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Management-Based Regulatory Strategies

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This paper focuses on a governance strategy that seeks directly to promote the management of private firms in ways that meet public goals. Of course, one might say that all regulatory strategies purport to encourage private firms to manage their affairs in ways that reduce social harms. Yet management-based regulatory strategies are distinctive in that they specifically require regulated firms to do their own planning and decision-making about how to achieve socially-desirable goals.

Traditionally, government authorities have adopted regulatory standards that either (1) command firms to use specified technologies or processes that governmental decision makers believe will achieve social goals (“technology-based regulation”), or (2) command firms to achieve specified levels of socially-desirable outputs or performance but give them flexibility in deciding what technologies or processes to use to achieve that performance (“performance-based regulation”). In contrast, what we refer to as management-based regulation commands firms to engage in the planning and decision-making needed to identify both technologies and performance targets needed to achieve socially-desired goals.¹ This management-based approach to governance is currently being pursued or considered for application in the areas of food safety, occupational health, environmental protection, and other regulatory areas.

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¹ Neil Gunningham and his co-authors 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. Neil Gunningham & Peter Grabosky, *Smart Regulation: Designing Environmental Policy* 40, 187 (1998).

This paper analyzes the potential for privatizing regulation through a management-based approach to regulation. With policy actors increasingly taking interest in management-based regulation, management-based approaches to regulation deserve further consideration because in some cases these approaches may well help overcome some of the well-known limitations associated with more conventional approaches to regulation, and in other cases they may be the only feasible option for addressing public regulatory goals. In the first part of this paper, we begin by reviewing some of the generally-accepted limitations of conventional regulatory strategies and discussing the theoretical advantages of a management-based regulatory approach. In the second part, we develop an analytical framework for deciding when to use management-based regulation as opposed to technology-based or performance-based regulation. In the third part, we apply our framework to the emerging use of management-based regulation in the area of food safety.

I. The Potential for Management-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. Such regulation is needed to correct failures in the market, such as where monopolies exist, information is scarce, or there are externalities or commons problems.² In these areas regulation can be used to correct deficiencies in the marketplace. Although traditional, 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. Traditional 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.³ Regulation which imposes requirements for specific technologies may also inhibit innovation in new, potentially more effective technologies. Conventional regulation often provides little incentive for firms to go beyond compliance and achieve further improvements in regulatory goals.

An alternative to technology-based regulation is performance-based regulation, an approach according to which government specifies the desired outcome but gives firms flexibility to meet the specified outcomes. Such an approach avoids locking in a technological fix, allowing firms to innovate and search for less costly means of achieving the desired outcome. Even greater cost-effectiveness can be achieved by

² For extended discussions of the rationales for regulation, see W. Kip Viscusi, John M. Vernon, and Joseph E. Harrington, *Economics of Regulation and Antitrust* (2000); Neil Komesar, *Imperfect Alternatives: Choosing Institutions in Law, Economics, and Public Policy* (1994); Cass Sunstein, *After the Rights Revolution* (1989).

³ See, e.g., Robert W. Hahn, ed., *Risks, Costs, and Lives Saved: Getting Better Results from Regulation* (1996).

allowing firms to achieve average levels of performance across time, facilities or products, and firms. So-called market-based or economic regulatory instruments, such as tradable permits or emissions taxes, offer a special kind of performance-based regulation.⁴ Market-based instruments 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). These methods give firms the flexibility to achieve higher levels of performance in those processes or facilities where it is cheaper to do so, making the achievement of regulatory goals even more cost-effective or efficient. They also provide firms with incentives to innovate and go beyond what current technologies can do.

Although market-based performance regulation may approximate the theoretically ideal form of regulation, its main limitation lies in the difficulty of implementing it in many areas of social concern. Not insignificantly, these approaches have proved to be politically difficult to create and probably will be still more difficult to expand into new areas.⁵ Hence, in the area of environmental regulation, emissions trading regimes have proved useful for achieving cost-effective reductions in non-toxic pollutants, such as sulfur dioxide emissions, but it would be challenging, if not problematic, to create a market in workers' injuries. More significantly for our purposes, it is simply difficult or costly to measure accurately many of the harmful activities that the government is trying to control and administratively difficult to create a functioning market in all these harms. This is a fundamental limitation of performance-based regulation generally. Governmental authorities simply lack the resources to measure and monitor all the potentially harmful activities of all economic firms.⁶

Management-based regulation, the approach of concern to us here, presents itself as an alternative to both technology-based and performance-based regulation. 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

⁴ There is a large literature on market-based regulatory instruments. See, e.g., Robert N. Stavins, "What Can We Learn from the Grand Policy Experiment? Lessons from SO₂ Allowance Trading," *Journal of Economic Perspectives* 12:69-88 (1998); Tom Tietenberg, "Economic Instruments for Environmental Regulation," *Oxford Review of Economic Policy* 6:17-33 (1990); Robert Hahn & Gordon Hester, "Marketable Permits: Lessons for Theory and Practice," *Ecology Law Quarterly* 16:361-406 (1989).

⁵ For a discussion of the political economy of market-based regulation, see Nathaniel Keohane, Richard Revesz, and Robert Stavins, "The Choice of Regulatory Instruments in Environmental Policy," *Harvard Environmental Law Review* 22: 313-367 (1998).

