direct Regulation by OSHA?’ (1988) 16(3) Policy Studies J 602-614; Bridget M Hutter, *Regulation and Risk: Occupational Health and Safety on the Railways* (OUP 2001); Robyn Fairman and Charlotte Yapp, ‘Enforced Self-Regulation, Prescription, and Conceptions of Compliance within Small Businesses: The Impact of Enforcement’ (2005) 27 L & Policy 491-519.

¹¹ W Edwards Deming, *Out of the Crisis* (MIT, Center for Advanced Engineering Study 1986) 88; Ronald D. Moen and Clifford L. Norman, ‘Circling Back: Clearing Up Myths about the Deming Cycle and Seeing How It Keeps Evolving’ (2010) 43 *Quality Progress* 22.

¹² David Schoenbrod, Richard B. Stewart and Katrina M. Wyman, *Breaking the Logjam: Environmental Protection That Will Work* (Yale University Press 2010) 3-29.

pollution prevention by mandating that industrial facilities' managers engage in planning aimed at getting their operations to reduce their use of toxic chemicals.¹³ For example, the Massachusetts Toxic Use Reduction Act (TURA) requires facilities' managers to engage in analysis and planning to reduce their facilities' use of toxic materials—even though it does not actually mandate that any facility actually reduce the use or emissions of toxics. Instead, regulated firms must engage in toxic use analysis, create toxic use reduction plans, and submit annual reports identifying the toxics their operations used, released as waste products, and included in the final products manufactured. Over a dozen other states have adopted similar pollution prevention planning laws.¹⁴

B. Avoiding chemical explosions

In the unlikely event of an accident in a facility employing large volumes of chemicals, the consequences can be catastrophic—including loss of life, damage to property, and vast contamination to the environment and natural resources. The accident at the Union Carbide facility in Bhopal, India in 1984—which resulted in thousands of fatalities—spurred regulators to put in place new regulations aimed at preventing similar incidents from occurring.¹⁵ In the United States, Congress called for a management-based regulatory approach, and the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) responded by issuing management-based rules: OSHA's Process Safety Management (PSM), and EPA's Risk Management Planning (RMP).¹⁶ Echoing the commonalities of other management-based regulations, both OSHA's and EPA's approaches involve similar steps: hazard analysis, risk ranking, identification of risk reduction interventions, development of operating and emergency procedures, continuous review and improvement, documentation, and regular auditing.

C. Ensuring food safety

About forty-eight million people become sick as a result of food contamination each year in the United States—with an estimated 128,000 hospitalizations and 3,000 deaths annually.¹⁷ Foodborne illnesses, however, are usually preventable.¹⁸ Although

¹³ Lori S Benneer, 'Are Management-based Regulations Effective? Evidence from State Pollution Prevention Programs' (2007) 26 *Journal of Policy Analysis & Management* 327-348.

¹⁴ *Ibid.*

¹⁵ Thoms J. Lueck, 'Chemical Industry Braces for Tougher Regulation' *New York Times* (New York City, 15 August 1985) <<https://nyti.ms/29pGKL9>> accessed 4 February 2019; Charlene Crabb, 'Revising the Bhopal Tragedy' (2004) 306 *Science* 1670-1671.

¹⁶ Coglianese and Lazer (n 1).

¹⁷ Centers for Disease Control, 'CDC Estimates of Foodborne Illness in the United States' <http://www.cdc.gov/foodborneburden/pdfs/factsheet_a_findings_updated4-13.pdf> accessed 24 June 2017.

