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# Management-Based Regulation: Using Private-Sector Management to Achieve Public Goals

**Cary Coglianese and David Lazer**

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Cary Coglianese

John F. Kennedy School of Government
Harvard University
79 John F. Kennedy Street
Cambridge, MA 02138
(617) 495-1402
Email address: cary_coglianese@harvard.edu

David Lazer

John F. Kennedy School of Government.
Harvard University
79 John F. Kennedy Street
Cambridge, MA 02138
(617) 496-0102
Email address: david_lazer@harvard.edu

**Management-Based Regulation:**
**Using Private Sector Management to Achieve Public Goals**

Cary Coglianese[*]
David Lazer[**]

All regulation seeks to modify the behavior of private actors in ways that meet public goals. Regulation may be needed to correct failures in the market, such as where monopolies exist, information is scarce, or there are externalities or commons problems (Komesar, 1994; Viscusi, Vernon & Harrington, 2000; Sunstein, 1989). In these areas regulation can be used to correct deficiencies in the marketplace. The last several decades, however, have witnessed an increasing awareness of the costs that regulation imposes on society, with resulting efforts to move away from traditional command and control regulatory strategies that command firms to use specified technologies or processes that governmental decision makers believe will achieve social goals. Market-based regulatory approaches, aimed at providing incentives to regulated parties to achieve socially-desired goals, have received much attention in recent years. In this paper we identify another rapidly emerging regulatory strategy that we label "management-based"

[*] Associate Professor of Public Policy and Chair, Regulatory Policy Program, Center for Business and Government, John F. Kennedy School of Government, Harvard University.

[**] Assistant Professor of Public Policy, Center for Business and Government, John F. Kennedy School of Government, Harvard University.

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regulation. Management-based regulatory strategies shift the locus of decision-making from the regulator to regulated firms by requiring firms to do their own planning and decision-making about how to achieve public goals.

Management-based approaches to regulation are currently being pursued or considered for application in the areas of food safety, occupational health, environmental protection, and other regulatory areas. These efforts have largely arisen independently, and this paper represents an initial effort to analyze the potential of management based regulation. In particular, we examine whether this approach overcomes some of the well-known weaknesses of command and control and market-based approaches to regulation, focusing, in particular, on the substantial enforcement challenges that management-based regulation can pose.

In the first part of this paper, we begin by reviewing some of the generally-accepted limitations of conventional regulatory strategies and develop an analytical framework for deciding when to use management-based regulation as opposed to technology-based or performance-based regulation. In the second part of the paper we develop further the enforcement strategies needed to make management-based regulation an effective regulatory approach. In the third part, we illustrate the application of management-based approaches with examples of government programs that have been adopted in three areas: food safety, chemical accident avoidance, and pollution prevention. In the final part, we assess the promise of management-based regulation and highlight key issues involved determining how it can best be deployed as an effective government strategy.

## I. The Potential for Management-Based Regulation

Regulation may intervene at one of three stages of the production process: at the planning, processing, or output stages. [1] Outputs may include both private and social goods— that is both saleable products or services (private goods), as well as positive and negative externalities (social goods and bads). Social goods include the traditional notion of public goods (e.g., clean environment) as well other cases of "market failure" (e.g., worker safety). The regulatory challenge is that private actors will tend to underproduce social goods, and there is thus the need for the regulator to intervene.

Clearly, the ultimate goal of all regulation is to change the production of outputs; however, intervention at any of these stages will potentially affect outputs. Traditional regulatory approaches intervene in the process stage, specifying technologies to be used or steps to be followed. Performance-based approaches, including market-based strategies, intervene at the output stage. Management-based approaches, in contrast, intervene at the planning and process stages. The question we address in this part of the paper is under what circumstances should the government use which approach, and, in particular, under what circumstances might a management-based approach be effective.

[FIGURE ONE HERE]

[1] Gunningham & Grabosky (1998) also refer to three types of regulation which track the typology we employ here, though they use the phrase "design or specification standards" to refer to what we call technology-based regulation and "process-based standards" to refer to management-based regulation.

The optimal location for the government to intervene in the production process, we argue, is a function of the transaction costs associated with intervention at a particular stage of the production process. Just as in a world where there are no transaction costs in the market there are no market failures, in a world where the government faces no transaction costs, there are no government failures (Komesar, 1994). If technology-based regulation were used, the government could craft an infinitely detailed regulation, where each technological requirement was delicately balanced as to the benefits and burdens imposed on society and where regulatory change was appropriately elastic in the face of new technological developments. If performance-based tools were used, the government would precisely determine the social costs of particular outputs, impose the appropriate tax (or industry-wide quota for a trading system), and business would effortlessly adjust internal processes to internalize these costs. And if management-based tools were used, government would easily evaluate the planning and subsequent implementation of controls on the production of social goods and bads by private actors.

Of course, we live in a world where both government and market face substantial transaction costs, inevitably resulting in government and market failure. What, then, is the ideal regulatory instrument? The answer must lie, in part, with where the transaction costs in government and market are. Our first working assumption is that the transaction costs for market actors to understand the linkages between process and outputs is at least as good and usually better than government actors. That is, we assume that it is easier for a market actor to determine the ideal output of social goods than the government.

This assumption, by itself, does not determine the choice of instrument, since market actors do not have the motivation to incur transaction costs to achieve social

goods nor to reveal their superior knowledge of the relationship between process and outputs (Ayres & Braithwaite, 1992). The key question is then whether the state take advantage of the lower transaction costs that private actors face in evaluating the ideal output of social goods to regulate where traditional regulatory approaches yield transaction costs greater than net social benefits? This question, we would argue, turns on how good is the state at determining outputs, what the process is, and the linkage between process and output, and input and output.