⁶ See Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* 103 (1992).

compliance and third-party auditors or periodic audits by regulators can be used to certify compliance.⁷

Thus, for example, fish inspection underwent a world-wide revolution in the 1990's, shifting to a hazard analysis and critical control points (HACCP) regulatory regime. HACCP requires firms that handle fish to do an analysis of where likely points of contamination of fish are, and to develop a plan that avoids contamination. For example, a plan might identify a particular transfer point as a critical control point and specify particular controls needed at that point. HACCP requires documentation of follow through on the firm's plan. The first country to introduce a mandatory HACCP program was Canada in 1992, although the U.S. had introduced a voluntary program in 1989. The Codex Alimentarius Commission, an international food standards organization, developed a HACCP standard shortly thereafter, in significant part based on the Canadian rule, and HACCP then spread rapidly throughout the world. HACCP has spread across sectors as well, with the U.S. (among other countries) moving toward HACCP-type rules as an alternative to the traditional, "poke and sniff" approach to inspecting meat.⁸

Environmental management systems (or EMSs) are another prominent example of a management-based approach to regulatory problems. EMSs are formal, institutionalized practices which industrial firms and other organizations adopt to help them achieve their environmental objectives.⁹ These systems, which may take a variety

⁷ Management-based regulation bears certain affinities to what Ayres and Braithwaite call "enforced self-regulation." *Id.* at 102-108. See also an earlier discussion of mandated self-regulation in Joe Rees, *Reforming the Workplace: A Study of Self-Regulation in Occupational Health and Safety* 9 (1988). A good management system within a firm 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 describe it, has companies drafting their own rules which the government ratifies and then enforces as it could any law. *Id.* at 131. 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 resemble the model used by US EPA in Project XL, through which EPA negotiated separate regulatory agreements and site-specific rulemakings with individual firms. See Eric Orts & Kurt Deketelaere, *Environmental Contracts: Comparative Approaches to Regulatory Innovation in the United States and Europe* (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. See Serge Taylor, *Making Bureaucracy Think: The Environmental Impact Statement Strategy of Administrative Reform* (1984).

⁸ Part III of this paper provides an extended discussion of the HACCP approach to food safety.

⁹ For a discussion of environmental management systems and their implications for regulatory policy, see Cary Coglianese and Jennifer Nash, *Regulating from the Inside: Can Environmental Management Systems Achieve Policy Goals?* (2001).

of forms, generally involve the establishment of organizational goals for environmental performance and the development of internal policies on resource use, emissions control, and pollution prevention. Third party assessors audit EMSs and, where appropriate, certify them as meeting international standards, such as those set forth in ISO 14001. Environmental management systems are increasingly viewed as a potential approach for moving beyond the limits of the existing system of environmental protection. Private sector interest in EMSs is booming. And regulators around the world are watching closely the trend toward the increased use of EMSs. The US Environmental Protection Agency has endorsed the use of environmental management systems and is currently investigating possible ways to incorporate such systems into its regulatory programs. A number of jurisdictions are beginning to adopt so-called "green tier" systems under which firms with approved environmental management systems can be exempted from otherwise applicable regulations.

Private sector, 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.¹⁰

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.¹¹ 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.¹² Privatized 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 more reasonable and legitimate, therefore being less resistant to compliance.¹³

¹⁰ See Ayres and Braithwaite, *supra*, at 110-111.

¹¹ *Id.* at 113; Coglianese and Nash, *supra*, at 10-11.

¹² Enforcement, after all, is almost always "incomplete." See Kip Viscusi and Richard Zeckhauser, "Optimal Standards with Incomplete Enforcement," *Public Policy* 27: 437-456 (1979).

¹³ Cf. Paul Kleindorfer, "Understanding Individuals' Environmental Decisions: A Decision Science Approach," in Ken Sexton et al., eds., *Better Environmental Decisions: Strategies for Governments, Businesses, and Communities* (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. Conditions for Effective Management-Based Regulation

We recognize that the case we have just made for management-based regulation accentuates only the positive potential for this approach. The preceding discussion is intended, of course, only to suggest the viability of the strategy as one possible option within the government's regulatory toolbox. These approaches are surely not without their disadvantages, though. By placing the locus of decision-making within the firm, for example, management-based approaches by themselves may not provide sufficient incentives for firms to incur costly changes that might be needed to achieve social goals. As Ayres and Braithwaite put it, even if firms "are more capable, they are not necessarily more willing to regulate effectively."¹⁴ When appropriate technologies to achieve social goals are easily knowable to the government, or when government can easily define and measure desired performance, it is likely that technology-based or performance-based approaches remain superior to management-based regulation. The challenge, which we take up in this part of the paper, is to clarify the conditions under which management-based regulation is an appropriate choice for governmental decision makers.

We begin with a simple model of private behavior. Private production occurs when a private actor makes some plans, processes inputs, and produces some set of outputs (figure 1). Actors anticipate and learn what processes produce what outputs, producing feedback used in the planning process. Those 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 are those goods that the public has some interest in the production of. This includes the traditional notion of public goods (e.g., clean environment) as well other cases of "market failure" (e.g., worker safety). The first working assumption we make in this paper is that private actors maximize private gain, and will thus potentially underproduce social goods. The question then is: How should the government intervene to increase the production of social goods? One key part of the answer must lie in the stage of the production process at which government intervenes: planning, process, or outputs.

¹⁴ Ayres & Braithwaite, *supra*, at 106.