¹⁸ National Institute of Diabetes and Digestive and Kidney Diseases, 'Foodborne Illnesses' (*NIDDK*, June 2014) <<https://www.niddk.nih.gov/health-information/digestive-diseases/foodborne-illnesses>> accessed 13 January 2019.

food safety regulation has traditionally centered on the inspection of food processing facilities by inspectors' looking and smelling for rotten or contaminated food, this approach has proven incapable of detecting the microscopic sources of contamination—the bacteria, viruses, and microbes that cause the majority of illnesses.¹⁹ Moreover, the variety and size of food-processing facilities further make comprehensive government inspection difficult. Management-based regulation has offered a viable and widely implemented alternative in the form of Hazard Analysis Critical Control Point (HACCP) regulations.²⁰ Today, food safety regulations in the United States, Europe, and other advanced economies follow the HACCP model.²¹

HACCP regulations call on food businesses to identify the sources of hazardous conditions and articulate the best ways to prevent harm from occurring. Although different subsets of the food sector—for example seafood, fruit juice, and meat processing, as well as retail and food service operations—have somewhat different management requirements, all HACCP regulations include seven core, mandated activities: (1) conduct a hazards analysis; (2) identify critical control points (CCPs); (3) set limits for CCPs; (4) monitor CCPs; (5) pursue corrective action when CCPs exceed critical limits; (6) perform continuous assessment of CCPs and critical limits; (7) Document procedures and implementation.²²

D. Promoting security at high-hazard facilities

The terrorism events of September 11, 2001 raised concern about the security of major parts of the United States' critical infrastructure, including the vulnerability of nuclear reactors and large chemical facilities.²³ Regulators at the US Department of Homeland Security (DHS) turned to management-based regulation in an effort to spur such potential targets to managing the security aspects of their operations in a more thorough manner.²⁴ Under DHS requirements, for example, major facilities operating with hazardous materials must engage in “vulnerability assessments” and then develop plans and procedures that aim to improve the security of their operations.²⁵ These plans must include security measures designed to resist different methods of terrorist violence, including cyberattacks, and must include procedures for maintaining

¹⁹ Peter May, ‘Social Regulation,’ in Lester M. Salamon, *The Tools of Government: A Guide to the New Governance* 156-185 (OUP 2002).

²⁰ Coglianese and Lazer, (n 1).

²¹ Ibid; David Lazer, ‘Regulatory interdependence and international governance,’ (2001) 8(3) J of Eur Pub Policy 474-492; Ladina Caduff and Thomas Bernauer, ‘Managing Risk and Regulation in European Food Safety Governance’ (2006) 23(1) Rev of Policy Research 153-168.

²² Sara Mortimore and Carol Wallace, *HACCP: A Practical Approach* (3rd edn, Springer 2013) 1.

²³ PBS NOW with Bill Moyers, ‘Science and Health: Homeland Insecurity’ (PBS, 21 March 2003) <<https://www.pbs.org/now/science/chemsafe.html>> accessed 13 January 2019; PBS NOW with Bill Moyers, ‘Science and Health: Nuclear Plant Security’ (PBS, 2 December 2005) <<https://www.pbs.org/now/science/nuclearsafetyupdate.html>> accessed 13 January 2019.

²⁴ Department of Homeland Security, 2007. ‘Chemical Facility Anti-Terrorism Standards,’ Federal Register 72:17688-17745.

²⁵ Ibid.

monitoring and security alarm system.²⁶ The DHS requires that facilities' vulnerability assessments and security plans be submitted to the government for review and approval.²⁷

E. Preventing offshore oil spills

Following the Gulf Coast oil spill disaster in 2010, the federal government adopted a management-based regulation intended to reduce the risks of accidents and spills during offshore oil drilling. The Bureau of Ocean and Energy Management, Regulation and Enforcement (BOEMRE) within the U.S. Department of Interior turned to a set of safety and environmental management standards (SEMS) that an oil industry trade association, the American Petroleum Institute (API), had adopted and required its members follow. The Department of Interior incorporated the API standards into federal law, making them legally binding on all offshore drilling operations. The departmental regulation requires drilling operators to put in place a comprehensive safety management system which includes, among other things, a hazards analysis, safety plan, operating procedures, training, emergency response plans, auditing, and documentation. The government requires managers at these operations to "[e]stablish goals and performance measures, demand accountability for implementation, and provide necessary resources, ... [a]ppoint management representatives who are responsible for establishing, implementing and maintaining an effective SEMS program, ... review the SEMS program to determine if it continues to be suitable, adequate and effective, and document the observations, conclusions and recommendations of that review."²⁸ In addition, companies are required to notify BOEMRE thirty days in advance of each internal audit of their SEMS, so as to allow BOEMRE inspectors to participate in the audit as well.

