

# Cooperative Implementation of Federal Regulations

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*Professor Michael examines regulatory programs in which the federal government leaves many compliance decisions up to the regulated entities themselves. Drawing on prior research and theory in the area, he concludes that such "cooperative implementation" is feasible if three principles are observed: (1) regulatory standards are written to leave discretion in methods of compliance and that discretion is within the competence of the regulated entities; (2) there are economic incentives to offset the additional costs to these entities; and (3) the entities self-report their own compliance, the agency closely monitors the program, and the agency maintains a residual program of traditional surveillance and direct enforcement. Next, Professor Michael examines existing programs which fall within the definition of "cooperative implementation" programs. These programs include voluntary and mandatory programs of self-enforcement and self-reporting in workplace safety and health, air and water pollution control, food safety, and transportation safety. In each instance, those programs that conform most closely to the three principles are more successful. Moreover, those programs that were not wholly successful failed to satisfy one or more of these principles. The Article concludes with general recommendations on how to expand the use and ensure the success of cooperative implementation.*

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## Introduction

Reflecting on his experience as Office of Price Administration administrator during World War II, Chester Bowles said that 20 percent of the regulated population would automatically comply with any regulation simply because it is the law of the land, 5 percent would attempt to evade it, and the remaining 75 percent would go along with it as long as they thought the 5 percent would be caught and punished.<sup>1</sup>

Bowles' assessment of regulatory policy fifty years ago is simple yet enduring. However, the depth and breadth of modern federal regulation and limits on federal resources make it increasingly difficult to find that evasive five percent. Because of this difficulty, the cooperation of the vast majority is put in jeopardy. Between vigorous traditional enforcement and reliance on completely outside motivations, there is an intermediate area where different regulatory strategies are needed.

Enforcement policy and implementation strategy are critical parts of regulatory reform,<sup>2</sup> a topic of significant current interest as policy makers throughout the federal government are increasingly insistent that regulations be more efficient, less intrusive, and less costly.<sup>3</sup> Past researchers, however,

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1. EUGENE BARDACH & ROBERT A. KAGAN, *GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS* 65-66 (1982) (citing CHESTER BOWLES, *PROMISES TO KEEP: MY YEARS IN PUBLIC LIFE 1941-1969*, at 25 (1971)). Or, as more fully developed and formally stated, "compliance may remain high so long as the members of the group trust each other to comply, [but] violations by a relatively small number of members can precipitate a rapid breakdown of compliance throughout the group as a whole." ORAN R. YOUNG, *COMPLIANCE AND PUBLIC AUTHORITY* 27 (1979). Other regulators have provided additional anecdotal evidence supporting this 95% estimate of essentially voluntary compliance. See Robert A. Kagan & John T. Scholz, *The "Criminology of the Corporation" and Regulatory Enforcement Strategies*, in *ENFORCING REGULATION* 67, 76 (Keith Hawkins & John M. Thomas eds., 1984) [hereinafter *ENFORCING REGULATION*].

2. See AL GORE, *FROM RED TAPE TO RESULTS: CREATING A GOVERNMENT THAT WORKS BETTER & COSTS LESS: REPORT OF THE NATIONAL PERFORMANCE REVIEW* 117-19 (1993) (stressing innovative program design, and citing as examples negotiated rulemaking and alternative dispute resolution); AL GORE, *FROM RED TAPE TO RESULTS: CREATING A GOVERNMENT THAT WORKS BETTER & COSTS LESS: IMPROVING REGULATORY SYSTEMS: ACCOMPANYING REPORT OF THE NATIONAL PERFORMANCE REVIEW* 26-27 & n.25 (1993) (recommending publication of a "Deskbook on Regulatory Design," which would examine "not only the design of the regulation, but also the effectiveness of implementation" and which should discuss "innovative approaches to enforcement"). See also Thomas O. McGarity, *Reforming OSHA: Some Thoughts for the Current Legislative Agenda*, 31 *HOUS. L. REV.* 99, 110-11, 113-15 (1994) (proposing as part of regulatory reform of OSHA that employees be "empowered" with a positive and structured role in enforcement).

3. See, e.g., Memorandum of April 21, 1995: Regulatory Reform - Waiver of Penalties and Reduction of Reports, 60 *Fed. Reg.* 20,621 (1995) (memorandum from President Clinton to departments and agencies authorizing a penalty waiver for small businesses and directing a reduction by 50% in the frequency of reporting required by the government).

have noted the lack of significant combined empirical-theoretical research in the areas of policy implementation and enforcement.<sup>4</sup>

Any system of direct enforcement by detection and prosecution will necessarily be incomplete; and further study is needed into the ways regulators exercise their discretion not to punish through cooperative rather than adversarial means.<sup>5</sup> Moreover, “[g]iven the potentially large savings in implementation costs that might be realized in attaining regulatory objectives, . . . it is surprising that more research has not gone into ways of enforcing and monitoring compliance.”<sup>6</sup>

This study attempts to add to this needed empirical-theoretical work by examining federal agency use of one promising alternative: cooperative implementation, which is reliance by the federal government on the regulated entities themselves to interpret and enforce regulations.<sup>7</sup> In many instances, federal agencies have enlisted the regulated entities themselves in enforcing laws and regulations by providing incentives to comply, combined with self-

4. See Donald S. Van Meter & Carl E. Van Horn, *The Policy Implementation Process: A Conceptual Framework*, 6 ADMIN. & SOC’Y 445, 449-52 (1975). A later review of the research literature, though noting that “[i]t would be difficult for any responsible study of the functioning of federal regulatory agencies to lay claim to novelty,” classified regulatory reform as only one of six areas of the study of the functioning of federal regulatory agencies generally. *Federal Regulation: Roads to Reform*, 1979 A.B.A. COMM’N ON LAW & ECON. 13-14. Reviewers of economic research, writing on the need for future empirical and theoretical work, concluded that “far too much of the effort of economists has been directed toward asking whether there should or should not be regulation, and far too little effort directed at how to improve the performance of regulatory policies.” Paul L. Jaskow & Roger C. Noll, *Regulation in Theory and Practice: An Overview*, in STUDIES IN PUBLIC REGULATION 1, 35 (Gary Fromm ed., 1981). See also MURRAY L. WEIDENBAUM, THE FUTURE OF BUSINESS REGULATION 150-51 (1979).

5. Colin S. Diver, *A Theory of Regulatory Enforcement*, 28 PUB. POL’Y 257, 259-60 (1980).

6. Anthony C. Fisher et al., *Setting Regulatory Priorities*, in ATTACKING REGULATORY PROBLEMS: AN AGENDA FOR RESEARCH IN THE 1980s 145, 153 (Allan R. Ferguson ed., 1981). Fisher and the critics cited in the previous notes were writing at least 15 years ago, and much promising work has been done since then. See for example the study of mine safety regulation in JOHN BRAITHWAITE, TO PUNISH OR PERSUADE (1985). “John Braithwaite is one of a few scholars who have made empirical studies of how corporations regulate themselves.” JAY A. SIGLER & JOSEPH E. MURPHY, INTERACTIVE CORPORATE COMPLIANCE 190 (1988); see also *id.* at 191-92 (citing and favorably discussing John T. Scholz, *Voluntary Compliance and Regulatory Enforcement*, 6 LAW & POL’Y 385 (1984)).

This study follows closely on the author’s and the Administrative Conference’s earlier work on self-regulation which focused on reliance by agencies on intermediate groups known as “self-regulatory organizations.” See Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171 (1995). This study differs from the previous work by focusing solely on the self-regulatory activities of the regulated entities without the presence of any intermediary organization. However, many of the conclusions reached in the previous work regarding the benefits of self-regulation generally are equally applicable here. This model of cooperative implementation is similar to the model of “enforced self-regulation” developed in IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION 101-32 (1992), and the model of “interactive compliance” developed in SIGLER & MURPHY, *supra* at 143-65.

7. For a more detailed description of cooperative implementation, see *infra* Part I.B.

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monitoring and reporting requirements. This is an enforcement strategy short of traditional direct enforcement, but also short of leaving the regulated population on its own in the perhaps vain hope that predisposition to obey alone will extract compliance.

Part I of this study defines cooperative implementation and examines how it might best be designed and why it might be advantageous. Part II is a survey of executive departments' and independent agencies' efforts at enforcement innovation, each summarized and compared with the theoretical bases of Part I. Part III extracts from this survey a model for choosing and designing a program of cooperative implementation, though the details of any program would depend in each instance on the underlying basis for the regulation.

### I. The Theory of Cooperative Implementation

Cooperative implementation is a mode of general policy implementation which focuses primarily on the activities of the individual regulated entities.<sup>8</sup> This Part first describes how cooperative implementation is developed from general theories of implementation and compliance. Next, building on this foundation, specific elements of a cooperative implementation program are identified. Finally, the potential advantages of this program are discussed.