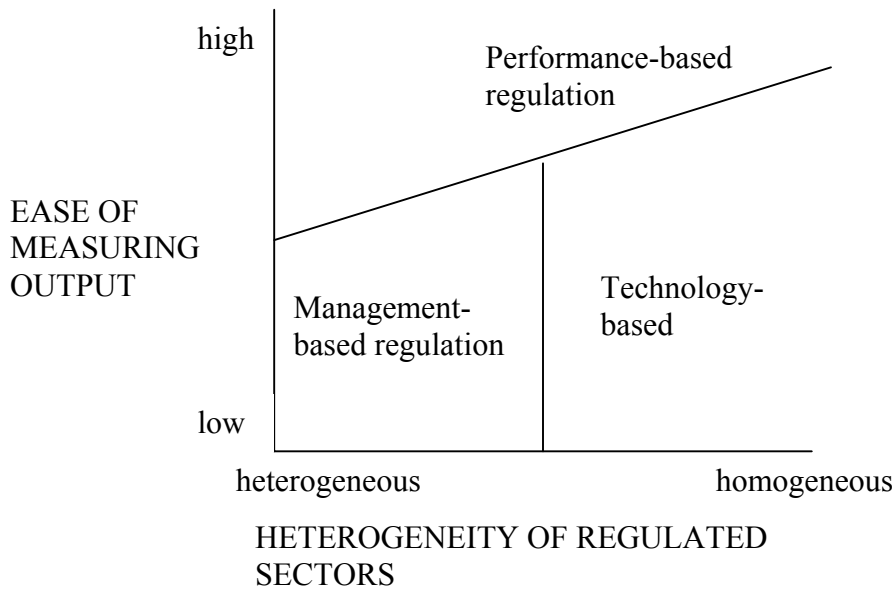
outputs.¹⁵ The key question then becomes where the relative competencies of the state lie. How good is the state at determining outputs, what the process is, and the linkage between process and output, and input and output?

Consider, then, two dimensions tracking the competence of government (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.¹⁶ 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. If the

¹⁵ Note that there may be a collective interest in regulation, since a bad outcome for one party (e.g., product safety) affects the whole industry. There may therefore be a private collective interest for government intervention (or, alternatively, industry certification and self regulation).

¹⁶ 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: Framework for Selecting Regulatory Strategies



population of regulated parties is highly homogeneous, one-size-fits-all technological standards become more practical, because everyone is the “same size.”

Our assessment is that performance-based regulation, including 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. In such cases, the role of the government should be to provide incentives to private parties to produce the desired outputs. Such “incentive-compatible” or “market-based” policies would include creating a tax or a subsidy proportional to the output of social bad or good, or determining quotas and allowing trading among private firms to occur. Alternatively, if such incentive-compatible policies are impossible, performance standards would still be most appropriate as they give firms flexibility to choose the lowest cost approaches to achieve the desired performance levels.

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.

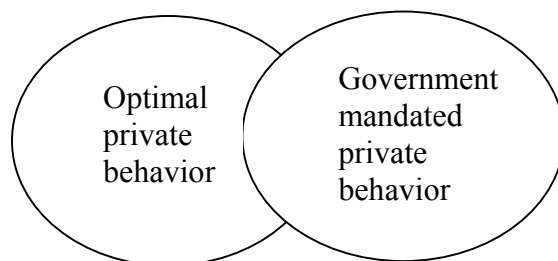
However, it often is not possible to accurately measure critical outputs. For example, in food safety, sensory inspection (“poke and sniff”), as discussed below, does

not detect many important contaminants, and it is impractical to sample enough of a shipment of food to accurately measure contamination. Under circumstances where the regulated sector is homogeneous and it is not practical to measure outputs (lower right quadrant of Figure 2), it should be possible to cheaply produce a technological standard based on “best practices.”

The most difficult regulatory scenario is where it is impossible to cheaply and accurately measure social outputs—making performance-based regulation impractical—and heterogeneity is high—making technological regulation impractical. 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.

To summarize, figure 3 represents two sets of actions—the set of actions that private actors would take if they perfectly incorporated the public interest in their behavior, and the set of actions that the government requires of them. As one moves from the lower right in figure 2 to the lower left, the overlap between these two sets becomes smaller and smaller. The regulated actors have the capacity, informationally, to achieve a far better overlap than the government is able to.

Figure 3: Overlap of Optimal Private and Government Mandated Behavior

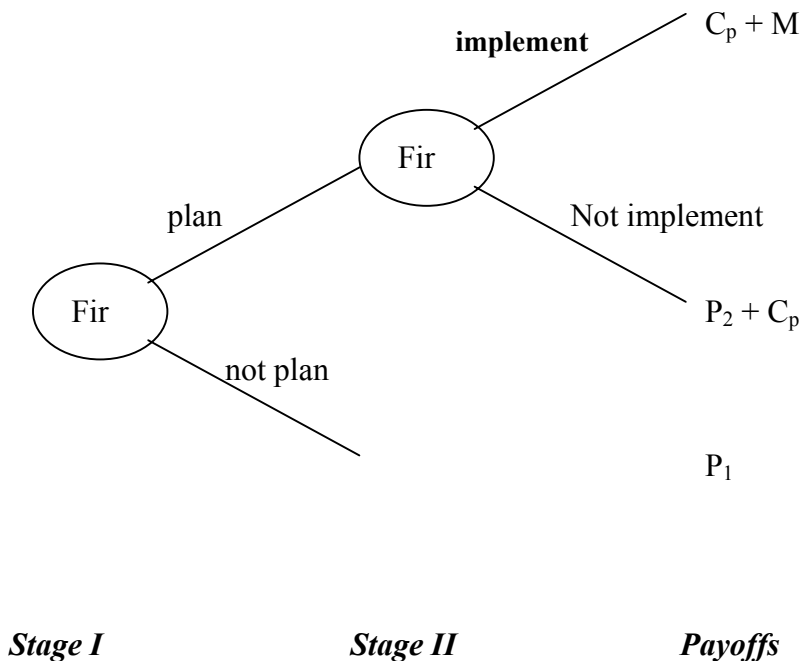


The informational advantage of the firm, however, is only part of the condition necessary for the success of management-based regulation. The other part is overcoming principal-agent concerns in regulating firm behavior. That is, how are the incentives confronting the firm restructured so that they better take into account the public’s

interests in its behavior? This will turn on the government's capacity to influence behavior that we are assuming that it does not well understand nor cannot easily measure.