Consider, then, two dimensions that track the transaction costs of government intervention at these three stages (Figure 2). The first dimension is how capable the government is at evaluating the social outputs of a private party. By "evaluating social output" we mean that the government is able to tangibly measure outputs and to evaluate their social impact. For example, in the environmental area this would mean that the government is able to measure emissions and evaluate the health impact of those emissions.[2] When ease of measuring social output is high, we are assuming that the government can cheaply measure and evaluate social outputs. The second dimension is the heterogeneity of regulated parties. We define heterogeneity as encompassing both location and time. For a sector to be homogeneous it means that (1) at a given point in time that most industry actors have very similar operations and (2) the technology used by industry actors is stable. Below we discuss the relationship between these two dimensions of "governance transaction costs" and the choice of regulatory instrument.

[2] This incorporates cases where the regulator can accurately project social outputs based on process. For example, in the case of CO2 emissions, it is possible to project how much CO2 will be emitted based on particular inputs. It is therefore not necessary to have CO2 detectors to measure CO2 emissions—it is only necessary to measure particular inputs.

[FIGURE 2 HERE]

*Technology-based regulation*. Traditional command-and-control regulation consists of government-imposed rules requiring that firms adopt specific technologies or methods designed to promote social goals such as environmental quality, worker safety, or consumer protection. Although technology-based regulation has been effective in correcting certain market failures, it has become increasingly accepted that these regulatory approaches suffer from their own kinds of failures. Technology-based regulation is often either over or under inclusive, meaning that uniform standards sometimes require too much in areas where the costs of regulation exceed the benefits, or too little in areas where the benefits of regulation would outweigh the costs (Hahn, 1996).

A dynamic analysis reveals further disadvantages to technology-based approaches. Regulation which imposes requirements for specific technologies may eliminate incentives for firms to seek new technologies which better achieve public goals. Thus, even if at time t = 1 a technology-based regulation achieves a large overlap in figure 1, the future may reveal a decreasing overlap as compared to a counterfactual where firms had an incentive to improve performance. In short, the more heterogeneous and dynamic a sector, the more acute the over and under-inclusion disadvantages of a technology-based standard.

*Performance-based regulation*. An alternative regulatory approach that provides such an incentive is performance-based regulation—i.e., regulation aimed directly at the output of social goods and bads of a firm. Performance-based regulation may be grouped

by performance standards and by incentive-compatible or market-based approaches. A performance standard will specify the level of performance required of a firm, but does not specify how they achieve that level of performance. Thus, for example, a regulation may limit exposure of workers to particular hazardous chemicals, but not specify how those exposure levels are achieved. Such an approach would provide firms an incentive to find ever less costly ways to achieve these performance levels, but does not provide an incentive to exceed those performance levels even if there were a net social benefit to doing so. Further, performance standards will not equilibrate the marginal benefits to achievement of social benefits to marginal costs of achievement of social benefits because of the heterogeneity of sites. That is, there are still potentially major over and under-inclusion issues with performance standards.

Market-based approaches, in theory, will result in such an equilibration (Hahn & Hester, 1989; Stavins, 1998; Tietenberg, 1990). Market-based instruments, such as tradable permits or emissions taxes, seek to make use of market dynamics to overcome the limitations of both technology-based and static performance-based regulation. They either create internal costs through taxes to match the external costs of production, or they create a market in rights to engage in socially costly behavior (such as pollution). Thus, the production of "social goods" will shift to those firms for whom it is cheapest to produce those goods. Dynamically, these methods give firms the flexibility and incentive to, over time, increase the level of production of social goods at lower cost.

Our assessment is that performance-based regulation, especially performance-based regulation that employs market-like incentives, dominates the alternatives when it is easy to measure output. Further, as heterogeneity of regulated sectors increases, and it

becomes more difficult to regulate process or technology, performance-based regulation may be desirable even when measuring output becomes relatively more difficult or costly.

Under these circumstances, in short, there is a clear division of labor between government and private actors. The government determines the social value of the outputs of private parties and structures incentives of the private parties accordingly. The private parties then engineer their processes accordingly.

Although market-based performance regulation may approximate the theoretically ideal form of regulation, these approaches have proved to be politically difficult to create and probably will be still more difficult to expand into new areas.[3] Further, and most critically, it is often difficult or prohibitively expensive to measure critical outputs (Ayres & Braithwaite, 1992). For example, in food safety, sensory inspection ("poke and sniff"), as discussed below, does not detect many important contaminants, and it is impractical to sample enough of a shipment of food to accurately measure contamination. Thus, as one moves in figure 2 from the case where it is easy to measure output to difficult, performance-based strategies become less desirable.

As noted above, under circumstances where the regulated sector is homogeneous and it is not practical to measure outputs (lower right quadrant), it should be possible to cheaply produce a technological standard based on "best practices." The most difficult regulatory scenario the government faces, however, is when it is not capable of measuring output, nor can develop a "one-size-fits-all" technology-based standard due to industry heterogeneity.

[3] For a discussion of the political economy of market-based regulation, see Keohane, Revesz, & Stavins (1998).

*Management-based regulation*. The most challenging regulatory scenario is where it is difficult to measure social outputs -- making performance-based regulation impractical -- and heterogeneity is high -- making technological regulation ineffective. This is the case where there is a general understanding of how to achieve those social objectives, but exactly how to do that in particular situations depends on contextual factors. It is in this case where we would argue that there is a theoretical justification for management-based regulation: where the government (1) lays out criteria for planning, as well as general parameters for process; and (2) certifies (and enforces) private behavior consistent with these processes. That is, as one moves from the lower right-hand quadrant to the lower left-hand quadrant of figure 2, the larger becomes the informational advantage of firms, and the greater the potential social benefit to granting firms greater flexibility in how they achieve the regulator's goals.