#### A. *General Theories of Policy Implementation*

Whether implementation is deterrence-based, focusing on punishment of violations, or compliance-based, focusing on prevention of violations,<sup>9</sup> it involves finding actual or incipient violations and encouraging changes in behavior accordingly. Although these regulatory functions are often performed directly by federal government employees, much of modern regulatory reform focuses on the use of private "agents" to do this governmental work, such as the use of intermediaries as third-party standard setters, auditors or regulators.<sup>10</sup> Cooperative implementation is the use of intermediaries who are agents or employees of the regulated entity itself, as opposed to the government or any third party.

Cooperative implementation also involves a broader part of implementation policy: the development and interpretation of rules. It is true

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8. "Compliance signifies more than the identification of appropriate statutes and rules; it means the construction of an appropriate strategy for changing the behavior of American businesses in a direction determined by prevailing public policies." SIGLER & MURPHY, *supra* note 6, at 104.

9. Albert J. Reiss, Jr., *Selecting Strategies of Social Control Over Organizational Life*, in ENFORCING REGULATION, *supra* note 1, at 23-24 (developing taxonomy of deterrence- and compliance-based enforcement).

10. See generally Michael, *supra* note 6.

that the enforcement of any command—even the most clear or simple—involves at least some interpretation and discretion.<sup>11</sup> However, implementation often involves the application of rules which do not simply state the required steps or actions. Rather, it involves the application of “transparent” rules: those which state the intention of the rule or the desired outcome.<sup>12</sup> For example, “speed limit 55 m.p.h.” would be the most simple rule, while “do not exceed a reasonable speed” would be the most transparent. Clearly, the latter rule will not produce identical outcomes, but that is an advantage, not a drawback, of transparent rules.<sup>13</sup> These rules are superior in cases where, unlike in the speed limit example, the same processes are not appropriate for each regulated entity.<sup>14</sup> In such cases, cooperative implementation, employing transparent rules, necessarily leaves a significant amount of discretion to the regulated entity. This is not to say that “simple” rules, by contrast, are necessarily easy rules. Simplicity of rules is a function of the “number of steps required by the regulation’s decision rule and the quantity and accessibility of the evidentiary inputs that it demands.”<sup>15</sup> The United States’ system of self-assessment of the federal income tax, for example, is not meant to leave a significant amount of discretion to each taxpayer. These rules are simple, but not simplistic. Finally, while discretionary rules are few and far between, simple rules abound.<sup>16</sup>

Implementation as defined above has two components: interpretation of a transparent rule and enforcement, or the assurance of compliance. Cooperative implementation, therefore, is governmental reliance upon agents or employees of the regulated entities themselves to interpret and enforce applicable regulations. The government’s role under such a system would be substantially changed, for it would no longer be in the business of writing

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11. “An officer who decides what to do or not to do often (1) finds facts, (2) applies law, and (3) decides what is desirable in the circumstances after the facts and the law are known. The third of these three functions is customarily called ‘the exercise of discretion’ . . . .” KENNETH CULP DAVIS, *DISCRETIONARY JUSTICE* 4 (1969).

12. See Colin S. Diver, *Regulatory Precision*, in *MAKING REGULATORY POLICY* 199, 200 (Keith Hawkins & John M. Thomas eds., 1989).

13. *Id.* at 201-02.

14. It could be argued that a transparent rule might be appropriate for our speed limit example. If the desired outcome is the reduction of accidents rather than a uniform highway traffic speed, and this is best accomplished by driving at a speed safe for the driver, the equipment, and the road conditions, then the rule “do not exceed a reasonable speed” may in fact produce more consistent outcomes.

15. Diver, *supra* note 12, at 201.

16. Continuing the income tax example, I.R.C. § 162(a) (1995) permits as a deduction “a reasonable allowance for salaries or other compensation . . . .” What is “reasonable” is to be determined “under all the circumstances.” 26 C.F.R. § 1.162-7(b)(3) (1995). Although there appears to be some discretion inherent in this rule, in practice decisions are normally based not on reasonableness, but on whether the payment is actually payment for personal services as opposed to something else. See 1 BORIS I. BITTKER, *FEDERAL TAXATION OF INCOME, ESTATES AND GIFTS* 22-20 (1981).

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“command-and-control” rules; rather, the rules would be of the “transparent” type discussed above. The government would rely on the regulated entities to develop specific and individual implementation plans, and would thus restrict its role to assisting in and providing incentives for self-implementation programs, and to maintaining a credible residual program of detection, surveillance and enforcement.

As compared to similar proposals, cooperative implementation as defined above is a more informal arrangement between the agency and the regulated entity. For example, Sigler and Murphy would treat certification of the entity’s implementation program as compliance with the law although those entities “would not be excused from meeting essential legal obligations,”<sup>17</sup> a term left undefined. Ayres and Braithwaite would go further at the other end of the spectrum, however, and make “violation of the privately written . . . rules . . . punishable by law.”<sup>18</sup> Cooperative implementation retains as the legal standard the transparent rule from the statute or regulation. The regulated entity’s impetus to self-develop its implementation program is its desire to avoid more intrusive agency activity in assuring compliance, or to simplify and make more certain the process of applying for government licenses, permits or other benefits.<sup>19</sup>

To be successful, cooperative implementation must reinforce an entity’s fundamental predisposition to comply with the law. In the economist’s traditional theory, an actor complies with a rule where the actor’s own calculation yields costs of compliance which are outweighed by the likely benefits of compliance or punishments for noncompliance. Therefore, the rate of compliance can be affected by the government if it can reduce the costs of compliance or increase the expected benefits or punishments.<sup>20</sup> This economic theory extends from the individual to the group: part of the individual’s calculus is whether benefits are obtained from others’ compliance, and whether

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17. SIGLER & MURPHY, *supra* note 6, at 149.

18. AYRES & BRAITHWAITE, *supra* note 6, at 106.

19. See *infra* Part I.B.2 below.

20. SIGLER & MURPHY, *supra* note 6, at 98. “The economist provides us with a model for predicting deterrent impact: a person subject to a legal command will be deterred from violating that command if the expected cost (to him) of the violation equals (or exceeds) its expected benefit.” Diver, *supra* note 5, at 262. “Conventional wisdom explains the criminal activities of individuals in terms of a pleasure-pain calculus—the law is disobeyed when the gain derived from the crime exceeds the potential pain of being caught and punished.” Kagan & Scholz, *supra* note 1, at 69. “Even when there are no public authorities and social pressures are absent, individual subjects may conclude that the expected value of compliance outweighs that of violation.” YOUNG, *supra* note 1, at 18. As Young implies, the costs of violation can be imposed otherwise than through regulation. For a comprehensive review of the incentives behind private corporate codes of conduct, in conjunction with and in spite of government commands for such codes, see SIGLER & MURPHY, *supra* note 6, at 47-54, 67-77, and Harvey L. Pitt & Karl A. Groskaufmanis, *Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct*, 78 GEO. L.J. 1559, 1560-61, 1634-36 (1990).

others are more likely to comply if the individual complies.<sup>21</sup>

The level of compliance also affects the individual's own calculation of the likelihood of violations being detected and prosecuted. "[W]here there is an extremely high risk, such as in the antitrust or environmental area, and particularly where there is a high likelihood of discovery and prosecution, such as in the area of employment discrimination, it is generally accepted that the balance swings in favor of [adopting] compliance programs."<sup>22</sup> The theory of calculated action based on others' actions not only explains compliance, but also leads to the conclusion that there is an optimum level of direct enforcement; that is, detection, surveillance and prosecution will have decreasing returns, and at some point it is more efficient to rely on alternative methods of enforcement.<sup>23</sup> It follows that if deterrence has ceased to provide efficient motivation, the government should turn to the other two factors in the compliance formula: decreasing the costs of compliance or increasing the expected benefits from compliance.

Yet apart from explicitly economic motivations, individuals, particularly business enterprises, comply with rules because they see a larger good in compliance itself.<sup>24</sup> In addition to a strictly moralistic motivation to comply, individuals might agree that a system of rules is better because it permits individuals to determine how to comply, thus reducing the intrusion and discretion of public officials, or because a lack of general adherence to common rules would be chaotic.<sup>25</sup> There are other factors, too, which are related to the economic calculus described above, but which are not often explicitly considered. For example, compliance may reduce the likelihood of civil liability, or may result in an improved "corporate image" as a "model citizen," which might give an indirect or long-term boost to profitability.<sup>26</sup>

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21. See Malcom Feeley, *Coercion and Compliance: A New Look at an Old Problem*, in COMPLIANCE AND THE LAW 51, 51-65 (Samuel Krislov et al. eds., 1972). The classic statements of this theory relating to economic activity are by George Stigler and Richard Posner; see Diver, *supra* note 5, at 262 & n.14 (citing Richard Posner, *The Behavior of Administrative Agencies*, 1 J. LEGAL STUD. 314 (1972) and George Stigler, *The Optimum Enforcement of Laws*, 78 J. POL. ECON. 526 (1970)). The classic statement relating to political activity is by James Buchanan and Gordon Tullock; see Feeley, *supra* at 52 (citing JAMES M. BUCHANAN & GORDON TULLOCK, *THE CALCULUS OF CONSENT* (1962)).