We begin by assuming that from a firm's perspective management-based regulation has two stages: planning and implementation (Figure 4). 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 p_1 ; the penalty for planning and not implementing is p_2 ; 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 p_1 , p_2 , c_p , and $E(M)$, and at stage II based on p_2 , c_p , and M .

Figure 4: Private Firm Decision Tree Under Management-Based Regulation



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, 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.¹⁷ 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 stages,* where $E(M) + C_p < 0$ and $M < 0$, the regulator needs to enforce at both the planning and implementation stages.

¹⁷ Some firms could view voluntary efforts as a strategy to fend off further governmental regulation. If so, the firms may perceive it within their private interest to incur voluntarily some social costs if doing so decreases the chances of more costly requirements in the future.

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 of any kind of regulatory regime 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.¹⁸ For example, with food safety it may be virtually impossible to process shellfish safely without monitoring the temperature that the shellfish are 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.¹⁹ In the United States, guidelines for

¹⁸ 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.

¹⁹ Of course, the problem of specificity is not limited solely to management-based regulation. See, e.g., Eugene Bardach and Robert Kagan, *Going by the Book: The Problem of Regulatory Unreasonableness* (1982); Colin Diver, "The Optimal Precision of Administrative Rules," *Yale Law Journal* 93:65 (1983). For a provocative argument hypothesizing that this tension reaches an equilibrium over time, with regulatory systems created at the extremes of generality or specificity tend

management-based standards also need to withstand challenge for vagueness under conventional principles of administrative law.

III. Management-Based Regulation of Food Safety

In this part, we discuss the application of management-based regulation in the area of food safety. Food safety is a classic case of asymmetric information as the basis for government intervention. It is difficult, if not impossible, for consumers to identify contamination of the food they are purchasing. Furthermore, if a consumer is harmed by the consumption of contaminated food, foodborne illness is not always recognized as such.²⁰ Even when the nature of the illness is correctly identified, the consumer may not be able to determine which food caused it, and even if the food is identified, it is possible (particularly in the case of meat purchased uncooked) that the consumer will not be able to identify which of the several distributors from which the product came or whether they caused the contamination.²¹ Consumers can have difficulty establishing that the contamination was caused by the manufacturer's or distributor's actions rather than by their own improper storage or preparation.²² As a result, firms are unlikely to internalize all of the costs of food safety lapses without some government intervention. In all, the CDC estimates that there 5,000 deaths each year and 76 million illnesses that can be traced to food.²³

The roots of the regulatory regime around food safety in the U.S. date to the public outrage over the slaughterhouse conditions described in Upton Sinclair's *The Jungle*.²⁴ In response, Congress passed both the Federal Meat Inspection Act (FMIA)²⁵,

to converge toward each other, see Frederick Schauer, "The Convergence of Rules and Standards," Regulatory Policy Program Working Paper RPP-2001-07 (2001).

²⁰ For example, the Centers for Disease Control and Prevention (CDC) estimates that salmonellosis only accounts for more than \$1 billion a year in lost wages and medical costs (Centers for Disease Control, "Foodborne Illness: Technical Information," http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_t.htm), but that only 1 in 38 cases is actually diagnosed and reported to public health authorities. Centers for Disease Control, Foodborne Illness: General Information, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#howdiagnosed.

²¹ See Sharlene W. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 *Willamette L. Rev.* 411, 435.

²² *Id.* at 417-18.

²³ CDC

²⁴ See James A. Albert, *A History of Attempts by the Department of Agriculture to Reduce Federal Inspection of Poultry Processing Plants -- A Return to the Jungle*, 51 *La. L. Rev.* 1183, 1184-89 (1991); Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems, 60 *Fed. Reg.* 6774, 6775-76 (Feb. 3, 1995).

giving the United States Department of Agriculture (USDA) jurisdiction over most meat and poultry products, and the Pure Food and Drugs Act, which charged the Food and Drug Administration (FDA) with oversight of most other food products (including seafood).²⁶ The FMIA requires continuous inspection of meat production plants by USDA personnel. The inspectors must conduct a visual inspection of each slaughtered animal, and must maintain a “continuous inspection” presence in meat processing plants, overseeing the inspection process and verifying sanitary conditions in the plant each day.²⁷ The FDA also inspects plants under its jurisdiction, but it relies to a greater degree on manufacturers’ good faith in protecting food safety—even high-risk plants are typically inspected less than once a year.²⁸

The USDA’s “poke and sniff” inspection system was developed to address a certain kind of risk—namely, visibly diseased animals being prepared with simple processing technologies in a single geographic location. As animal husbandry improved, the diseased-animal risk declined, while a variety of processed foods became popular.²⁹ The new multi-step production processes and the industry’s growing size created new demands on inspectors’ time, while higher consumer expectations and the lengthy processing methods focused new attention on microbial food safety concerns.³⁰ New processing technologies also made adulteration harder to detect by quick visual inspection.³¹

²⁵ Federal Meat Inspection Act of 1906, ch. 2907, 34 Stat. 1260 (codified at 21 U.S.C. §§ 601-95).

²⁶ Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (Federal Food Drug and Cosmetics Act now codified at 21 U.S.C. §§ 301-397).

²⁷ See 21 U.S.C. §§ 601-24 for a description of FMIA inspection requirements.