III. Management-Based Regulation, Non-State 'Regulators,' and Global Governance

All of our examples are of regulations adopted or agreed to by governmental bodies, but, as the example of BOEMRE's incorporation of industry standards for SEMS shows, management-based regulation is not only a strategy that can be adopted by governmental regulators; it can also be a tool employed by private actors.²⁹ Trade associations can use management standards to seek to control individual firms in their sector; multinational corporations can use them to oversee their individual facilities or those of their suppliers; and non-governmental organizations seeking to shape the

²⁶ Ibid.

²⁷ Ibid.

²⁸ Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), 2010. 'Oil and Gas and Sulphur Operations in the Outer Continental Shelf – Safety and Environmental Management Systems,' Federal Register 75:63650, Sec. 250.1909.

²⁹ Richard M. Locke, *The Promise and Limits of Private Power: Promoting Labor Standards in the Global Economy* (Cornell University Press 2013).

behavior of private actors can adopt them and encourage their use. For example, General Motors and Ford have demanded that their suppliers implement environmental management systems.³⁰ A major non-governmental organization, the International Organization for Standardization (ISO), has adopted a series of criteria for environmental management systems—the so-called ISO 14000 series—that have been widely implemented around the world.³¹ Closer to home, HACCP-like requirements have formed part of an innovative public-private partnership to improve food safety for fresh produce. The California Leafy Greens Product Handler Marketing Agreement (LGMA) brings regulators together with handlers buying eighteen distinct leafy green vegetables to determine best practices for mitigating food safety at the point of farm production, enforced via commitments by handler-members to deal only with growers compliant with LGMA standards and on-site auditing conducted by state inspectors.³²

Moving from private or public-private initiatives to the broadest scale of international cooperation, management-based regulation has proven at times to be an attractive model for multinational efforts to address global problems. For example, the 2015 Paris Agreement on climate change includes the “core elements of management-based regulation”:

Countries submit their own mitigation plans; they agree to follow certain transparency guidelines in connection with their progress in reducing greenhouse gas emissions; and they commit to taking stock in five-year intervals to strive for improvements. Substitute “nations” for “businesses” and it is clear that this is classic management-based regulation.³³

Much like with national or subnational examples of management-based regulation, the Paris Agreement does not impose any binding performance standards on nation-states to reduce their greenhouse gas emissions; instead each participating government agrees to develop its own commitments and plans.

IV. When To Use Management-Based Regulation

Before deciding to use management-based regulation, decision-makers must first determine if there is a need for regulation at all. Assuming an affirmative answer,

³⁰ Cary Coglianese and Jennifer Nash, ‘Management-Based Strategies: An Emerging Approach to Environmental Protection,’ in Cary Coglianese and Jennifer Nash (eds.), *Leveraging the Private Sector: Management-Based Strategies for Improving Environmental Performance* 10 –11 (Resources for the Future Press 2013).

³¹ Aseem Prakash and Matthew Potoski, *The Voluntary Environmentalists: Green Clubs, ISO 14001, and Voluntary Environmental Regulations* (CUP 2006).

³² Charles F. Sabel and William H. Simon, ‘Contextualizing Regimes: Institutionalization as a Response to the Limits of Interpretation and Policy Engineering’ (2012) 110(7) *Mich L Rev* 1265-1308.