22. SIGLER & MURPHY, *supra* note 6, at 70. See also YOUNG, *supra* note 1, at 18.

23. See Diver, *supra* note 5, at 264 ("One implication of this analysis is that complete deterrence is not socially optimal."). For a different development of this theory, see YOUNG, *supra* note 1, at 111-34.

24. See YOUNG, *supra* note 1, at 22-24, Kagan & Scholz, *supra* note 1, at 76 ("While we have seen no polls on the subject, it is plausible to believe that well-educated, upper-middle-class corporate officials, with their private concerns about social stability and their institutional concern for an orderly business environment, tend to be strong adherents of the basic principle of law-abidingness.").

25. See Feeley, *supra* note 21, at 35, 45-46.

26. See Kagan & Scholz, *supra* note 1, at 75-77; YOUNG, *supra* note 1, at 19; BARDACH & KAGAN, *supra* note 1, at 61.



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Any predisposition toward compliance is limited, however; individuals will voluntarily comply with rules only when such rules are perceived as reasonable, and violation serves as a rebellion against illegitimacy.

Corporations that are generally disposed to obey the law may adopt a strategy of selective noncompliance when regulations . . . impose unreasonable burdens. Corporate officials we interviewed, and many scholarly studies as well, repeatedly referred to instances of government arbitrariness: ill-conceived and conflicting regulations; officious and poorly trained government inspectors; unreasonable paperwork requirements; bureaucratic delay; governmental indifference to the disruption or inefficiencies . . . caused by literal enforcement of regulations. . . . They ask why they should waste time and money complying with regulations that might seem to make sense in theory but that are impractical or unduly costly in particular cases.<sup>27</sup>

Thus, regulatory reasonableness is an important qualification in a system of cooperative implementation. If the government expects a significant level of voluntary compliance with its rules, the rules must be recognized as reasonable even apart from their economic impact.

### B. *Elements of a Cooperative Implementation Program*

The theories of compliance discussed above suggest several characteristics essential to any enforcement program relying on voluntary compliance by the regulated entities. Standards must be designed to allow for discretion in implementation; the regulated entities must have some incentive to invest in standards design; and there must be effective monitoring of the entities' performance.

#### 1. *Standards Design*

Cooperative implementation by definition requires independent judgment

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27. Kagan & Scholz, *supra* note 1, at 75. Sigler and Murphy relate this to the above-discussed economic motivation:

After all, most business executives share a general commitment to social order. Business activity may, at times, create pollution, unsafe drugs, unclean food, and unsafe products, but this is not to say that businessmen aim to profit by their antisocial acts, but that their cost-benefit calculations have not given sufficient weight to compliance with the law. For the most part, business people would like to be able to adhere to reasonable laws and regulations.

SIGLER & MURPHY, *supra* note 6, at 99.

on the part of the regulated entities or their agents—this is one of its distinct advantages in areas where different interpretations or solutions may realize the same policy goal. Because performance or output standards are transparent<sup>28</sup>—stating the desired outcome or result—and leave much of the detail of compliance to the regulated entity, they will be perceived as more reasonable.<sup>29</sup> As indicated above, perceived unreasonableness of rules breeds contempt and noncompliance.<sup>30</sup> “Self-made” rules are inherently more likely to be considered reasonable by the regulated entity, and will therefore be looked upon more favorably.<sup>31</sup>

However, cooperative implementation is self-defeating, if not dangerous, when left to entities unskilled in compliance. This is especially so if the regulation is intended to prevent harmful occurrences (for example, toxic contamination, industrial accidents, or adulterated food products), and not just to punish the responsible entities after the fact. The agency must be able to assure itself that there is a basic level of expertise throughout the regulated population or that such expertise can be quickly supplied. Often the agency steps into the role of compliance educator in cooperative implementation programs. Indeed, researchers have concluded that government inspectors will be more effective with production/output regulations if they work as consultants rather than police.<sup>32</sup> In some instances, private expert bodies may be a source of knowledge and advice, while still leaving the implementation up to the regulated entity.<sup>33</sup> If the expertise is inherently lacking, it will be difficult to muster a credible cooperative implementation program.<sup>34</sup>

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28. See *supra* notes 11-15 and accompanying text.

29. See *infra* note 80 and accompanying text.

30. See *supra* text accompanying note 27.

31. See Michael, *supra* note 6, at 183-84.

32. See Paul Danaceau, *Developing Successful Enforcement Programs*, in SOCIAL REGULATION: STRATEGIES FOR REFORM 139, 156-57 (Eugene Bardach & Robert A. Kagan eds., 1982) [hereinafter SOCIAL REGULATION] (A program based on performance standards will work best when inspectors are given discretionary authority, allowing them “to develop the cooperative working relationships with business, industry, and local communities that a regulatory program must have in order to succeed.”). See generally Kagan & Scholz, *supra* note 1, at 68 (unless deterrence is the goal, government should act to persuade the regulated business of the rationality of the regulation or to educate it in compliance). See *infra* notes 166-67 and accompanying text (guidance given by Food Safety and Inspection Service to meat and poultry processors in designing cooperative implementation programs).

33. See Michael, *supra* note 6, at 181-82 (technical expertise in self-regulatory organizations).

34. Consider, for example, the rangeland grazing program discussed *infra* Part II.D.4. Ranchers, it was envisioned, would consider and implement some non-ranching uses of their lands as a condition of extended grazing permits. Critics of the plan, while not necessarily attributing any cynical motives to the ranchers, indicated that the ranchers simply lacked the expertise in rangeland management (beyond ranching) to do the job and had no economic motivation to acquire it.

### 2. *Incentives*

Cooperative implementation policies should undoubtedly draw on any existing internal motivation, but must recognize that motivation to comply is in most cases profit-driven and thus externally supplied.

An analysis which takes these [corporate cost-benefit] factors into account leads to the conclusion that mere exhortations to comply cannot realistically be expected to produce results. Rather, government must start with the basic proposition that it is necessary to give something in order to get something. If corporations are asked to accept the potentially significant costs and risks of enhanced compliance activities and if it is recognized that this is done for the substantial benefit of society, then it is necessary to change the equation so that the balance moves in favor of compliance. In short, it is necessary to provide significant incentives to achieve this result. These incentives must involve both a reduction in the risk associated with compliance activities and positive rewards for commitment to compliance.<sup>35</sup>

Cooperative implementation is more likely to succeed where deterrence has failed if the benefits of compliance are increased or the costs of compliance are reduced.

Cooperative implementation should transform existing rules from negative commands into conditions for a government reward, such as a license, permit, grant, or a lighter burden of direct regulation.<sup>36</sup> This makes the individual's economic calculus easier, and explicitly states the incentive to comply. A regulatory system so designed can also achieve the benefits traditionally associated with incentive and transfer systems based on licenses in cases where it is impossible to adopt such a system. For example, although acid rain deposition is controlled through a system of transferrable allowances to emit pollution,<sup>37</sup> it is doubtful that a similar program could be developed for trafficking in industrial accidents, unsafe aircraft, or tainted meat or poultry. However, performance standards could nonetheless be substituted for existing proscriptions, and the achievement of those standards held out as a condition for other benefits. Indeed, cooperative implementation and performance or output standards go hand-in-hand because they both respond to the same

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35. SIGLER & MURPHY, *supra* note 6, at 149.

36. Reiss, *supra* note 9, at 24 ("Compliance systems . . . either reward or withhold imposing penalties to induce states of compliance.").