²⁸ See Michael R. Taylor, “Preparing America’s Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?” 52 Food Drug L.J. 13, 15-18 (contrasting the USDA and FDA food safety paradigms). A continuing obstacle to coherent food safety strategy is the fragmented nature of its overseers. About twelve federal agencies (and numerous state and local entities) are involved in food safety regulation. This means that change such as the adoption of HACCP tends to be piecemeal, and that similar products may face very different patterns of oversight. For example, frozen pepperoni pizza makers, regulated by the USDA, receive daily inspections, while FDA-regulated frozen cheese pizza makers can expect an inspection about once every ten years. *Id.* at 18; Caroline Smith DeWaal, “Food Safety Inspections: A Call for Rational Reorganization,” 54 Food Drug L.J. 453

²⁹ 60 Fed.Reg., *supra*, at 6775.

³⁰ *Id.* at 6775-76.

³¹ *Id.*

The regulatory system did not readily adapt to these changes. Not until 1994 did the USDA recognize microbial contaminants such as *E. coli* and *Salmonella* to be adulterants, because for many years it was believed that these could easily be killed by proper cooking.³² This was a late response to a substantial risk. In 1995, the USDA estimated that pathogenic microorganisms in poultry could account for more than 4,000 deaths and nearly 5 million cases of foodborne illness annually.³³ However, in practice, it was difficult for either FDA inspectors, whose numbers permit them to visit each plant only very infrequently, or USDA inspectors, who use about half of their time on the mandatory visual inspections of individual slaughtered animals, to play an extensive role in monitoring or testing for microbial hazards.³⁴

In response to these challenges, regulators developed a new regulatory approach, based on requiring processors to develop a *Hazards Analysis and Critical Control Points* plan (HACCP—pronounced “Hassip”). We describe this approach below, but first we evaluate the regulatory challenge along the two dimensions addressed earlier in figure 2: the ease of output measurement and the heterogeneity of firms.

A. Ease of Output Measurement

The traditional model of sensory detection (“poke and sniff”) of contaminated meat is 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. One of the key drawbacks to microbiological testing is that it takes some time to achieve results, so that, particularly in the case of perishable items, the product often must be shipped out before the results are received.³⁵ Moreover, some contaminants vary greatly in concentration even within the same lot, and the representativeness of a sample also depends on the firm’s consistency in its production processes.³⁶

However, the most significant reason that federal agencies’ monitoring is not enough is the sheer number of sources of hard-to-detect risk. When it attempts to monitor visually for hazards, the inspecting agency might easily focus attention on one set of production activities while missing a substantial risk posed by another.³⁷ Even

³² Taylor, *supra*, at 17.

³³ 60 Fed. Reg., *supra*, at 6781.

³⁴ Taylor, *supra*, at 21-22.

³⁵ An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients, National Academy of Sciences: National Academy Press 50 (1985) at <http://books.nap.edu/books/0309034973/html/> This, at least, was the case in 1985. It is possible that testing proceeds more quickly now.

³⁶ *Id.* at 132-44.

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. 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 microbial threats are likely to result from their processes.³⁸

B. Heterogeneity

The food processing industry is also extremely heterogeneous. As the FDA noted in a recent rule implementing HACCP in the area of juice safety, “[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.”³⁹ The USDA exercises some jurisdiction over producers of products ranging from milk to meat-topped pizza to uncooked ground beef to processed egg products.⁴⁰ Within each category, firms may employ many different combinations of processes to create the finished product. Inevitably many firms will have, but the USDA 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.⁴¹

Furthermore, food safety issues, while not as dynamic as some areas, are subject to abrupt changes. For example, new strains of *E. Coli* have recently emerged in lettuce and apple juice, and new strains of *Salmonella* in alfalfa and breakfast cereal. Food safety decisions must be made quickly to avert harm.⁴² As the FDA noted in the juice rule, “HACCP is ideally suited to respond to emerging problems because a HACCP

37 Id. at 48-49.

38 Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 *Food Drug L.J.* 681, 709-710 (1998).

39 *Federal Register*: January 19, 2001 (Volume 66, Number 13): 6141.

40 See Taylor, *supra*, at 18-20, for a discussion of how food safety oversight is allocated. The FDA, too, has broad jurisdiction, overseeing most non-meat food items. Id. at 15.

41 A National Academy of Sciences report advocating the dissemination of HACCP explained, “From a regulatory standpoint, a complete familiarity with and understanding of processes and product flows would greatly aid agency assessment of the effectiveness of a food firm’s programs designed to assure product safety and quality. [HACCP] would do much to obviate need for an investigator to know everything about the intricacies of a firm’s processing systems.” *An Evaluation of the Role of Microbiological Criteria*, *supra*, at 311-12.

42 DeWaal, *supra*, at 453.

system is a dynamic system that must be validated periodically to ensure that all hazards reasonably likely to occur are identified and controlled via CCP's.”⁴³

C. A Management-Based Regulatory Instrument

HACCP is an attempt to deal with the heterogeneity of the food industry. It sets forth a number of mandates that require firms to evaluate, monitor, and control potential dangers in the food-handling process. The United Nations Food and Agriculture Organization’s Codex Alimentarius Commission has identified 7 principles that comprise the HACCP system,⁴⁴ and these have been incorporated into U.S. federal regulations defining the firm’s obligation to produce an HACCP plan. These are as follows:

1. Hazard analysis. Firms must first identify the potential hazards associated with all stages of food production, and assess their likelihood of occurring. The USDA version of the HACCP regulations requires meat processors 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.⁴⁵

2. Determine critical control points (CCP). The next two steps involve identifying the best methods for addressing food safety hazards. The firm must identify its critical control points—points in the production process at which the hazards defined in the first step can likely be eliminated, minimized, or reduced to an acceptable level.⁴⁶

3. Establish critical limits. 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.⁴⁷

4. Establish a system to monitor CCPs. Having developed a methodology for dealing with hazards, the firm must ensure that it adheres to 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.⁴⁸

⁴³ Federal Register: January 19, 2001 (Volume 66, Number 13): 6142.