³³ Cary Coglianese, ‘When Management-Based Regulation Goes Global,’ *The Regulatory Review* 12 December 2008) <<https://www.theregreview.org/2015/12/23/coglianese-when-management-based-regulation-goes-global/>> accessed 2 August 2016; Coglianese (n 8).

the next question then becomes whether to use a management-based approach or one of its main alternatives: means-based or performance-based regulation.

Means standards may offer greater certainty of effectiveness and tend to be easier for inspectors to monitor for compliance, because they are clear and uniform. Yet, due to these same qualities, they can be a blunt and costly way to regulate. By contrast, performance standards impose an obligation on regulated entities to achieve a desired outcome, granting firms flexibility to search out better and cheaper solutions. It can, however, sometimes be quite difficult to operationalize the outcome into a regulatory standard that is actually enforceable, and monitoring outcomes may involve prohibitive costs. For example, when the outcome desired is the avoidance of a low-probability catastrophe or terrorist incident, then traditional performance standards may be unrealistic.

The disadvantages of means and performance standards may not be intrinsic to these approaches to regulation but rather more of a function of the resource constraints—both financial and informational—under which regulators operate. If regulators actually faced no resource constraints, they could craft means standards that fit precisely with each individual firm's operations, or they could craft perfectly calibrated performance goals that could be effortlessly and fully monitored. Yet because regulators do face real resource constraints, the key factors in choosing between means, performance, or management standards largely hinge on factors related to those resource constraints. If it is easy to define and monitor outcomes, then performance standards will make an excellent choice. If all the firms to be covered by a regulation are the same in all relevant respects, then a one-size-fits-all means-based approach will make sense.

But some regulatory problems are ones where the firms to be regulated are quite heterogeneous and where it is difficult either to define or monitor outcomes. For those problems, management-based regulation offers a promising alternative. By mandating that each firm regulate itself from the inside, firms can choose the means of solving problems that are appropriate to their operations and they can even find and designate relevant proxies that can be measured for outcomes that could be difficult to measure. HACCP, for example, not only calls upon firms to find appropriate means for preventing pathogen growth during food production (by hand washing, for example), but they must also identify critical control points where contamination can occur and find ways to measure how well those control points are being managed (for example, periodically swabbing certain pieces of equipment and testing for pathogen growth).

It is possible, of course, that some aspects of a regulatory problem or some parts of a firm's operations will be amenable to means or performance standards, while management standards could still be usefully applied. In other words, management standards can be both substitutes for as well as complements to means and performance standards. In the domain of food safety, for example, means and performance standards can be used. Every food producer needs to use refrigeration for storage (means) and some limited number of food samples can be pulled off the production line and tested for pathogens (performance). But since exposure to just a single e coli bacterium can cause severe health effects, no sampling strategy can be complete, and reliance solely on a performance standard would not provide sufficient assurance of food safety.

In addition, some problems or facets of problems might be said to stem more immediately from poor quality management itself. For example, to protect workers from factory fires, regulation calling for the adoption of particular technology—such as sprinkler systems or unlocked emergency exits—will likely make great sense for all facilities. Yet, technology will not, on its own, likely ensure that workers will know how to escape that same factory safely—such as knowing where the nearest exits are to their workstations, how to avoid smoke inhalation, or how to file out safely and seek help. These other steps require thinking and planning—or at least the creation of plans and training—to prepare people and manage their behavioral responses in the event of a low-probability but high consequence event like a factory fire. Because regulatory problems like accidents can also sometimes occur because the moving parts in a complex industrial process are not well-coordinated and managed,³⁴ management-based regulation will be promising as it aims at the root cause of those problems.³⁵

V. Design Choices in Management-Based Regulation

If a regulator decides to establish management standards, it will face a series of design choices, including:

- Whether to mandate planning only or the implementation of plans too;
- What level of detail to provide in the criteria for a mandated plan;
- Whether to require review and approval of plans in advance of any granting of a permit or license to operate a regulated facility or sell products or services; and
- What requirements to impose for record keeping and auditing.