37. See *infra* text accompanying note 236.

problem: inordinately complex regulatory problems created in a large organization with decentralized authority. The same conditions militate against both "command and control" regulation and direct enforcement.<sup>38</sup>

Supplying economic motivation is not difficult. Sometimes the motivation is a function of the agency's specific power to grant or withhold a license or permit. Other times, the motivation can be provided by offering a reduced enforcement presence, such as fewer inspections or a "safe harbor" approach to otherwise ambiguous rules. Both of these techniques are well-known ways to "create" economic motivations where the agency otherwise has no favors to grant.<sup>39</sup> These incentives are distinct from granting leniency when violations are discovered outside of the cooperative implementation program. Ultimately, the decision to pursue violations of any type grows out of the agency's core enforcement discretion and is difficult to limit by rule.<sup>40</sup>

Cooperative implementation will be more successful where the harm to be prevented is universally recognized and where all regulated entities will benefit from compliance. Universality underscores the moral obligation to comply as well as the economic incentive. For example, if one producer's adulterated drug or tainted meat or poultry harms consumers, demand for everyone's products may be affected.<sup>41</sup>

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38. See John T. Scholz, *Cooperation, Deterrence, and the Ecology of Regulatory Enforcement*, 18 LAW & SOC'Y REV. 179, 183 (1984) ("It is generally agreed that cooperative strategies are most important when the complexity of compliance situations makes it impossible to specify in unambiguous legal rules the behavior required to achieve intended policy purposes. . . . In such situations, cooperative enforcement can lead to greater social benefits through flexible enforcement.").

39. See *id.* at 204-06; Peter P. Swire, *Safe Harbors and a Proposal to Improve the Community Reinvestment Act*, 79 VA. L. REV. 349, 369-78 (1993).

40. For example, EPA recently adopted a policy of eliminating punitive penalties for regulated entities "that voluntarily identify, disclose and correct violations" according to the policy's conditions. Voluntary Environmental Self-Policing and Self-Disclosure Interim Policy Statement, 60 Fed. Reg. 16,875, 16,875 (1995). However, the agency reserved the right, even where the conditions for leniency are otherwise met, "to collect full civil penalties for criminal conduct, violations that present an imminent and substantial endangerment or result in serious actual harm, or repeat violations." *Id.* at 16,876. One related alternative, which does not compromise the public agency's enforcement discretion, is to permit compliance to be a shield of some sort in private actions. SIGLER & MURPHY, *supra* note 6, at 143-44. Regarding relief from criminal penalties, Sigler and Murphy recognize the difficulty in limiting agency discretion by the agency itself, and suggest that any programmatic leniency be set forth in the statute. *Id.* at 152-53.

41. See Thomas P. Grumbly, *Self-Regulation: Private Vice and Public Virtue Revisited*, in SOCIAL REGULATION, *supra* note 32, at 93, 115 ("[I]t is not by accident that voluntarism seems to have made the greatest strides in areas like food and drug regulation, where statutes have been on the books for decades, and in which there seems to be little doubt concerning the necessity of action.").

### 3. *Monitoring*

In order to be effective and accountable, a system of cooperative implementation must include disclosure of performance by the regulated entities and periodic assessment by the regulatory agency. This monitoring is carried out by the regulated entities through self-certification or self-reporting, and by the agency through a traditional direct enforcement program.

Monitoring through reports is a necessary component of any form of regulation.<sup>42</sup> The disclosure involved in this instance, however, is distinct from disclosure as a regulatory technique generally. The reports which are required under a system of cooperative implementation are not intended merely to inform the consumers of their choices, as is typical for such reports.<sup>43</sup> Rather, the report is itself intended to modify the conduct of the regulated entity, and it thereby becomes part of the cooperative implementation technique. "In the overall system of protective regulation, paperwork functions as an enforcement mechanism in very much the same way as do inspectors who look directly into matters under their jurisdiction, and this mutual substitutability cannot be emphasized too strongly."<sup>44</sup>

Even where required reports do not affect conduct, they generate several benefits. They provide a source of information from which the agency can judge the regulated entity's conduct over time; they allow the regulated entity to build justifications for its conduct; they demonstrate rationality in the entity's regulatory process; and they assist in "consciousness raising" of the regulated.<sup>45</sup> In addition, monitoring through reports is part of a program of residual direct regulation, which is an essential part of a program of cooperative implementation.<sup>46</sup> The reports are also essential to the meaningful monitoring of the regulated entity and the agency by the public.<sup>47</sup>

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42. Eugene Bardach, *Self-Regulation and Regulatory Paperwork*, in SOCIAL REGULATION, *supra* note 32, at 315, 316 ("[M]ost regulatory enforcement is really based on self-inspection accompanied by some type of reporting or certification to the regulatory agency that the citizen has complied with the law."); Fisher et al., *supra* note 6, at 153 ("An important component of [any] enforcement strategy is of course some form of monitoring.").

43. STEPHEN G. BREYER, REGULATION AND ITS REFORM 163 (1982) ("Ordinary standards governing primary conduct oftentimes forbid or dictate the type of product that must be sold or the process that must be used. . . . Standards governing disclosure, however, do not restrict conduct beyond requiring that certain information be provided.").

44. Bardach, *supra* note 42, at 321.

45. *Id.* at 322-27.

46. *See infra* text accompanying notes 49-54.

47. *See* Stephen E. Ronfeldt & Russell W. Galloway, Jr., *Beneficiary-Based Enforcement of Federal Regulatory Programs: Strategies for Compelling Federal Agencies and Regulatees to Comply with Public Interest Laws*, 26 HOW. L.J. 1365, 1372-77 (1983) (discussing collection and use of "compliance data" in citizen-based enforcement). There is an especially effective statutorily-authorized public monitoring and enforcement provision in the Clean Water Act. *See infra* notes 215-216 and accompanying text.

Residual reliance on direct enforcement is necessary in a system of self-regulation for several reasons. First, of course, there must be some method of verifying the regulated entities' compliance. Second, there will inevitably be regulated entities who will not comply, most likely because they still perceive the costs of compliance to be greater than the consequences of a detected violation.<sup>48</sup> Unless the regulator maintains the perception that violations will be detected and prosecuted, there will be a breakdown in the regulated entities' reliance on each others' compliance,<sup>49</sup> which is essential to successful cooperative implementation.<sup>50</sup> Third, direct enforcement will be necessary because no population of firms or individuals is homogeneous; therefore, there will not be one regulatory technique which fits all.<sup>51</sup> Fourth, direct regulation and proscription are necessary where the harms from violation cannot be internalized by the entity,<sup>52</sup> or where it would be politically and socially unacceptable implicitly to permit an activity, such as racial discrimination.<sup>53</sup> And finally, the government must remain flexible, because compliance will fluctuate over time. Indeed, if a program of self-regulation becomes successful, the inducements to compliance that are at its core may become unduly expensive, and a greater emphasis on direct enforcement may ultimately be necessary.<sup>54</sup>

48. See generally BRAITHWAITE, *supra* note 6, at 84-118.

49. Accord YOUNG, *supra* note 1, at 25-27. This is the source of compliance of Bowles' estimated "75 percent" in the introductory quote; see *supra* text accompanying note 1. It is important to underscore "the threat of legal sanctions in the background" in the theory of voluntary compliance. It is not *entirely* voluntary. Indeed, compliance would perhaps dissipate if there were virtually *no* threat of regulatory enforcement or if firms believed their competitors were regularly violating the law with impunity and were thereby gaining a competitive edge.

Kagan & Scholz, *supra* note 1, at 76. See also BRAITHWAITE, *supra* note 6, at 118 ("One is inclined to listen to the persuasive overtones of an inspector if the consequences of not listening is his replacing the velvet glove with the iron fist."); Diver, *supra* note 5, at 297 ("Enforcement is necessary not only to control the aberrant lawbreaker, but also to defend the legitimacy of governmental intervention that sustains voluntary compliance."); Robert A. Kagan, *Understanding Regulatory Enforcement*, 11 LAW & POL'Y 89, 101 (1989) ("Trading legal forbearance for cooperative problem-solving maximizes regulatory goals, so long as it is backed by credible threats of sanctions.").

50. See *supra* notes 21-22 and accompanying text.

51. See Kagan & Scholz, *supra* note 1, at 85 ("[I]ndiscriminate reliance on any single theory of noncompliance is likely to be wrong, and when translated into an enforcement strategy, it is likely to be counterproductive.").

52. See *infra* notes 95-96 and accompanying text.

53. Richard B. Stewart, *Reconstitutive Law*, 46 MD. L. REV. 86, 111-12 (1986).

54. YOUNG, *supra* note 1.

[T]here is an important asymmetry between enforcement and inducement from the point of view of public authorities. . . . This is so because punishments must be meted out in the wake of violations while rewards must be distributed when subjects actually comply. Paradoxically, this suggests that a public authority confidently expecting to succeed in its efforts to obtain compliance is more likely to rely heavily upon enforcement than one possessing a lower sense of efficacy.

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There are legal and policy limitations on the authority of the government to extract “voluntary” information from regulated entities when it is simultaneously maintaining a direct enforcement program. The individuals and firms must report honestly, but at the same time they should not be expected routinely to invite civil or criminal penalties, or to place themselves at a competitive disadvantage as a result of their reports.