⁴⁴ Codex Alimentarius Commission, Guidelines for the Application of the Hazard Analysis Critical Control Point System (CAC/GL, 18-1993) in Codex Alimentarius, Vol. 1 B, General requirements (food hygiene), p. 21-30, Rome, FAO/WHO.

⁴⁵ 9 C.F.R. § 417.2; 21 C.F.R. § 123.6.

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ Id.

5. Establish corrective actions. The plan should also indicate all of 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.⁴⁹

6. Establish verification procedures. The firm should also have 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. In the initial period of validation, the firm should “repeatedly test the adequacy of the CCP’s, critical limits, monitoring and record-keeping procedures, and corrective actions,” and frequently review its HACCP records (described below) in the context of other validation activities. It must 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 frequent reassessment of the plan as a whole. This should take place at least annually, and whenever any changes occur that could affect the hazard analysis or the rest of the plan (e.g., differences in personnel, production volume, sources of raw materials).⁵⁰

7. Establish documentation concerning the plan and its procedures. Finally, one of the essentials for effective self-evaluation and government oversight is the record-keeping requirement under HACCP. To document its HACCP system, USDA-regulated meat and poultry firms are required to maintain:

- a written version of the hazard analysis and the full HACCP plan;
- dated records of the monitoring of CCPs (including numerical values); verification actions and their results, and corrective actions;
- a signed record of a review establishing that all critical limits were met, the review to take place before product is shipped;

These records must be kept for at least one to two years.⁵¹

The Food Safety Inspection Service (FSIS), a USDA inspection arm, then verifies the firm’s compliance with HACCP requirements. It may request the right to review the HACCP plan itself, the documentation of CCP observations and corrective actions, and other records pertaining to the plan. The FSIS may also collect samples and make its own direct observations and measurements.⁵² Firms need not get the FSIS’ pre-approval

⁴⁹ 9 C.F.R. § 417.3; 21 C.F.R. § 123.7.

⁵⁰ 9 C.F.R. § 417.4; 21 C.F.R. § 123.8.

⁵¹ 9 C.F.R. § 417.3. See 21 C.F.R. § 123.9 for FDA requirements, which are less specific and appear somewhat more limited.

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.⁵³

In addition, the individuals charged with developing or reassessing the HACCP must have completed a training course “in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.”⁵⁴

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).⁵⁵ 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.

Notably, while HACCP regulations offer a great deal of flexibility to firms, regulators do lay out particular constraints with respect to the control of specific hazards. For example, the presence of histamines is a potential danger in tropical fish, thus an acceptable HACCP plan with respect to tropical fish must incorporate monitoring of histamines somewhere in the process.

D. Enforcement challenges

The critical question regarding HACCP is whether it 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.⁵⁶ Furthermore, regulators may evaluate the processes that it

⁵² Id.

⁵³ 9 C.F.R. § 417.6. See 21 C.F.R. § 123.10 for the analogous FDA requirement.

⁵⁴ 9 C.F.R. § 417.7.

⁵⁵ 9 C.F.R. § 417.2; 21 C.F.R. § 123.6.

actually observes. Are regulators competent enough to evaluate the quality of HACCP plans? Clearly, they can judge whether they meet the broad constraints they lay out (e.g., the example with histamines and tropical fish above), but it is less clear how well regulators can evaluate whether firms “optimize” within those constraints.

At the implementation stage, the FDA, in particular, heavily relies on the paperwork trail that the HACCP should generate. The FDA inspects each fish processor once a year, examining their plan, their records, and the actual process associated with 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.⁵⁷

Further, if firms candidly share data, those manufacturing records, once in the hands of the regulator, could become available to the general public, to the news media, and even to competitors under the Freedom of Information Act.⁵⁸ In response, the FDA has reiterated its commitment to an existing regulation that exempts from disclosure “trade secret or confidential commercial or financial information.”⁵⁹ However, some have questioned whether all HACCP documents, especially adverse safety data, would fall within this exemption.⁶⁰

All of these present disincentives for firms to seek out and plan for correction of the hazards that are most difficult to address—the ones that might result in deviations from the CCP despite diligent effort.⁶¹ One critic of HACCP warns that firms have little

⁵⁶ 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).

⁵⁷ Note that the FDA has tried to reassure firms that it will not automatically declare food adulterated simply because of a small deficiency in the HACCP, but rather will tailor its response to the seriousness of the problem). Even if the FDA’s response to some adverse information is measured, firms must be concerned about the possibility that citizens alleging foodborne illness in a lawsuit will gain access to the information during discovery. *Id.*

⁵⁸ Delilah Dill Schuller, “Pathogen Reduction Through ‘HACCP’ Systems: Is Overhaul of the Meat Inspection System All It’s Cut Out To Be?” 8 S.J. Agri. L. Rev. 77, 94-95 (1998).

⁵⁹ McNamara, *supra*, at 46.

⁶⁰ *Id.*

⁶¹ A similar problem occurs in the area of environmental management systems, 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

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.⁶² 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 resolved cheaply. The HACCP system is designed to incorporate a firm's specialized expertise in its product and processes into the safety plan, and *yet the 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.*⁶³

There are two factors that counterbalance the above: (1) that HACCP record keeping requirements may assist inspectors to conduct a more effective inspection; and (2) that monitoring capital investments consistent with the HACCP plan will be easier than monitoring day-to-day behavior.