In management-based governance, firms are required to produce plans that comply with general criteria outlining how to achieve the public goals in question. These plans may be subject to approval by regulators, and sometimes are even developed with their assistance. These plans generally require firms to produce documentation of subsequent compliance and third-party auditors or periodic audits by regulators can be used to certify compliance.[4]

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[4] Management-based regulation bears certain affinities to what Ayres and Braithwaite call "enforced self-regulation." (Ayres & Braithwaite, 1992: 102-108). See also Rees (1988) for an earlier discussion of mandated self-regulation. A good management system within a firms will surely generate internal rules and procedures to be followed. As such, much of the discussion in the literature of enforced self-regulation applies to what we mean by management-based regulation. However, enforced self-regulation, at least as Ayres and Braithwaite (1992: 131) describe it, has companies drafting their own rules which the government ratifies and then enforces as it could any law. In this way, their particular approach seems closer to one of regulatory covenants or contracts, rather than to requirements that firms develop plans and management systems -- which in many settings need not be approved in advance by government and do not directly take on the force of law. For those familiar with recent innovations in environmental regulation, the notion of enforced self-regulation seems to us to more closely to resemble the model used by US EPA

Management-based approaches hold a number of potential advantages over traditional regulation. They place the locus of regulatory decision-making at the level with the most information about processes and potential control methods. Thus, the behavior that firms adopt under a management-based approach has the potential to be less costly and more effective than they would be under cruder, government-imposed technology standards. (Ayres and Braithwaite, 1992: 110-111).

Moreover, by placing the locus of standard-setting authority at the firm level, it can be expected that there will be a greater "buy-in" from firm management, which should lead to greater compliance with the standards and which could eliminate certain barriers to "beyond compliance" behavior (Ayres and Braithwaite, 1992: 113, Coglianese & Nash, 2001: 10-11).[5] It is well recognized that government enforcement resources are inadequate to ensure thorough oversight of regulated firms. Hence, much compliance with government regulation is, in a sense, already voluntary compliance, since in many cases the probability of a violation being detected is low.[6] Management-based regulation may be able to overcome this limitation somewhat both by enlisting the assistance of private, third-party certifiers, as well as through the potential "buy in" effect that comes from firms creating their own standards. Firms are likely to see their own standards are

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in Project XL, through which EPA negotiated separate regulatory agreements and site-specific rulemakings with individual firms (Orts & Deketelaere, 2001). The closer analogy to what we mean by management-based regulation might be the environmental impact assessment requirements imposed on government agencies under NEPA (Taylor, 1984).

[5] This fits more generally with management strategies that leave in which goals are specified from above but with discretion over means, so as to take advantage of knowledge and abilities regulated parties have over the best ways to achieve those objectives (Hackman, 1990).

[6] Enforcement, after all, is almost always “incomplete” (Viscusi & Zeckhauser, 1979: 437-456).

more reasonable and legitimate, therefore being less resistant to compliance (Kleindorfer, 1999).

Finally, by giving firms flexibility to create their own regulatory approaches, management-based approaches can promote innovation and social learning. The ISO standards governing environmental management systems, for example, require firms to deliver continual improvement, holding forth the prospect that these firms will have an incentive to seek out innovative solutions that actually go beyond compliance with existing environmental regulations. The potential for diverse approaches to achieving regulatory goals will allow for experimentation, which can lead to solutions that government standard-setters perhaps would never have even considered.

## II. Enforcing Management-Based Regulation

The informational advantage of the firm, however, is only part of the condition necessary for the success of management-based regulation. The other part is overcoming principal-agent concerns in regulating firm behavior. By shifting the locus of decision-making to the firm management-based approaches by themselves do not provide sufficient incentives for firms to incur costly changes that might be needed to achieve social goals. The critical question is how are the incentives confronting the firm restructured so that they better take into account the public's interests in their behavior? This will turn on the government's capacity to influence behavior that we are assuming that it does not well understand and cannot easily measure. Below we outline a two-stage model of enforcement, incorporating parameters that capture the regulator's capacity to

alter a firm's incentives to incorporate public goals in its planning and subsequent implementation process.

We begin by assuming that from the firm perspective management-based regulation has two stages: planning and implementation (Figure 3). The government has some capacity to monitor whether a firm plans according to stated criteria, and then some capacity to monitor whether the firm has implemented. Assume the following: the expected value of the penalty for not planning (and not implementing) is p1; the penalty for planning and not implementing is p2; the cost of implementation, known at stage I, is $c_p$ (< 0); and there is a payoff from implementation of the plans developed of M, which is not known until stage II, but where the expected value of which, E(M), is known at stage I. Thus, the firm makes a decision at stage I based on p1, p2, $c_p$, and E(M), and at stage II based on p2, $c_p$, and M.

[FIGURE 3 HERE]

What implications can be derived from the above model for enforcement strategy on the part of the government? There are four cases possible under this model, ranging from no enforcement needed to enforcement of both the firm's planning and implementation of its plan.

*Case I: No enforcement necessary*. First, there is a subset of cases where, even if fines were set to 0, that firms would still "regulate" themselves. That is, where $E(M) + C_p > 0$ and $M + C_p > 0$, firms will voluntarily develop and implement plans to produce social outputs. This is the theory underlying voluntary environmental management standards,

such as ISO 14001, under which firms develop planning to evaluate where waste occurs in the manufacturing process on the premise that pollution can be indicative of inefficient processes.

This first category is not significant from a regulatory standpoint, because, by definition in these cases no regulation would be necessary at all. However, noting this case highlights the large leap from voluntary management standards to mandatory standards. Voluntary standards are actually managerial innovations that further the private interests of private actors (e.g., where environmental management that leads to less pollution leads to less waste—see Porter & van der Linde, 1995). Success may indicate the potential of such programs to achieve public goals, but does not demonstrate that *mandatory* programs will reach this potential. The only way to reach this potential is to overcome the enforcement challenges in cases II, II, and IV.