The Fifth Amendment protection against self-incrimination prohibits the government from requiring an individual to report criminal violations. This issue is important because most regulatory statutes studied here have provisions making some violations criminal offenses.<sup>55</sup> However, courts have upheld reporting requirements which are “essential to a public, regulatory scheme, rather than designed to obtain private information . . . or evidence of criminal activity.”<sup>56</sup> Traditionally, the factors applied in distinguishing legitimate requests for information from unconstitutional compulsion are: (1) whether the reported behavior or event is essentially regulatory or an “area permeated with criminal statutes”; (2) whether the statute is directed to the public at large or a select suspected group; and (3) whether the reports required are facially neutral or require admission of a crucial element of a crime.<sup>57</sup>

Application of these factors might prove difficult in some cases. The group in each case is relatively select and the information required would, in many instances, establish violation of a criminally-punishable legal rule. In addition, the admitted purpose of the reporting is to monitor and thereby encourage compliance, which suggests there could be sanctions, possibly criminal sanctions, awaiting reports of noncompliance. Balanced against these factors is the nature of the information itself: it is clearly regulatory, part of and analogous to a category of required disclosures recognized as almost presumptively permissible.

An organized society imposes many burdens on its constituents. It commands the filing of tax returns for income; it requires producers and distributors of consumer goods to file informational reports on the manufacturing process and the content

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*Id.* at 22.

55. See, e.g., Toxic Substances Control Act, 15 U.S.C. § 2615(b) (1994); Food, Drug, and Cosmetic Act, 21 U.S.C. § 333 (1994); Poultry Products Inspection Act, 21 U.S.C. § 461(a) (1994); Federal Meat Inspection Act, 21 U.S.C. § 676(a) (1994); Occupational Safety and Health Act, 29 U.S.C. § 666 (1994); Clean Water Act, 33 U.S.C. § 1319 (1994); Clean Air Act, 42 U.S.C. § 7413(c) (1994) (point sources of pollution), § 7524 (mobile sources of pollution); Federal Land Policy Management Act, 43 U.S.C. § 1733 (1995).

56. CHARLES H. WHITEBREAD & CHRISTOPHER SLOBOGIN, CRIMINAL PROCEDURE 342 (3d ed. 1993).

57. See Jeremy H. Temkin, Comment, “Hollow Ritual[s]”: *The Fifth Amendment and Self-Reporting Schemes*, 34 UCLA L. REV. 467, 480 (1986) (quoting *Albertson v. Subversive Activities Control Bd.*, 382 U.S. 70, 79 (1965)).

of products, on the wages, hours, and working conditions of employees. Those who borrow money on the public market or issue securities for sale to the public must file various information reports; industries must report periodically the volume and content of pollutants discharged into our waters and atmosphere. Comparable examples are legion.

. . . . But under our holdings the mere possibility of incrimination is insufficient to defeat the strong policies in favor of a disclosure called for by statutes like [these].<sup>58</sup>

Even if constitutional problems were found, a cooperative implementation scheme could nonetheless remain effective. It is possible that criminal sanctions are not needed to provide sufficient compliance incentives. After all, the existence of a self-regulatory scheme in the first place suggests that deterrence has been found to be largely ineffective. Some commentators have suggested granting “use immunity” for regulatory disclosures which admit criminal violations.<sup>59</sup> The more compelling threat in any event may be the withdrawal of government benefits, rather than criminal prosecution.<sup>60</sup>

In addition to possibly fueling criminal prosecution, reports by regulated entities might be used in civil cases as well. However, such reports may be shielded from disclosure in some cases. Courts have recognized in various circumstances a limitation on the discovery of materials prepared by an entity

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58. *California v. Byers*, 402 U.S. 424, 427-28 (1971) (plurality opinion).

59. See Temkin, *supra* note 57, at 495-503; Daryl J. Lapp, Comment, *Mandatory Self-Reporting Under Section 922(e) of the Gun Control Act of 1968: Its Infringement on the Fifth Amendment Privilege Against Self-Incrimination*, 81 NW. U. L. REV. 263, 283-86 (1987).

60. It is possible that loss of benefits could be considered “punitive,” and the revocation of those benefits thus a “criminal proceeding” within the meaning of the Fifth Amendment. See WHITEBREAD & SLOBOGIN, *supra* note 56, at 340 (“compulsion would seem to apply to many situations in which the government asks citizens for information via registration forms, welfare applications, professional license applications and the like”), 347 (“In deciding whether a proceeding is ‘criminal’ for purposes of the privilege, courts look principally at whether ‘punitive’ sanctions could be imposed at the proceeding in question, not at the label—i.e. ‘civil’ or ‘criminal’—traditionally affixed to the proceeding.”). Even if this were true, however, the threat of withdrawal of benefits may not be considered “compulsion,” since the reporting entity always has the choice of forfeiture of the benefit. See *Selective Serv. Sys. v. Minnesota Pub. Interest Research Group*, 468 U.S. 841, 856-57 (1984) (holding that denial of loan benefits to students who failed to register for the draft did not compel students to admit nonregistration or late registration, which were criminal offenses, “since a nonregistrant is bound to know that his application for federal aid would be denied, [and] he is in no sense under any ‘compulsion’ to seek that aid”). See also WHITEBREAD & SLOBOGIN, *supra*, at 340 & n.30.

In addition, many of the statutes cited *supra* note 55, contain civil as well as criminal fines. A civil fine is not subject to the Fifth Amendment, see *Ward v. Coleman*, 423 F. Supp. 1352 (W.D. Okla. 1976) (civil fine under Federal Water Pollution Control Act). But, as discussed above, Congress’ label on the remedy is not controlling. WHITEBREAD & SLOBOGIN, *supra* at 347. See also *Austin v. United States*, 113 S.Ct. 2801 (1993) (Eighth Amendment prohibition of “excessive” fines applies to civil as well as criminal proceedings).



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for an internal review of its compliance with the law, known as the “self-critical analysis” or “self-evaluative” privilege.<sup>61</sup> In general, the privileged communication is “a review of a major policy or procedure, conducted by or for top management to permit the evaluation and improvement of an organization’s operations.”<sup>62</sup> The purpose of the privilege is to ensure completeness and candor which might otherwise be lacking if the evaluations prepared would be available to the public.<sup>63</sup> The privilege has most often been held to protect confidential peer reviews, internal investigations of misconduct, and the documents evaluating equal employment policies which are required to be filed with the government under Title VII of the Civil Rights Act of 1964.<sup>64</sup>

In general, the privilege has three broad limitations. First, it applies only to the conclusions and opinions expressed in the critiques or evaluations, not to independently discoverable facts.<sup>65</sup> Second, it does not apply if the evaluation itself is the subject of the litigation.<sup>66</sup> Finally, and most importantly for this study, the privilege does not ordinarily apply to the government as

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61. See Peter A. Gish, *The Self-Critical Analysis Privilege and Environmental Audit Reports*, 25 ENV'T L. 73 (1995); James F. Flanagan, *Rejecting a General Privilege for Self-Critical Analyses*, 51 GEO. WASH. L. REV. 551 (1983); Joseph E. Murphy, *The Self-Evaluative Privilege*, 7 J. CORP. L. 489 (1982); Note, *The Privilege of Self-Critical Analysis* 96 HARV. L. REV. 1083 (1983).

62. Flanagan, *supra* note 61, at 556.

63. *Id.* at 554-55 (discussing the first case formulating the policy, *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970), *aff'd*, 479 F.2d 920 (D.C. Cir. 1973)); Note, *supra* note 61, at 1087-88 (same); Gish, *supra* note 61, at 78-79 (same).

64. 42 U.S.C. § 2000e (1994). See Gish, *supra* note 61, at 79-80; Flanagan, *supra* note 61, at 554-55; Note, *supra* note 61, at 1087-91. There are cases in a variety of other areas. “The . . . privilege has been extended to . . . accounting records; to securities law; . . . to railroad accident investigations; to product safety assessments; and to products liability.” *Reichhold Chemicals, Inc. v. Textron, Inc.*, 157 F.R.D. 522, 525 (N.D. Fla. 1994) (citations omitted). The court in *Reichhold Chemicals* held the privilege applicable to documents prepared by a current owner of a plant site in an action for recovery of environmental cleanup costs. *Id.* at 527.

65. Gish, *supra* note 61, at 82; Flanagan, *supra* note 61, at 556-57.

66. See, for example, the discussion in *Reichhold Chemicals*, of the difference between knowledge acquired before the act which allegedly caused the plaintiff’s injury and knowledge acquired afterwards.

The fact that an actor had actual prior knowledge of the harm that would or could result from a course of action, and, nevertheless, deliberately chose to act is highly relevant in a negligence action and should ordinarily be discoverable. However, retrospective analysis is generally not relevant. Public knowledge of such analysis, and especially the potential use of such an analysis in litigation, would chill candid self-assessment and the preservation of such self-evaluation records.