The discussion below highlights these design questions, noting that the choices to be made with respect to specific problems may need to vary in different regulatory contexts.

A. What to Mandate?

Sometimes a management-based regulation will mandate planning only, as with the Massachusetts TURA, while other times, as with HACCP, both planning and the implementation of a plan will be mandatory. Deciding what to mandate will depend on other incentives facing the firm. For example, even though TURA does not require firms to implement their plans nor actually to reduce their use of toxic chemicals, researchers Monica Becker and Ken Geiser have reported that eighty percent of the firms they surveyed had implemented at least part of their mandated toxic use reduction

³⁴ Charles Perrow, *Normal Accidents: Living with High Risk Technologies*. (PUP 2011).

³⁵ Coglianese (n 2).

plans, presumably because in the course of planning they found ways to lower their costs by reducing their use of toxics.³⁶

Firms will generally not need to be required to implement their plans whenever managers suffer from a myopia that leads them to underestimate their expected net benefits from planning and implementation. Even if they do estimate these private net benefits correctly (and they are still too low to justify action), once firms have sunk costs into planning (because they were mandated to do so), they may then find sufficient benefits to justify going forward to implement once the required planning is completed. In some instances, the mere documentation of problems in a plan may give rise to a background risk of tort liability to a firm if it fails to implement its plan, a legal incentive that may be sufficient to induce implementation without any additional regulatory compulsion.

If firms lack any background incentive to implement their plans, then mandating implementation should be considered. Yet, before making plan implementation mandatory, one of the potential disadvantages of such a mandate should be taken into account. If firms are required to implement their plans (or face background tort liability to do so), they may well plan less thoroughly or ambitiously than they would otherwise. Plans that must be implemented, after all, may become plans that are easily achievable. If what is really needed to solve a problem is to motivate managers to probe their operations thoroughly and to create stretch goals, and if there is some expectation that if they gain greater awareness of the problem they will have a positive reason to fix it, then it will likely be better not to require implementation of mandated plans.

B. Specificity of management criteria

When designing management standards, regulators need to choose how to specify the required management steps. Some requirements are very general. TURA, for instance, calls only for a “comprehensive economic and technical evaluation of appropriate technologies, procedures, and training programs for potentially achieving toxics use reduction.”³⁷ By contrast, EPA’s RMP rule dictates that firms prepare “clear instructions or steps” addressing:

(1) initial startup; (2) normal operations; (3) temporary operations; (4) emergency shutdown operations; (5) normal shutdown; (6) startup following a normal or emergency shutdown or a major change that requires a hazard review; (7) consequences of deviations and steps required to correct or avoid deviations; and (8) equipment inspections.³⁸

³⁶ Monica Becker and Ken Geiser, ‘Evaluating Progress: A Report on the Findings of the Massachusetts Toxics Use Reduction Program Evaluation,’ prepared by The Massachusetts Toxics Use Reduction Program, University of Massachusetts, Lowell 1997.

³⁷ Coglianese (n 2).

³⁸ Ibid.

The degree of specificity will likely depend on how well understood the problem is and how confident the regulator is about what quality management related to that problem will entail. The greater the heterogeneity in firms and in the relationship between their management and the underlying problem, the less specific a management standards' prescriptions likely should be.

C. The role for the regulator in planning

As noted above, the DHS's anti-terrorism planning regulation requires covered facilities to submit their vulnerability assessments and security plans to the government for review and approval before they can be considered final. This is a more common approach in Europe with a form of management-based regulation known as "safety case" regulation.³⁹ By contrast, other management-based regulations require firms to submit a management plan to the government, but not for approval (for example, EPA's RMP regulation). Still other management standards simply call for the required plan and other documentation to be kept on file and made available upon request by government inspectors (for example, the Food and Drug Administration's HACCP). Which of these options to select will depend on the factors such as the time and resources available to the regulator to review plans as well as the regulator's confidence in its ability to assess quality planning.