*Case II: Enforcement necessary at planning stage*. Second, where $E(M) + C_p < 0$ and $M > 0$, the state needs only to enforce at the planning stage (i.e., set $P1 < 0$, and $P2$ to 0). This is the case where the planning process is expensive, and where the procedures developed yield some benefits to the firm (as well as to the public), but where the costs to the firm of planning exceed the benefits from implementation. Thus, if the regulator is successful in pushing the firm to study the problem, the firm will then "self-regulate" because its interests will coincide with the public's.

*Case III: Enforcement necessary at implementation stage*. Where $E(M) + C_p > 0$ and $M < 0$, the state needs only to enforce implementation (i.e., set $P1$ to 0, and $P2 < 0$). This is the case where the firm would expect gains from planning and implementation, but upon planning finds that implementation is more expensive than it expected or the

private benefits smaller than expected. In this scenario, the firm presumably plans without government incentives to do so, but then needs to be pushed to follow through.

*Case IV: Enforcement necessary at planning and implementation stage.* Where $E(M) + C_p < 0$ and $M < 0$, the regulator needs to enforce at both the planning and implementation stages.

Cases II, III, and IV raise the question of the government's relative capacity to monitor planning and implementation, which, in turn, will dictate if and when management-based regulation is an effective regulatory approach.

If the enforcement challenge falls into case II, it may be satisfactory for the regulator to simply be able to evaluate the expense and effort that the firm took in examining certain processes. Thus, for example, if the firm hires individuals with particular training, and has studied the causes of certain types of waste in its process, then it is likely that an improved process will naturally follow.

The enforcement challenges of cases III and IV blur together, in that in case III the private actor knows what is the "right" thing to do but will hide it from the regulator, and in case IV, the private actor does not know what the right thing to do is. A key challenge in enforcement is to translate fuzzy and flexible standards into bright line rules for the purposes of assessing violations. This is a particular challenge for evaluating the planning that a firm does, because once the firm creates a plan, it creates its own standards for the implementation stage. Should private plans be directly enforceable by the government, this may increase the likelihood that private firms will hide knowledge from the government and adopt plans they know are less than optimal.

Key to the success of management-based regulation, therefore, is for the regulatory regime to lay out parameters for acceptable plans and resulting processes.[7] For example, with food safety it may be virtually impossible to process meat safely without monitoring the temperature that the meat is stored at. A process that did not incorporate that feature would necessarily be unacceptable. It will sometimes be possible for the government to lay out a set of parameters that are important for any effective private response and are easy to enforce, yet which permit an enormous variety of processes and allow for continued innovation to achieve regulatory goals more cost effectively.

Management-based regulation, however, confronts twin dangers. On the one hand, it may be tempting for government to make its parameters so specific, in which case management-based regulation is reduced to technology-based regulation, and perhaps an ineffectual technology-based regulation at that. On the other hand, the parameters government selects may be so general that it may prove to be too difficult for enforcers to monitor in a non-arbitrary way.[8]

## III. Applying Management-Based Regulation

Despite the tensions inherent in designing and enforcing management-based regulation, government is increasingly relying on management-based strategies to address

[7] Moreover, the enforcers could well be independent, private auditors, rather than government officials, which creates another layer to the agency problem. In such cases, government would need standards that are adequately specified for it to oversee the overseers.

[8] Of course, the problem of specificity is not limited solely to management-based regulation. See Bardach & Kagan, 1982; Diver, 1983: 65.

a range of regulatory problems. In this part, we examine the application of management-based regulatory strategies in the areas of food safety, chemical accident avoidance, and pollution prevention. The following illustrations reveal not only the characteristic features of the emerging management-based strategies, but also how the issues we have discussed in this paper resonate with the experience to date with management-based approaches.

*Food safety*. Ensuring the safety of foods has long been a major government responsibility. In the U.S., the federal government's involvement in the regulation of food safety dates to the early part of the twentieth century when public outrage emerged over the slaughterhouse conditions described in Upton Sinclair's *The Jungle* (Albert, 1991). At that time, the Congress adopted the Federal Meat Inspection Act (FMIA), giving the United States Department of Agriculture (USDA) regulatory authority over most meat and poultry products, and the Pure Food and Drugs Act, which charged the Food and Drug Administration (FDA) with the regulation of the safety of most other food products (including fish). The FMIA requires USDA to provide continuous inspection of meat processing plants. USDA inspectors must conduct an on-site inspection of every slaughtered animal and maintain a "continuous inspection" presence in meat processing plants to verify sanitary plant conditions throughout the production process, an inspection regime commonly referred to as "poke and sniff" because of the methods inspectors use for identifying detectably diseased carcasses.

Since the early 1900s, animal husbandry techniques have improved and the risk of animal diseases has decreased. However, new challenges have emerged for food safety (USDA, 1995). A variety of processed foods have become popular and new production

processes have placed new demands on inspectors' time. In addition, heightened public expectations and the new processing methods have led to increasing attention to microbial food contamination. In particular, the newer processing techniques have made food contamination harder to detect by the traditional "poke and sniff" methods. The U.S. Centers for Disease Control estimates that about 5,000 deaths each year and 76 million illnesses are linked to food safety concerns (Mead, Slutsker, Dietz, McCaig, Bresee, Shapiro, Griffin & Tauxe, 1999).

In response to these challenges, regulatory authorities around the world have developed an alternative regulatory strategy called HACCP, for *H*azards *A*nalysis and *C*ritical *C*ontrol *P*oints. HACCP requires firms to evaluate, monitor, and control potential dangers in the food-handling process. It is, in short, a form of management-based regulation. In 1997, the USDA issued new regulations requiring meat and poultry processing firms to undertake several management steps so as to reduce the incidence of food contamination.[9] The steps include (1) a rigorous hazards analysis of risks at every stage of production; (2) identification of critical control points (CCP's)—points in the production process at which hazards identified at the first step can be managed; (3) establishment of critical limits for each CCP at which the point must be controlled in order to eliminate the hazard; (4) a system to monitor CCP's; (5) corrective actions if a critical limit for a CCP has been exceeded; (6) continuous validation of the selection of CCP's and critical limits; and (7) documentation of implementation of HACCP plan.