*Reichhold Chemicals*, 157 F.R.D. at 527. See also *University of Pa. v. EEOC*, 493 U.S. 182, 189-90 (1990) (holding that 1972 amendment of Title VII of the Civil Rights Act of 1964, extending the Act to higher education, eliminated any claim of privilege in university’s faculty promotion file where the denial of promotion was allegedly discriminatory).

plaintiff.<sup>67</sup>

Thus, the self-evaluation privilege may boost the usefulness of cooperative implementation by precluding the use of that implementation itself to establish civil liability.<sup>68</sup> The underlying facts are, of course, discoverable, but the entity's critical conclusion that there was something wrong and that it needed to be fixed would be privileged.<sup>69</sup> However, if that evaluation is itself the cause of the plaintiff's injury, the privilege obviously should not apply. Furthermore, although arguments can be made that privileges should apply to the government and private plaintiffs alike,<sup>70</sup> the courts have consistently held that specific statutes with enforcement provisions indicate a congressional interest in disclosure which outweighs any harms. As currently articulated by the courts, the privilege may assist in establishing the usefulness of cooperative implementation without hindering the government agency's full monitoring and oversight authority.<sup>71</sup>

Outside of litigation altogether, there is the loss of secrecy inherent in any public filing. Firms participating in a cooperative implementation monitoring program would have sensitive information about the development of their plan and any failures or corrections made publicly available under the Freedom of Information Act (FOIA),<sup>72</sup> absent an exemption from disclosure.

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67. Gish, *supra* note 61, at 84. In this context, the Supreme Court noted that "[w]e are especially reluctant to recognize a privilege in an area where it appears that Congress has considered the relevant competing concerns but has not provided the privilege itself." *University of Pa. v. EEOC*, 493 U.S. at 189. This will be the case in most instances involving a federal agency investigating compliance with its own laws. *See Federal Trade Comm'n v. TRW, Inc.*, 628 F.2d 207, 211 (D.C. Cir. 1980) (FTC subpoena); *United States v. Noall*, 587 F.2d 123, 126 (2d Cir. 1978) (IRS subpoena).

68. Murphy, *supra* note 61.

Clearly the protection the [self-evaluative privilege] may offer is uncertain. It may be recognized in a judge's discretion and applied to protect opinions, evaluative remarks, recommendations for improvement, and efforts to discipline employees. The [privilege] may protect minutes of a self-evaluative committee, or at least the subjective elements of such minutes.

*Id.* at 494. Of course, where the self-enforcement does not work, the fact that the program was in place may be of little value in either a civil or criminal context. It is normally no defense that an employee's unlawful act was contrary to specific instructions if the act was otherwise within the scope of employment. *See Pitt & Groskaufmanis*, *supra* note 20, at 1606-14.

69. SIGLER & MURPHY, *supra* note 6.

This is similar to the evidentiary rule generally barring the introduction of evidence that a defendant took corrective measures to ameliorate the underlying cause of the litigation. In such a case it may be recognized that the subsequent efforts have some relevance but it is nevertheless determined that society's need to encourage corporations to take corrective measures outweighs the need for litigants to obtain evidence.

*Id.* at 158 (citation omitted).

70. *See, e.g.*, Murphy, *supra* note 61, at 496.

71. Sigler and Murphy argue that the self-evaluative privilege needs to be "definite, consistent, and strong" with significant penalties for disclosure of self-evaluations. SIGLER & MURPHY, *supra* note 6, at 158-60.

72. Pub. L. No. 89-487, 80 Stat. 250 (1966) (codified as amended at 5 U.S.C. § 552).

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The most likely basis for an exemption from disclosure is FOIA's exemption (4) for "trade secrets and commercial or financial information obtained from a person and privileged or confidential."<sup>73</sup> The portion of this exemption most likely applicable to cooperative implementation reports is that pertaining to confidential<sup>74</sup> commercial information.<sup>75</sup> The scope of "confidentiality" under exemption (4) has broad and uncertain boundaries, depending on whether the reliability of the information will be impaired or if the regulated entity will suffer substantial competitive harm if the information is disclosed.<sup>76</sup>

The resolution of these issues under FOIA may not be essential to the design or oversight of a cooperative implementation program, since the agency's treatment of the information, once received, cannot create or destroy a FOIA exemption. One agency noted its belief that such plan records will likely qualify for exemption (4), but suggested that most of the problems could be avoided if the records were not submitted to the agency. Instead, the records would be kept by the regulated entity on site and available for inspection, thereby preventing the plans from becoming an "agency record" subject to FOIA at all.<sup>77</sup>

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73. 5 U.S.C. § 552(b)(4).

74. Commercial information must be either confidential or privileged to fall within exemption (4). Because the self-evaluative privilege discussed above does not apply to the government, it is uncertain whether it would form a basis for exemption as "privileged." Thus, the issue will likely be whether the information is "confidential."

It is possible that a privilege issue could be raised based on an interpretation of dictum in *United States v. Weber Aircraft Corp.*, 465 U.S. 792 (1984), a case under FOIA exemption (5), which covers "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5) (1994). The Supreme Court noted that "respondents' contention that they can obtain through the FOIA material that is normally privileged would create an anomaly in that the FOIA could be used to supplement civil discovery. We have consistently rejected such an application of the FOIA." *Weber*, 465 U.S. at 801. Although the self-evaluative privilege would not apply to the government in discovery, the result would be that the private party could obtain through FOIA what it could not get in private litigation (since the privilege applies to private parties but not to the government), clearly contrary to the policy stated in *Weber*. This reasoning, though not applied to the self-evaluative privilege, has been held to be a basis for exemption under FOIA exemption (4) as "privileged information." See *Washington Post Co. v. Dep't. of Health & Human Serv.*, 603 F. Supp. 235, 237-38 (1985), *rev'd on other grounds*, 795 F.2d 205 (D.C. Cir. 1986). See also 1 JAMES T. O'REILLY, *FEDERAL INFORMATION DISCLOSURE* 14-23 (1994).

75. The other types of information within the exemption, financial information and trade secrets, are not likely to be part of a cooperative implementation plan. The information is not financial. Whether the information is a "trade secret" depends upon the circumstances surrounding the development of the plan, though a cooperative implementation plan certainly could be a trade secret. See JUSTIN D. FRANKLIN & ROBERT F. BOUCHARD, *GUIDEBOOK TO THE FREEDOM OF INFORMATION AND PRIVACY ACTS* 4-4 to 4-7 (1995); O'REILLY, *supra* note 74, at 14-11 to 14-13.

76. See generally FRANKLIN & BOUCHARD, *supra* note 75, at 4-11 to 4-38; O'REILLY, *supra* note 74, at 14-25 to 14-26.

77. See *Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems*, 60 Fed. Reg. 6774, 6821 (1995) (to be codified at 9 C.F.R. §§ 308, 310, 318, 320, 325-328).

### C. *Potential Advantages of Cooperative Implementation*

Cooperative implementation has great potential to produce better regulation, and to produce it more efficiently, because the regulated entities themselves would be developing the regulations—that is, the actual restrictions on conduct. Theoretically, this should result in better standards and greater compliance. A combination of cooperative implementation backed by residual direct enforcement will yield a “welfare-maximizing agency striv[ing] to focus its energies where it can do the most good, guided by a sense of what is legally, technologically, economically and politically possible.”<sup>78</sup>

Because cooperative implementation relies on rules developed by the regulated entities, the agency’s rules can be “transparent,” stating only the outcome or result desired.<sup>79</sup> These rules, known as performance or output standards, have long been recognized by researchers in administrative reform to have unique potential to be more flexible, coordinated and rational.<sup>80</sup> In addition to benefiting the regulated entities and the intended beneficiaries of the regulatory program, these standards should benefit the agency as well.<sup>81</sup> Not only can programs thereby be improved, but the consequently simpler and more routine enforcement strategy can make the regulatory program less expensive and more efficient, either lowering altogether the government’s costs or allowing the agency to concentrate those resources on other problems.<sup>82</sup>

Rules developed by the regulated entity itself should have the inherent advantage of being perceived as reasonable by those who must comply.

There are many reasons to think that private, internal regulators can be more reasonable than their public counterparts. They are more

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78. Kagan, *supra* note 49, at 93.