D. Record keeping and auditing

It is hard to find examples of management standards that do not require any documentation; on the contrary, the preparation of analysis documents, plans, procedures, checklists, forms, and audit trails are common to management standards. But these requirements can vary, depending on the extent and frequency of documentation and reporting required. So too can management standards vary in the nature and frequency of auditing required by the firm itself or by third-party auditors. If third-party auditing is required, the regulator will need to contemplate how to ensure the credibility of these auditors, in terms of requirements for auditor accreditation as well as the degree to which the regulator will engage in ongoing auditing of the auditors.⁴⁰

VI. The Impact of Management-Based Regulation

Given that management-based regulation has been adopted to tackle a range of policy problems, assessing the impact of such standards will be important for

³⁹ National Academy of Sciences (n 6), at 77-84, 109.

⁴⁰ Shana Starobin and Erika Weinthal, 'The Search for Credible Information in Social and Environmental Global Governance: The Kosher Label,' (2010) 12(3) Business and Politics Article 8, DOI: 10.2202/1469-3569.1322.

determining whether they are working and can reliably form part of other regulators' toolkits and under what conditions.⁴¹ Some fragmentary evidence suggests that management standards have made a positive contribution in reducing some of the problems they have aimed to address. For example, for at least the first several years after the federal government mandated HACCP to address food safety, cases of major bacterial foodborne illnesses declined by more than twenty percent.⁴² Controlling for production levels, chemical firms in Massachusetts reduced their use of toxic chemicals by forty-one percent for nearly a decade after TURA's adoption and dropped their emissions of toxic chemicals by over eighty-five percent.⁴³ In the chemical industry, property insurance claims declined by forty percent following the introduction of risk management planning regulation.⁴⁴ However, other research indicates only a more "modest decline in reported accident frequency and worker injury rates."⁴⁵

Whatever one makes of these temporal changes in indicators of regulatory problems, it is difficult to attribute these measurable improvements to management-based regulation in particular—as opposed to other possible factors contributing to improvements during the same periods. For example, with respect to the Massachusetts TURA, toxic releases in many other states in New England declined by similar amounts during the same time period. To overcome this limitation, Lori Benneer undertook a differences-in-differences analysis of a panel dataset of about 31,000 facilities during the period 1988-1999.⁴⁶ She compared toxic chemical releases at facilities located in the fourteen states with toxic pollution planning laws to releases at plants located in states without such laws. She found that facilities subject to laws requiring management-based regulation decreased their overall releases of toxic chemicals to a greater extent—on average thirty percent more (60,000 pounds)—than facilities not subject to similar regulations. Notably, she also found evidence that facilities subject to the planning laws also engaged more frequently in activities related to pollution prevention. She did find, however, that the differences across the two groups of facilities disappeared after about six years, suggesting the possibility that management standards encourage firms to find low-hanging fruit but that over time the benefits they deliver will decline. This finding is not inconsistent with a concern that firms can sometimes respond to management requirements as rote, paperwork exercises, rather than earnest efforts to self-regulate.

⁴¹ Coglianese (n 2) 161.

⁴² Coglianese and Lazer (n 1).

⁴³ Dara O'Rourke and Eungkyoon Lee, 'Mandatory Planning for Environmental Innovation: Evaluating Regulatory Mechanisms for Toxics Use Reduction' (2004) 47 J of Env'tl Planning & Management 181-200.

⁴⁴ Ibid.

⁴⁵ Paul R. Kleindorfer, Robert A. Lowe, Isadore Rosenthal, Rongwei Fu and James C. Belke, 'Accident Epidemiology and the RMP Rule: Learning from a Decade of Accident History Data for the U.S. Chemical Industry' (2007) Final Report for Cooperative Agreement R-83033301 Between Risk Management and Decision Processes Center, the Wharton School of the University of Pennsylvania and Office of Emergency Management, U.S. Environmental Protection Agency. <http://opim.wharton.upenn.edu/risk/library/2007_EPA-Wharton_RMRule.pdf> accessed 2 August 2016.