HACCP first requires firms to identify the potential hazards associated with all stages of food processing and to assess the risks of these hazards occurring. Food

[9] In addition, the Food and Drug Administration has imposed similar HACCP requirements on other food producers, and globally HACCP has become a well-accepted regulatory strategy for addressing food safety.

processors are expected to use a flow chart to aid them in analyzing the risks at every stage of production, including before and 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," or points in the production process at which hazards can likely be eliminated, minimized, 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 minimize the hazard.

Having developed a methodology for dealing with hazards, the firm must 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 expected to develop a methodology for evaluating the validity of the HACCP itself. The plan must implement supplementary procedures and tests designed to establish that the HACCP is working effectively. The firm is required to undertake ongoing validation activities, which might include calibration of process-monitoring equipment, direct observation of monitoring and corrective actions, and continuing

records review. The HACCP system also requires reassessment of the plan as a whole at regular intervals, at least annually.

Finally, in order to permit effective self-evaluation and government oversight, HACCP imposes a record-keeping requirement on firms. To document their HACCP systems, USDA-regulated meat and poultry firms are required to maintain: a full, written HACCP plan; records of the monitoring data on CCPs; documentation of verification and corrective actions; and a signed affirmation that all critical limits have been met before products are shipped.

The Food Safety Inspection Service (FSIS) of the USDA verifies the firm's compliance with HACCP requirements. The FSIS has the right to review the HACCP plan and all records pertaining to it. In addition, it may also collect samples and make its own direct observations and measurements. Firms need not get the FSIS' pre-approval for their HACCP plans, although they may be found noncompliant if their plans fail to meet the requirements described above, or if they result in the production of adulterated products.

To help persuade firms that they are best qualified to make many crucial risk management judgments, regulators provide substantial latitude throughout the framework created by the HACCP regulations. The regulations give only examples of possible hazards, they do not require the selection of any particular points as CCPs, and they direct firms to choose for themselves what limits to set on the CCP (within the constraints of existing law and regulation). However, regulators have produced guides that describe how to develop HACCP plans, and inventory important hazards and how to control them. While these guides do not carry the weight of law, presumably they indicate how the

regulator will use the substantial discretion they are given with HACCP, and this places a burden on firms to justify deviations.

*Avoiding Chemical Accidents*. As with food safety, government has an important role to play in promoting the safe handling of toxic, reactive, and flammable chemicals. One of the most tragic disasters occurred in Bhopal, India in 1989, where more than 2,000 workers and community members died as a result of a chemical accident at a Union Carbide facility. In that same year, a chemical accident at a plant in Pasadena, Texas resulted in 23 fatalities and more than a hundred injuries. Smaller accidents have occurred elsewhere, causing injury and death to workers and members of the public as the result of accidental releases or improper mixture of hazardous chemicals.

Following the Bhopal catastrophe, regulators in the United States began to consider new strategies for reducing the risk of chemical accidents. In 1990, the Occupational Safety and Health Administration (OSHA) announced that it was considering a new federal regulation governing the management of chemical processes. OSHA's proposed approach would establish standards for "process safety management" of highly hazardous substances. That same year, Congress adopted new amendments to the Clean Air Act which required the Labor Department (through OSHA) to finalize a set of regulations designed to protect workers from chemical accidents. The Act specified that OSHA develop a list of toxic, flammable, reactive, and explosive chemicals, and then that it develop a series of management practices that firms using specified levels of such chemicals must implement.

The regulation OSHA adopted in 1992 imposed management standards on firms across the entire economy, from manufacturing firms to chemical and pharmaceutical

firms, from the petroleum industry to public wastewater treatment facilities (OSHA, 1992). Much like with HACCP, the process safety management regulation requires 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.

The core of OSHA's process safety management protocol is a "process hazard analysis." Firms must undergo an extensive analysis of what could potentially go wrong in their facilities' processes and what steps must be in place to prevent such accidents from occurring. OSHA defines "process" broadly to mean any use, storage, handling, or manufacture of such chemicals at a site. Each such process must be analyzed separately, and then firms must rank each 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, OSHA requires that firms 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 well-positioned to make modifications that can improve worker safety.

OSHA's standard is designed primarily to protect workers from the hazards of chemical accidents. The U.S. Environmental Protection Agency (EPA) has adopted a similar management-based regulation designed to protect the broader public from the accidental release of hazardous chemicals. EPA's risk management program covers an even larger number of facilities nationwide. Like OSHA, EPA requires firms that use specified toxic or flammable chemicals to conduct a hazard analysis, establish a management plan to prevent accidental releases, and a plan for responding to emergencies (Jordan, 1997). Indeed, there is a considerable overlap between OSHA's requirements and EPA's. As a result, both agencies have coordinated their programs so that firms covered by both regulations are able to implement a single management system that satisfies both agencies' requirements.

The EPA and state environmental agencies are authorized to make unannounced inspections of facilities to determine whether firms have developed risk management plans consistent with EPA's regulation and whether firms have followed their own plans. EPA has also recently experimented with the use of private, third party auditors to ensure compliance with its management-based requirements (Kunreuther, 2001).

*Pollution Prevention*. Conventional regulatory efforts have aimed to reduce overall levels of pollution produced by firms. In the United States, these efforts have taken the form of a series of major environmental statutes and thousands of additional pages of federal and state regulations. Much of the existing system of environmental regulation depends on technology-based standards and on the permitting of individual

facilities by state agencies that firms meet these requirements. Although these conventional regulations have significantly reduced the levels of certain pollutants (USEPA, 2000), other environmental concerns continue to persist. Moreover, by establishing specific technological requirements, existing regulation may discourage innovation and the diffusion of alternative means of improving environmental quality. In particular, firms that are required to invest in particular control technologies may come to rely on these technologies to reduce pollution, to the exclusion of other manufacturing or process that would actually reduce the amount of polluting chemicals used in production.