79. For a discussion of “transparent” and “simple” rules, see *supra* notes 11-15 and accompanying text.

80. See generally Cass R. Sunstein, *Administrative Substance*, 1991 DUKE L.J. 607, at 631-34 (discussing several methods of regulating with incentives rather than direct government controls); Stewart, *supra* note 53, at 104-09 (discussing “reconstitutive” strategies for regulation, including economic incentives and economic exchange and transfer systems); BREYER, *supra* note 43, at 185-88 (suggesting as a general guideline that “classical regulation ought to be looked upon as a weapon of last resort” and listing as exemplary alternatives economic incentives, bargaining and disclosure); Michael, *supra* note 6, at 181-88 (discussing general advantages of audited self-regulation).

81. See Sunstein, *supra* note 80, at 634 (“Indeed, the major advantage of incentive-based approaches may be the increase in democratic accountability [that] results from this cognitive shift.”); Stewart, *supra* note 53, at 107-08 (incentive-based strategies “lessen the current concentration of decisionmaking power within central bureaucracies and promote decentralization, flexibility, and diversity.”); THE BUSINESS ROUNDTABLE, TOWARD SMARTER REGULATION 23 (1995) (“Because agencies must consider the comparative performance of different machines or products to write the regulatory standard in the first place, it can be just as easy for the agency to base its standard on performance goals, such as fewer injuries or cleaner air.”).

82. See Fisher et al., *supra* note 6, at 153.

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specialized and more knowledgeable about the risks generated by their company's operation. They are more likely to have the trust of the people they regulate and thus to have access to finer-grained and more relevant information. Unlike government regulators, they sometimes can be seen by their firm's middle-level managers as contributing to the overall goals of the organizations in which they operate. They are freer to use discretion in the application of general standards to particular cases.<sup>83</sup>

Substantial research in behavior theories has confirmed these hypotheses.<sup>84</sup> One researcher develops a rigorous formal model of combined deterrence-based and cooperation-based enforcement strategies, concluding that

an enforcement strategy that combines cooperation and deterrence is likely to produce greater net benefits than a single-minded deterrence strategy. . . . The advantage of the combined strategy . . . increases with enforcement tradeoffs that reduce costs for cooperative firms, with diminishing returns that increase the advantages of cooperation, and with the degree to which the sanction structure favors cooperation over evasion. On the other hand, the advantage is limited by the maximum level of voluntary compliance determined by the given enforcement situation and by the firms' concern with the future.<sup>85</sup>

Greater effectiveness is possible if the responsibility for compliance in each regulated entity is decentralized and exercised by responsible, knowledgeable officers with the power to effect change.<sup>86</sup> However, the last point mentioned in the above excerpt is important to remember as cooperative implementation programs are considered: there will be failures, even if the program is

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83. BARDACH & KAGAN, *supra* note 1, at 219. These authors conclude that "the advantages of private regulation . . . to provide greater *reasonableness* than public regulation, make it worthwhile to explore ways to improve its *effectiveness* to the point that citizen expectations for ever higher levels of protection can be met." *Id.* at 219-20. *See also* Michael, *supra* note 6, at 183 ("[S]elf-regulation is likely to produce rules from an expert's knowledge base, tailored to the conditions of the particular industry or workplace. The rules therefore are perceived by the regulated entities, because of their participation, as more 'reasonable' from the outset compared with the more inflexible counterparts issued by government regulators."). *See also* AYRES & BRAITHWAITE, *supra* note 6, at 110-13 (asserting that self-developed compliance rules will be better tailored to each company, more responsive, more innovative, more comprehensive, and more widely followed).

84. For an extensive bibliography of research in this area, see Scholz, *supra* note 38, at 222-24.

85. *Id.* at 219.

86. *Id.* at 182-84.

functioning perfectly. The relevant comparison is not to zero faults or full compliance, but the results using any alternative regulatory technique.

Finally, cooperative implementation naturally shows the greatest potential where traditional enforcement cannot succeed. Traditional enforcement is virtually guaranteed to fail in cases if violations cannot be detected or where waiting to punish the harm after it occurs will have limited benefits.

The effectiveness of many regulations simply cannot be directly observed. It may be impossible to measure the amount of a particular regulated pollutant emitted into the air from the smokestack of one particular firm, or whether, and by how much, that amount varies from the baseline against which an increase or decrease in permitted pollution is measured.<sup>87</sup> Nonetheless, we want those emissions reduced. It may be impossible to determine whether a particular vat of ground beef is harboring *E. coli* bacteria without analyzing (and thus destroying) the entire amount. Nonetheless, we want those bacteria eliminated. It may be impossible to state generally what precautions are needed to make workplaces safe and health-promoting. Nonetheless, we insist that those measures be taken.

Such circumstances do not mean that these regulations are futile. Indeed, policy judgments—choosing among different types of transparent rules—are beyond the scope of this study. We take for granted that the pollutant contributes to sickness or to the destruction of crops or buildings,<sup>88</sup> that *E. coli* is what makes people sick,<sup>89</sup> and that we can identify the causes of workplace hazards without separate rules for each one. However, it is difficult to know when limits on pollution, bacteria, or risky and unhealthy working conditions are being complied with, even if they *are* effective. Thus, it is unrealistic to expect to be able to detect violations in a fashion which provides a convincing deterrent.<sup>90</sup>

Direct enforcement is likewise difficult where the regulated entities are large, complex organizations. Any large organization can function only by delegation of power and responsibility; by definition, the organization is too complex for one manager or group of managers to control directly. With that

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87. See *infra* note 240 and accompanying text.

88. The question of how much risk to human, plant or building life is too much is a separate question from whether science can establish a connection between the risk and the pollutant or measure the output of the pollutant. The former question is critical and often ignored. See generally STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 10-29 (1993) (discussing systematic problems that distort our ability to make rational risk assessments); THE BUSINESS ROUNDTABLE, *supra* note 81, at 14 (“The difficulty of allocating limited resources for maximizing risk reduction is compounded by the common failure of agencies to base their analyses on the most advanced scientific principles. Without sound science, risks cannot be accurately assessed and effectively compared.”).

89. Again, the issue is how much is too much. See *infra* note 132 and accompanying text.

90. Why we have such rules in the first place is a fascinating but separate question. See, e.g., BREYER, *supra* note 88, at 42-50.

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delegation necessarily goes a certain irreducible amount of unreviewable discretion, and with that discretion goes the trust that it will be appropriately exercised.<sup>91</sup> Because it is impossible for the manager to review directly all activities of the delegate, the detection and surveillance required for direct enforcement will, again, be difficult or impossible.<sup>92</sup>

Even if standards and science were certain, it may be simply impossible (within realistic resource constraints) to inspect the many regulated entities subject to these rules.<sup>93</sup> Selecting the major or largest entities for more frequent review lessens or eliminates the deterrent threat on the smaller entities, yet failing to do so runs the risk of failing to prevent the violations with the largest impact.<sup>94</sup>

Moreover, in many regulatory programs prevention is the key, and a traditional direct enforcement program, with its emphasis on the detection and punishment of violations, does little in the way of prevention. Many regulations seek to prevent harms which, if they occurred, would require many more resources to repair than would be available to the firm which caused them. In many areas of regulation, such as nuclear power production, agricultural quarantines, or toxic substance controls, restitution would be practically impossible. Therefore, it would also be impossible to set penalties at levels which would properly internalize these external costs and yet not force many or all firms out of production. Other harms are detectable only after long periods of time, thereby making any enforcement more difficult. The harms from polluting factories or unsafe workplaces, for example, may not be known for years. Where there are such significant externalities, it is not enough to punish the violator; the regulatory goal must be to prevent the violations.

Regulators should encourage industry to address harms *at their source*. In general, regulators should adopt strategies that will

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91. A similar amount of delegation is necessary in the regulatory agency as well, but it may be difficult to achieve. Delegation and the accompanying dilution of direct control may be politically unacceptable to those currently in control of the agency and policy. The beneficiaries of the regulatory scheme, if sufficiently politically organized, may act to prevent any such loss of control. See John T. Scholz, *Cooperative Regulatory Enforcement and the Politics of Administrative Effectiveness*, 85 AM. POL. SCI. REV. 115 (1991).

92. See Reiss, *supra* note 9, at 29.

93. "There are 2,000 [OSHA] inspectors nationwide to check 6 million workplaces with 93 million employees. On average, a company can expect to see an OSHA inspector once every 10 years, according to the agency." Frank Swoboda & Stephen Barr, *Guardian of Employee Safety is About to Get a Work-Over*, WASH. POST, May 16, 1995, at A16.