⁴⁶ Benneer (n 13).

Another set of concerns about management-based regulation centers on the government's ability to provide adequate enforcement oversight and other incentives for compliance. It is possible that the very same reason that management-based regulation may be attractive to regulators—namely, they lack any clearly effective means and cannot easily test outcomes—may ironically make it more difficult to enforce management-based regulation. Regulators may also need to re-train its inspectors, as the skills for evaluating a robust risk management plan will be different than the skills needed to determine if facilities are operating mandated equipment. These enforcement challenges may contribute to levels of compliance that are deemed to be low. In the area of seafood HACCP regulation, for example, the Food and Drug Administration has reported that a majority of fish processors have failed to develop plans in full compliance with the regulation.⁴⁷ Similarly, the USDA conducted an in-depth study of forty-seven processing plants subject to HACCP requirements and found that the vast majority of those plants (forty-four) were in significant violation of HACCP standards.⁴⁸ The Government Accountability Office (GAO), among others, have likewise reported concerns that food safety challenges persist in select facilities where HACCP-based approaches have been implemented—and that the USDA had not gathered sufficient data to evaluate the performance of this approach over time at select meat processing facilities.⁴⁹

A related concern, as alluded to already, is that firms may have incentives simply to “go through the motions” with management-based regulation, especially if enforcement oversight is weak. Although management-based regulation does present attractive opportunities for firms to use the flexibility afforded to them responsibly to find lower-cost solutions to public problems, these same firms also have opportunities to engage in rote compliance and not search very hard for hidden hazards or solutions to them that would be inconvenient or burdensome. Bridget Hutter found that the British railway services “paid more attention to the letter rather than spirit of the law” when implementing management-based safety regulations.⁵⁰ Similarly, Neil Gunningham and Darren Sinclair found “ritualistic responses or resistant subcultures” at some facilities in their study of the Australian mining industry's response to management-based safety regulation.⁵¹

⁴⁷ Coglianese and Lazer (n 1).

⁴⁸ Ibid.

⁴⁹ United States Government Accountability Office (GAO), 2013. GAO-13-775, *Report to the Chairman, Subcommittee on Livestock, Dairy, Poultry, Marketing and Agriculture Security, Committee on Agriculture, Nutrition and Forestry, U.S. Senate*, <<http://www.gao.gov/assets/660/657144.pdf>> accessed 2 August 2016. However, more recent statistical research indicates that HACCP has contributed to a decline in foodborne illnesses from fruit juices. Travis Minor and Matt Parrett, ‘The Economic Impact of the Food and Drug Administration’s Final Juice HACCP Rule’ (2017) 68 Food Policy 206, 210-11.

⁵⁰ Bridget M Hutter, ‘Is Enforced Self-regulation a Form of Risk Taking?: The Case of Railway Health and Safety’ (2001) 29 Intl J of the Sociology of L 379, 394.

⁵¹ Neil Gunningham and Darren Sinclair, ‘Organizational Trust and the Limits of Management-Based Regulation,’ (2009) 43(4) L & Soc’y Rev 865, 865-900.

A final concern about management-based regulation is that it can be far too burdensome on small businesses.⁵² Large firms will be much more likely to have the capacity for engaging in their own risk analysis and internal planning. Although it is possible that any kind of regulation could contribute to firm consolidation and serve as a barrier to competition, management-based regulation may place disproportionate burdens on smaller firms and exacerbate any potential anti-competitive effects of regulation.