The federal EPA and a number of state environmental agencies have adopted a variety of voluntary efforts to encourage firms to engage in "pollution prevention," or specifically to reduce their overall use of toxic chemicals. A few states have gone still further to impose requirements on firms to manage their operations in such a way as to achieve reductions in the use of toxic substances. The Massachusetts Toxic Use Reduction Act (TURA) represents one such effort at management-based regulation.[10] TURA requires firms that use large quantities of toxic chemicals to analyze 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 each plan be certified by a state-authorized pollution prevention planner. 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. Moreover, firms' plans are considered proprietary and are therefore not made available to the public, thus putting to the side possible community pressures that publicly available plans might

have generated. Nevertheless, the program aims to encourage firms to make gains in terms of pollution prevention by being forced to go through the required planning process. This particular program fits with case II as described in Part II of this paper, and achieves public gains only if, once firms have conducted their planning process, their private interests are well-aligned with the interests of the public.

## IV. Assessing Management-Based Regulation

The three programs described above represent innovative approaches to addressing regulatory problems and may well represent an important regulatory strategy for the future. Each program adheres to the basic characteristics of what we have called management-based regulation. They all direct firms to conduct analysis and planning directed toward public goals. The food safety and chemical accident programs also require firms to carry out the plans they have adopted and to audit themselves to assure compliance with the required management plans.

Each of these programs also responds to public problems which have the characteristics we discussed in part I, namely problems over which regulators confront significant difficulties in measuring outputs and where firms are too heterogeneous to make technological standards feasible. In the food safety area, the traditional model of sensory detection ("poke and sniff") of contaminated meat has proved ineffective at detecting microscopic contamination. The obvious alternative is to take samples from the final product of the handling process and test them at a laboratory, yet this takes time to achieve results and perishable products often must be shipped out before the results could

[10] Mass. Gen. Laws ch. 21I (1994 & Supp. 2000).

be received. Of course, in the area of chemical accident prevention, no simple laboratory test of any kind has yet to be devised to test for the safe handling and storage of chemicals.

The most significant challenge in all of these cases comes about from the large number of sources of hard-to-detect risk. Even with substantially greater inspection resources, government agencies would be hard pressed to identify and test for all of the invisible risks that foods might face in the large number of facilities that process food, or all the potential sources of risk of chemical accidents, or all the ways that pollution prevention could be achieved. OSHA's process safety standard governs more than 25,000 facilities nationwide, and EPA's risk management plan requirement affects more than 70,000 facilities. Firms themselves are likely to know more about the unique risks of their products and processes, and probably are in a better position to judge where and when public risks are likely to result from their processes.

The large number of firms covered by these regulations by itself suggests that the regulated population is also extremely heterogeneous. As the FDA noted in a recent rule implementing HACCP in the area of fruit juice safety -- certainly a relatively narrow industrial sector -- "[e]ven when producing comparable products, no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities."[11] The USDA exercises jurisdiction over producers of products ranging from milk to meat-topped pizza to uncooked ground beef to processed egg products (Taylor, 1984: 18-20). Even more extensive variation in the types of facilities and processes can be found in addressing chemical accident prevention and toxic use

[11] Federal Register: January 19, 2001 (Volume 66, Number 13): 6141.

reduction. Each of the three regulatory arenas described above encompass a sweeping array of firms that employ many different combinations of technologies, processes, resources, constraints, and conditions. Inevitably many firms will have, but the government will lack, an everyday knowledge of how a particular step in the process could go wrong, and the likely effects of a change in technologies on the cost and speed of the production line. Firms know something about the vulnerabilities of their personnel and equipment, and they may understand their own processes at a level of detail that allows them to foresee risks that an agency inspector would easily miss. Furthermore, plant conditions are always subject to abrupt changes and firms are better situated to identify those changes and adapt to them.

The critical question regarding management-based regulatory approaches is whether they can overcome the enforcement challenges outlined in Part II of this paper. Recall that we began there by assuming that firms will underinvest in safety measures absent government intervention. In the food safety area, new regulations grant inspectors access to essentially all records related to the HACCP, including the firm's choice of CCPs, its plans of action to ensure that safety is maintained at each CCP, and the records indicating whether the CCP has exceeded the critical limit.[12] Furthermore, regulators may evaluate the processes that it actually observes. The same is true for OSHA's and EPA's regulations aimed at preventing chemical accidents and releases.

Are regulators competent enough to evaluate the quality of firms' plans? Clearly, they can judge whether firms meet the broad constraints they lay out, but it is less clear

[12] 9 C.F.R. § 417.6; 21 C.F.R. § 123.10. There is some question as to whether agencies have legal authority to grant themselves access this broad. See Stephen H. McNamara, "A Legal Assessment of FDA's New HACCP Regulations," 52 Food Drug L.J. 39, 39-45 (1997).

how well regulators can evaluate whether firms take costly actions to "optimize" within those constraints. This is particularly the case when regulators rely primarily on the paperwork trail that a firm's management system generates. For example, under one of its HACCP programs, the FDA inspects fish processors only once a year, examining their plan, their records, and the actual process associated with only a single product line (usually one of the high-risk product lines). What this inspection process does not reveal is the effectiveness of the HACCP plans of non-inspected product lines. It also does not directly reveal whether the firm carries out its plan in the various contingencies specified in the plan that do not occur while the inspector is watching. Instead, inspectors must rely on the firm's records of what occurred. This leads to the question of whether firms will maintain an accurate record of their actions in those instances where damaging information may lead to the agency penalizing the firm.[13] One critic of HACCP warns that firms have little reason not to falsify records, particularly in the absence of whistleblower protections or other incentives for someone knowledgeable to verify what went on in the production line (Lassiter, 1997: 444-456). Even if firms are not outright untruthful, they would probably do themselves little good by including in the plan any hazards that an inspector is unlikely to spot on her own, particularly if these cannot be resolve cheaply. Management-based regulatory strategies are designed to incorporate a firm's specialized expertise in its product and processes into the safety plan, and yet the