FDA inspectors in particular often approach a firm with little knowledge of its operations, because of the infrequency of oversight. Inspectors will now be able to review the firm's records of how it chose its CCPs, the results of monitoring, and corrective actions taken.⁶⁴ With this history, they can get a far clearer picture of where they are likely to find unresolved health risks than if they had to make that judgment based on a quick observation of the firm's work processes.⁶⁵ USDA inspectors, while likely to be more familiar with a plant's operations, may also be better able to allocate their time effectively when it is not occupied by the mandated visual inspection tasks. In addition, getting firms to identify many safety hazards in advance has the potential to reduce enforcement costs.⁶⁶ Recalls of adulterated foods and participation in court proceedings to appeal such a decision are expensive ways to use regulatory resources. If firms are able to catch a problem further back in the pipeline, the savings can be used for cheaper forms of oversight.

environmental auditing documents will generally not be used against a firm. See, e.g., Cary Coglianese, "Policies to Promote Systematic Environmental Management," in Coglianese & Nash, *Regulating from the Inside: Can Environmental Management Systems Achieve Policy Goals?* (2001).

⁶² Lassiter, *supra*, at 444-56.

⁶³ 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. An Evaluation of the Role of Microbiological Criteria, *supra*, at 309-10.

⁶⁴ Taylor, *supra*, at 21-23.

⁶⁵ An Evaluation of the Role of Microbiological Criteria, *supra*, at 311.

⁶⁶ 60 Fed. Reg., *supra*.

A critical issue, then, with respect to the decisions of regulated firms are where the costs of compliance lie -- planning, capital expenses, or day-to-day behavior -- where the last is the most difficult for the regulator to monitor. Table 1 lists the mean costs associated with HACCP based on a survey of the industry.

Table 1: Mean Costs Associated with HACCP Compliance

HACCP Plan Development	\$1,338
HACCP Training	\$567
	\$15,077
Equipment Investment for HACCP Requirements	
Investment for Sanitation Requirements	\$10,190
Annual Cost of Routine Requirements of HACCP Regulation	\$14,174
<i>Total Cost</i>	<i>\$41,346</i>

(Source: *National Seafood Industry HACCP Implementation Survey Report: April 2000*)

Approximately a third of the costs associated with HACCP are “routine,” and thus difficult to monitor. The issue with respect to compliance is that the routine activities may be necessary to get most of the advantages of HACCP—for example, it does little good to have thermometers to gauge whether fish are being kept at the right temperature if nothing is done when they are not. From the perspective of the model outlined above, these routine activities may be viewed as stage II decisions on the part of the firm. The critical question is whether, having invested in the training and the equipment, does it pay to follow through with the plan if there is relatively little possibility of enforcement? If the answer is affirmative, then the FDA model of enforcement has some hope of being effective. If not, a far more regular inspection schedule, as with the USDA program, will be necessary. In fact, many other countries that have implemented HACCP for seafood inspection have far more regular inspections. Table 2 summarizes some of the key features of the HACCP programs for seafood in the US and Canada.

Table 2: Characteristics of Seafood Inspection Programs in Canada and the U.S.

<i>Program features</i>	<i>United States</i>	<i>Canada</i>
Industry required to register with oversight agency	No	Yes
Written hazard analysis required	No	Yes
Written HACCP plan required	No	Yes
Pre-implementation review of HACCP plans	No	Yes
Required HACCP training for industry	Yes	No
Sanitation requirements	Yes	Yes
Frequency of federal inspections	At least once a year	Quarterly

(Source: adapted from GAO 2001: 43)

The Canadian program entails far more oversight than the US system. The Canadians require documentation of the analysis underlying the HACCP plan a firm develops as well as pre-approval of a plan by the regulator. Further, the Canadians

inspect sites quarterly. The US system is designed for a regulator with far less capacity to monitor and inspect firms—with no pre-approval required, since the FDA would be unable to process the plans; no required hazard analysis, since the inspector would not have the time to examine; and only annual inspections of firms. Finally, the U.S. places a mandate on firms that some of their employees undergo certified HACCP training—which is very cheap to monitor but causally more distant from the objective of preventing food poisoning than evaluating the process a firm has implemented.

E. Assessment of success

The US only implemented HACCP programs in 1997 and 1998, and the available data on their success is limited and 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. For example, in large plants, the incidence of Salmonella in broilers dropped from 20% to 10.3%, in swine 8.7% to 4.4%, in ground beef from 7.5% to 5.8%, and in ground turkey from 49.9% to 34.6%.⁶⁷

The FDA has not tracked the incidence of pathogens as the USDA has. Instead, it has surveyed industry practice with respect to sanitation, and has found some large improvements in practice. For example, it has found that while in 1992 only 45% of cooked ready-to-eat manufacturers maintained adequately clean food contact surfaces, that number jumped to 74% in 1997 and 90% in 1999.⁶⁸ These achievements are counterbalanced by a recent GAO report which was harshly critical of the FDA program. Key concerns expressed in the GAO report included:

- Inadequate coverage. FDA exempts thousands of fishing vessels that “(1) harvest and transport fish without any further processing and (2) head, eviscerate, or freeze fish on board solely to prepare them for holding” even though contamination may occur at this stage of the process. (16)
- Especially inadequate coverage of imported seafood. Many importers do not have any records of foreign seafood firms’ compliance with HACCP, and when documentation is available it is often inadequate. Overall, less than a third of importers met FDA requirements. (26) Furthermore, when the FDA has conducted inspections of foreign seafood firms and has found violations and issued warning letters, it has not pursued additional enforcement actions against firms that have not improved compliance. (30)
- The inspection process often does not examine implementation. In one survey of FDA inspections, 48% of the time FDA inspectors did not inspect the process of the

⁶⁷ Figures from Progress Report on Salmonella Testing of Raw Meat and Poultry Products, USDA, 2000.