VII. Issues for the Future Study of Management-Based Regulation

We started this chapter by noting that management-based regulation has been used much more frequently than it has been studied. Interest in its role in the regulator's toolkit shows no signs of abating, and the theoretical work on this form of regulation would indicate that regulators' interest stems from management-based regulation's suitability for a range of problems where there exist no one-size-fits-all solutions and where outcomes are difficult to measure. Many problems, especially those with low-probability but high-hazard consequences, fit into this niche. This niche is also one for which it happens to be difficult to evaluate management-based regulation's impact, for it is difficult to evaluate any regulatory intervention's impact in addressing problems that occur only infrequently. In short, the very same challenges that might appear to justify regulators' interest in management-based regulation, namely its availability when outcomes are difficult to assess, will invariably present a challenge to researchers seeking to evaluate management-based regulation's efficacy.

In addition to the need for additional research on management standards' impact on regulatory outcomes, three related issues constitute worthwhile avenues for future research. First, given the various design choices available to regulators when establishing management standards, future research could do more to illuminate which of these design elements are more important and under what conditions. We know far too little about how management standards get implemented and about whether regulatory authorities find ways to develop the needed human capital to assess quality risk analysis and management planning to determine whether firms are fulfilling their management-based regulatory responsibilities.

Second, most management standards follow a linear, engineering model of how management should function. As illustrated by the examples highlighted earlier in this chapter, most of these standards adhere to a rational, plan-do-check-act model and rely on formal procedures and documentation. But what if 'good management' requires something different than (or in addition to) this kind of engineering tidiness? Robin Ely and Debra Meyerson show how one offshore oil extraction company saw its accident

⁵² Lori S Benneer, 'Beyond Belts and Suspenders: Promoting Private Risk Management in Offshore Drilling,' in Cary Coglianese (ed), *Regulatory Breakdown: The Crisis of Confidence in U.S. Regulation* 49-67 (Univ of Pa Press 2012); Richard Hyde, Amy Bryce Hoflund, and Michelle Pautz, 'One HACCP, Two Approaches: Experiences with and Perceptions of the Hazard Analysis and Critical Control Point Food Safety Management System in the United States and the EU' (2014) 48(8) Admin & Soc'y 962-987.

rate decline by eighty-four percent following the introduction of an intensive sensitivity and communication training for its workers that helped them break down some of their gendered patterns of behavior.⁵³ Perhaps interventions along these lines would do more to improve management and the attainment of regulatory goals than mandating the implementation of formal management ‘systems.’

Finally, researchers would do well to investigate how well management-based regulation scales up and down, and how well it works when adopted voluntarily by the private sector. We know too little about how management-based standards established by nongovernmental institutions fare compared with binding management-based regulations established by governmental authorities. We should also await insights from how the Paris Agreement works in order to understand better the potential for management-based global governance strategies. The international agreement reached in Paris in late 2015 has been heralded as a breakthrough due to its ‘bottom-up’ approach that parallels management-based regulation.⁵⁴ It will require some time to see how well this approach works at the global scale, but fruitful avenues for future research may only increase to the extent that other international agreements also follow a management-based model.

Conclusion

Management-based regulation has been relatively overlooked in the literature on regulatory instrument choice, but given that it is being applied in practice to address important and diverse public problems, researchers should pay more attention to it. Existing research shows why regulations that call for internal analysis and planning are likely to be an appropriate response to some of the most vexing problems that other regulatory approaches are unable to address, including those where there exist no one-size-fits-all solutions and where it is difficult to assess outcomes. Research also reveals the range of important design choices that call for regulators to take into account firms’ existing incentives for planning and implementation, as well as to consider other factors likely to affect management-based regulation’s effectiveness. In the end, management-based regulation has been demonstrated to make a positive difference in at least some domains, but questions remain about its long-term efficacy, its suitability for smaller firms, and how well its linear and hierarchical approach to organizational management holds up over time.

⁵³ Robin J. Ely and Debra E. Meyerson, ‘An Organizational Approach to Undoing Gender: The Unlikely Case of Offshore Oil Platforms,’ (2010) 30 *Research in Organizational Behavior* 3-34.

⁵⁴ Coglianese, ‘When Management-Based Regulation Goes Global’ (n 33); Coglianese (n 8).