[13] A similar problem occurs in the area of environmental management systems, such as ISO 14001, where internal plans and audit documents could potentially be used against a firm in an enforcement action. Government has responded to try to assure firms that environmental auditing documents will generally not be used against a firm (Coglianese, 2001).

very instances in which a firm's expertise would help it to identify hidden hazards are the ones in which the firm has the least incentive to do so.[14]

How have management-based strategies worked? The US only implemented HACCP programs in 1997 and 1998, and consequently the available data on their success is limited but also mixed. The USDA has sampled the incidence of Salmonella in the meat it inspects before and after it implemented its HACCP program, and has found dramatic reductions of Salmonella prevalence in poultry, beef, pork, and turkey (USDA, 2000). The ultimate metric for evaluating the success of HACCP is the incidence of foodborne illness. CDC surveillance data are ambiguous as to whether there is a downward trend in the incidence of foodborne illnesses.[15] The incidence of salmonella, for example, was 17% less in 2000 than in 1996—a non-trivial decline if not as large as the declines reported by USDA. However, this decline has not been a result of a year to year monotonic decrease, so it may just be a downward blip. Further, the dangerous E. coli actually had a higher incidence in 2000 than in 1996.

The data for the other applications of management-based regulation are also somewhat mixed. There is widespread acceptance that OSHA and EPA's chemical accident prevention programs have resulted in improved safety practices. An analysis of the losses in the chemical industry shows that the amount of damage claims in the industry declined by 40% between 1987 and 1997 (Marsh & McLennan, 1997). These

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[14] However, the food industry as a whole, and its various segments, have some interest in maintaining reputation, so that industry experts might be useful to the FDA in identifying appropriate CCPs and monitoring procedures for a particular type of product. The NAS report suggested the role that industry groups might play in creating processing guidelines, in providing technical input to regulators, and in developing HACCP training programs. (National Academy of Sciences, 1985: 309-10).

[15] Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2000, the MMWR Weekly, Center for Disease Control, April 6, 2001.

regulations have also won support from both industry and unions. In terms of pollution prevention, the state of Massachusetts claims that TURA has been at least partly responsible for a 41% decrease in the use of toxic chemicals by state firms between 1990 and 1999, and an 87% reduction in the a decline of toxic emissions from the state, a reduction that exceeds the national average (Massachusetts, 2001). However, overall many of the states in New England also saw better than average declines in toxic emissions, even in the absence of comparable management-based programs (Karkkainen, 2001).

Nevertheless, the US experience with each of the three programs discussed above provides some indication that a management-based approach can be a viable regulatory strategy. But other evidence suggests the some of these programs, at least as currently implemented in the U.S., may prove to be less than ideal. Critical reviews of the FDA's HACCP program, for example, suggest that the design of a management-based regulatory regime matters just as the design of technology-based and performance-based regimes matters. Unlike the USDA, the FDA inspects the food facilities under its jurisdiction only on an annual basis, which may well be too infrequent. It may be that management-based systems will prove to be more sensitive to the way that firms are monitored and requirements enforced, and more frequent inspections by government or independent third party auditors may well be critical to the success of management-based regulation. Yet management-based regulation need not be perfect to justify adopting it in areas where it is difficult to apply other forms of regulation. Rather, it simply needs to be better than the alternatives. As we have seen, it is difficult to develop standard technologies when facilities are heterogeneous and when contamination or accidents can

occur from practices which have no clear or uniform technological fix. It has also been difficult to apply realistic and effective performance measures in these areas. The test for management-based regulation will be whether it can provide some improvement over alternative regulatory practices.

## Conclusion

We have discussed an emerging approach to regulation called management-based regulation. Management-based regulation shifts the locus of policy design in the pursuit of public goals from the government to private parties. Instead of specifying technology or performance standards, government outlines general criteria for private sector planning and conducts varying degrees of oversight to ensure that firms are engaging in effective planning that satisfies the stated criteria.

We have argued that the preferred point of regulatory intervention in the production process—that is, at planning, implementation or output— will be driven by the transaction costs the regulator confronts in achieving public goals at each of these stages. Performance-based regulation will be effective only where the regulator can cheaply measure output and evaluate its social impact. Technology-based regulation will be effective only where the regulator can cheaply evaluate the relationship between process and output—especially unlikely in heterogeneous or dynamic settings.

Management-based regulation may prove the most effective under conditions where performance-based and technology-based regulation are not feasible. It takes advantage of private actors' understanding of the relationships between processes and outputs, compelling regulated parties to conduct their own evaluations, find their own control solutions, and document all steps taken.

Characterized this way, management-based regulation appears to be a strategy to apply to some of the most intractable regulatory problems. Problems such as worker fatigue, accident prevention, ergonomic injuries, and contamination of food are problems for which government often lacks clear performance measures (short of the dire consequences regulators seek to prevent in the first place). These are also problems for which government is often unable to prescribe uniform technological fixes. These kinds of problems require fine-grained analysis of local circumstances for which it is too costly, if not undesirable for other reasons, for government to provide. Management-based regulation may be the best available approach for government to take in such situations.

However, it should be kept in mind that the implementation of a set of prescribed management processes does not necessarily equate with *motivation* to achieve socially optimal results. Firms may go through the motions or game the system if they lack the motivation or incentive to use the planning process to achieve socially benefits. As we have also argued, management-based approaches still require a governmental enforcement presence to ensure that firms conduct the necessary planning and implement their plans as required. This enforcement challenge may be made more difficult because the same conditions that make it difficult for government to impose technological and performance standards also make it difficult for government to determine what "good management" is.