⁶⁸ Figures from FDA’s Evaluation of the Seafood HACCP Program for 1998/1999, FDA, December 8, 2000.

product line they were examining (typically because many of these products are seasonal and thus not being processed every day). (17)

- Overall low compliance. FDA data indicate that 22% of seafood firms in 1999 did not even have HACCP, and the majority of firms that did had HACCP plans that contained serious deficiencies. In a high-risk area that the GAO reviewed, ready-to-eat products, 40% of firms with HACCP plans did not establish cooking critical limits, which would be essential to eliminate potentially deadly pathogens.
- Overly slow processing of warning letters. On average, it took the FDA 73 days to issue warning letters that identify compliance issues and threatened fines. Firms not in compliance therefore will not quickly correct their behavior.

The ultimate metric for evaluating the success of HACCP is the incidence of foodborne illness. CDC data are ambiguous as to whether there is a downward trend in the incidence of foodborne illnesses. Table 3 summarizes the results of a CDC surveillance program. The year-to-year variations are too large to conclusively interpret these data, but it is difficult to discern dramatic declines from 1996 to 2000. 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. The dangerous E. coli actually had a higher incidence in 2000 than in 1996.

Table 3: Incidence of diagnosed infections per 100,000 population⁶⁹

<i>Pathogen</i>	<i>1996</i>	<i>1997</i>	<i>1998</i>	<i>1999</i>	<i>2000</i>
Campylobacter	23.5	25.2	21.4	17.5	20.1
Cryptosporidium	NR	3.7	2.9	1.8	2.4
Cyclospora	NR	0.4	0.1	0.1	0.1
Escherichia coli O157	2.7	2.3	2.8	2.1	2.9
Salmonella	14.5	13.6	12.3	13.6	12.0
Shigella	8.9	7.5	8.5	5.0	11.6
Vibrio	0.2	0.3	0.3	0.2	0.3
Yersinia	1.0	0.9	1.0	0.8	0.5

The US experience with HACCP provides some indications that a management-based approach can be a viable regulatory strategy, as is suggested by the USDA's finding of a lower incidence of Salmonella. But other evidence suggests the impact of HACCP, at least as it is currently implemented in the U.S., has been less than ideal. The critical reviews of FDA's HACCP program suggests that the design of a management-based regulatory regime matters just as the design of technology-based and performance-based regimes matters. It may well 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 HACCP's success. Yet the HACCP approach need not be perfect to justify adopting its management-based approach to food safety. Rather, it simply needs to be better than the alternatives. As we have seen, it is difficult to develop standard technologies when food processing facilities are so heterogeneous and when contamination can occur from practices which have no technological fix. It has also been difficult to apply realistic and effective performance measures. To some, the traditional "poke-and-sniff" approach to monitoring meat and poultry products hardly seems like an optimal regulatory strategy. So the test for management-based regulation will be whether it can provide some improvement over alternative regulatory practices.

Conclusion

The application of HACCP regulation in the area of food safety illustrates the potential, as well as some of the pitfalls, of management-based regulation in other policy areas. As we indicated at the outset of this paper, interest in management-based

⁶⁹ Preliminary FoodNet Data on the Incidence of Foodborne Illnesses—Selected Sites, United States, 2000, the MMWR Weekly, Center for Disease Control, April 6, 2001. Note that the number of sites in the Foodnet program expanded in 2000, but for comparability the data in this table only include the original 5 sites.

approaches is growing in a number of policy areas, including environmental and worker health and safety regulation. OSHA has been developing a rule -- yet to be proposed -- on the management of safety and health programs. In addition, management planning was part of the OSHA ergonomics rule recently withdrawn by congressional action. Environmental regulators are encouraging firms to implement environmental management systems, such as those that meet international standards like ISO 14000. Some new government programs promise benefits, including certain kinds of exemptions from existing procedures and requirements, to firms which demonstrate that they have implemented responsible management systems.

It is evident that management-based regulation increasingly competes in the regulatory toolbox with technology-based and performance-based regulation. We have argued that management-based regulation is preferable to its alternatives in those situations where (1) it is difficult for government to measure performance, and (2) where the target industry or sector is comprised of heterogeneous firms facing heterogeneous conditions. 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, 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 standard 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.

Yet as we have also seen from the HACCP case, the implementation of a set of 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 effectively. This enforcement challenge may be made more difficult because the same conditions that make it difficult for government to impose technological and performance standards may also make it difficult for government to determine what “good management” is.

The key question for decision makers appears to be whether firms can be sufficiently motivated to use management and planning to achieve greater social benefits than would arise from the use of alternative, command-and-control regulatory strategies. Management systems are a tool firms can use to reduce contamination, accidents, pollution, or other social bads. But how well individual firms use these systems will in all likelihood depend on the firm’s incentive structure, and this incentive structure may be affected by a number of factors, including: the frequency of system monitoring by governmental or nongovernmental auditors; the presence of performance measures and liability for system failures; the extent to which firms perceive a collective self-interest to prevent system failure; and the probability that firms will confront future, more costly technology-based or performance-based standards if they do not effectively deploy

required management strategies. If management-based regulation is to live up to the potential we outlined for it in the opening part of this paper, government will need to create policies that align firms' incentives so that they take seriously the idea of managing to reduce social harm. Yet even if these incentives cannot be fully aligned and management-based regulation proves only to be an imperfect strategy, it may well be useful to remember that the alternatives to management-based regulation have imperfections of their own.