In this paper, we have identified a new tool in the regulator's toolbox that holds promise for achieving public results, especially in otherwise hard-to-regulate realms. But this approach also raises a series of further theoretical and empirical questions that merit attention by researchers, managers, and policy makers. The first and most important

question is *how well does management-based regulation work in practice under varying conditions*. Compared with conventional regulation, management-based regulation has a limited track record. Moreover, management-based approaches have been applied (appropriately, we think) in situations where performance at the firm level is difficult for regulators to measure. These same difficulties pose challenges for program evaluation and empirical research. Of course, what may be too expensive to measure at the firm level may be possible to measure at the sectoral level, such as through sampling or through measures of public welfare that should be affected by the regulatory intervention (such as public health or environmental contamination).

A second remaining question is: *what type of enforcement regime yields the best compliance?* Different jurisdictions have approached enforcement differently. For example, under their HACCP program, the Canadians conduct *four times* the number of site visits than the US; however, unlike the US, Canada has no employee training requirements (GAO 2001: 43). Following the enforcement analysis earlier in the paper, the US is aiming its enforcement at stage I (planning and investment), and the Canadians at stage II (implementation). The critical question is under what circumstances is which enforcement strategy effective. An additional question about enforcement centers on the circumstances under which the regulators should rely on private certification that an actor is compliant under a management-based regulation. Private certification offers huge potential for regulators to extend their (typically meager) enforcement capacities; however, it also adds an additional level of agency concerns.

A third question is: *what is the optimal interweaving of private and public sectors in management-based regulation?* It is important to consider, for example, what role

industry associations might play in systems of management-based regulation. Voluntary trade-association standards have multiplied in recent years, and have attracted attention as an alternative to government regulation (e.g., Rees, 1997). In principle, trade-association standards may embody any of the three types of approaches we summarize here; however, some of the more prominent examples, such as the chemical industry's Responsible Care initiative, have taken a decidedly management-based approach. There are a variety of ways that government and trade-association may combine efforts. The government may, for example, require compliance with industry standards (thus overcoming the free-riding problems that King and Lennox (2000) identify). Or the government may allow substantial industry input into the process by which management-based rules are drafted. Finally, the government may simply rely on industry associations to translate the general management-based standards that the regulators promulgate into more specific plans that firms within different sectors may then adapt to their particular circumstances.

Management-based regulation has been an innovation born of the necessity to design smarter regulation. Regulators from a wide variety of spheres have independently concluded that they need to rely on the knowledge and capacity of the regulated to achieve public goals. Our objective in this paper has been to identify management-based regulation as a distinctive and potentially effective regulatory approach, and to point to the key empirical and theoretical issues regarding its application.

**Figure 1: Three Stages of Production and Three Types of Regulation**

| | | | | | |
|---|---|---|---|---|---|
| *Production*: | Planning | → | Processing Inputs | → | Outputs, good or bad |
| *Regulation*: | Management Based | | Technology Based | | Performance Based |

**Figure 2: Framework for Selecting Regulatory Strategies**

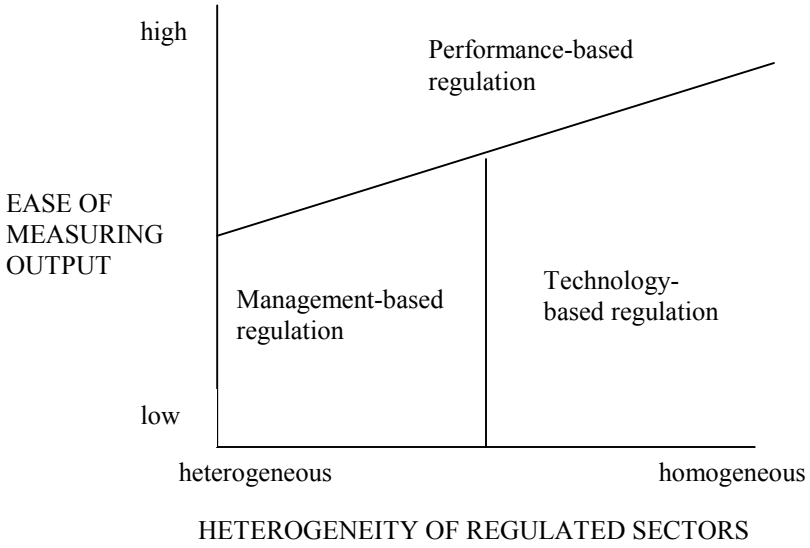
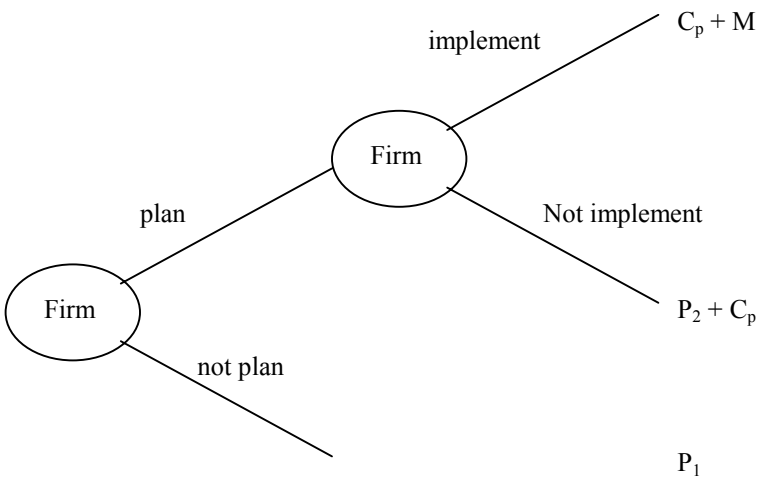


**Figure 3: Private Firm Decision Tree Under Management-Based Regulation**




*Stage I* *Stage II* *Payoffs*

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