94. Of course, the argument could be made that if there are too many regulated entities for traditional enforcement, there are also too many for even the limited monitoring and surveillance required in a program of cooperative implementation; see *supra* Part I. B.3. However, it should be noted that the program of surveillance and inspection can be more limited in an effective program of cooperative implementation, and the enhanced self-reporting may provide much of the routine information previously sought through these methods.

reduce the introduction of dangerous substances, instead of merely controlling substances that have already been introduced. In this regard, strategies that leave the means of obtaining reduction to industry, rather than specifying them in detail, will prove most effective in eliminating social harm.<sup>95</sup>

Short of prohibiting these activities, the regulator must work with the regulated entity to encourage compliance rather than await violations to punish.<sup>96</sup>

Enforcement is similarly difficult where the penalties imposed can be externalized by being partially passed on to others. For example, a fine imposed on a corporation, however significant, can be passed on to consumers, employees and investors. In the long run, of course, continued fines will make continuation of the business and the manager's employment less certain, but the deterrent impact of direct enforcement is muted.<sup>97</sup> If the direct enforcement system corrects for this problem by imposing non-transferrable (personal) fines and punishments, they will necessarily be out of proportion to that individual's direct involvement, and either will be considered unfair or will result in the cessation of the activity altogether.<sup>98</sup>

## II. Survey of Current Uses of Cooperative Implementation

Part I identified characteristics of a regulation and program which would suggest that cooperative implementation might be a successful technique. This Part surveys some existing programs of cooperative implementation, describing the regulations and their development and comparing their design and effect to the theories described above.

### A. *Workplace Safety*

Under the Occupational Safety and Health Act of 1970,<sup>99</sup> the Occupational Safety and Health Administration (OSHA) within the Department of Labor promulgates and enforces standards for workplace safety and health.<sup>100</sup> Industrial safety has been a recurring focus of regulatory reformers. Many researchers have considered this area a prime candidate for

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95. Sunstein, *supra* note 80, at 632.

96. *See id.* at 635; Reiss, *supra* note 9, at 26-27.

97. *See* Reiss, *supra* note 9, at 28 ("Thus the fining of the corporation can be borne by consumers so long as it does not fatally damage the competitive position of the corporation.").

98. *See id.*

99. Pub. L. No. 91-596, 84 Stat. 1590 (1970) (principally codified as amended at 29 U.S.C. §§ 651-78).

100. *See* 29 U.S.C. § 655 (1995) (promulgation of standards), §§ 657-59 (inspections, citations, and enforcement).



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adoption of cooperative regulatory strategies, given the practical difficulties accompanying direct enforcement of OSHA standards.<sup>101</sup>

In 1986, OSHA implemented the Voluntary Protection Program (VPP). Under VPP, employers who qualify can be removed from routine OSHA inspections for a period of up to three years.<sup>102</sup> OSHA completes a rigorous "pre-approval review" of a worksite before it is admitted into the VPP; this includes examination not only of the site's accident record, but the company policies and controls for ensuring health and safety, and interviews with both management and workers about those policies and controls.<sup>103</sup> And once a worksite is approved for the VPP program, OSHA still routinely reviews worker complaints, chemical leaks or spills, and any accidents. Furthermore, OSHA retains plenary investigation and enforcement authority,<sup>104</sup> and conducts a review similar to the pre-approval review (including a site visit) every three years. VPP programs are now in operation at approximately 170 worksites of 125 employers.<sup>105</sup>

The stated purpose of the program reveals many of the classic rationales for cooperative implementation.<sup>106</sup> The VPP provides incentives for cooperative implementation because (1) it may encourage employer (and therefore employee) innovation,<sup>107</sup> and (2) it will reduce the frequency of

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101. The question of enforcement of OSHA standards is discussed here apart from the related but separate question of how those standards should be chosen. *See, e.g.,* BREYER, *supra* note 88; JOHN M. MENDELOFF, *THE DILEMMA OF TOXIC SUBSTANCE REGULATION* (1988); and Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 *YALE J. ON REG.* 1 (1989) (reviewing OSHA's standard setting processes and offering suggestions for reform).

102. *See* Voluntary Protection Programs, 53 *Fed. Reg.* 26,339 (1988).

103. *See id.* at 26,346.

104. *See id.* at 26,347 ("Although the history of the VPP indicates that safety and health problems discovered during contact with worksites for VPP purposes are resolved cooperatively, OSHA must reserve the right, where the safety and health of employees is seriously endangered and site management refuses to correct the situation, to refer the situation . . . for review and enforcement action if warranted.").

105. Telephone Interviews with Frank Frodyma, Acting Director of Policy, and Kathy Oliver, Chief of Voluntary Programs, OSHA (Nov. 4, 1994).

106. *Supra* note 102.

OSHA has long recognized that compliance with its standards cannot [by] itself accomplish all the goals established by the Act. The standards, no matter how carefully conceived and properly developed, will never cover all unsafe activities and conditions. Furthermore, limited resources will never permit regular or exhaustive inspections of all the Nation's workplaces. In addition, employers and employees, because of their day-to-day experience in the workplace, acquire a special knowledge of the processes, materials and hazards involved with the job. This knowledge, combined with the ability to evaluate and address unique hazards quickly and to provide rewards for positive action, can be used by employers to improve workplace safety and health in ways simply not available to OSHA. *Id.*, at 26,341 (1988).

107. Most OSHA researchers have suggested giving workers a more formal say in the enforcement and compliance areas. *See* Thomas O. McGarity, *Reforming OSHA: Some Thoughts*

OSHA inspections.<sup>108</sup> Additionally, as empirical research reveals that some large employers attempt compliance beyond the scope of OSHA inspections,<sup>109</sup> there may be internalized motives at work as well. As with any program of cooperative implementation, reliable monitoring mechanisms are required.<sup>110</sup> The VPP reports, review of complaints and triennial reviews appear to meet these requirements.

The main difficulty is that the benefit provided—relief from annual inspections—will not be perceived as valuable so long as those inspections are not a realistic “threat” (possibility).<sup>111</sup> Thus, it may be difficult to extend VPP broadly, since the benefits are not credible and the monitoring ability is limited if the regulated population grows so large that it is no longer easily overseen.

OSHA was able to make relief from inspections a credible incentive in a recent test program now operating in three states. Using data on state workers’ compensation claims, OSHA concentrated on the worksites with the largest number of claims.<sup>112</sup> The agency found that there was not a large

for the Current Legislative Agenda, 31 Hous. L. Rev. 99, 113-17 (1994); Lawrence S. Bacow, *Private Bargaining and Public Regulation* in SOCIAL REGULATION, *supra* note 32, at 201; BARDACH & KAGAN, *supra* note 1, at 230-32; BREYER, *supra* note 43, at 180-81; Sunstein, *supra* note 80, at 640-41.

108. See Bacow, *supra* note 107, at 211-13 (describing precursor of VPP and how exemption from inspections provides significant incentives). An earlier discussion of a similar proposal questioned whether the OSHA inspection was itself sufficiently costly so that its avoidance was any incentive to management. See JOHN MENDELOFF, *REGULATING SAFETY: AN ECONOMIC AND POLITICAL ANALYSIS OF OCCUPATIONAL SAFETY AND HEALTH POLICY* 133-42 (1979) (describing the “THIRE”—Targeting High Injury Rate Establishments—proposal).

109. See Wayne B. Gray & John T. Scholz, *Does Regulatory Enforcement Work? A Panel Analysis of OSHA Enforcement*, 27 LAW & SOC’Y REV. 177, 200 (1993) (“We speculate that OSHA penalties . . . refocus managerial attention on safety and health problems that may have been ignored or overlooked. The initial focus on specific OSHA violations, though perhaps annoying to busy managers, triggers a broader review of performance that we suspect goes far beyond a legalistic response to OSHA standards.”).

110. See MENDELOFF, *supra* note 108, at 133-42.

111. Telephone Interview with Frank Frodyma, Acting Director of Policy, OSHA (Nov. 4, 1994). See also MENDELOFF, *supra* note 108, at 139. He discusses the problem of extending coverage of such a program to the smallest firms, although the incentive in those firms to avoid an OSHA inspection (because of its proportionately higher cost) may be greater. He concludes that “for the very small firms . . . a system of random inspections should be used to maintain a deterrent. An alternative would be to rely upon an intensive program of accident investigations so that small firms would learn that serious injuries bring inspections.” *Id.* He also suggests another reason why OSHA inspections may be limited in their effectiveness.

[I]t seems plausible that despite its small inspectorate and low average penalty, OSHA’s deterrent may be large enough to induce substantial compliance. It is conceivable that even with greatly expanded resources and larger penalties, OSHA would very quickly run up against a more fundamental constraint—the limited proportion of injuries caused by detectable violations.

*Id.* at 90.

112. Frank Swoboda & Stephen Barr, *Guardian of Employee Safety is About to Get a Work-Over*, WASH. POST, May 16, 1995, at A16.

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overlap between this list and the list of worksites slated for traditional inspections.<sup>113</sup> Under this test program, those frequent-claim sites that develop a satisfactory comprehensive safety and health program will be removed from OSHA's primary inspection list to a secondary list, presumably lessening the probability of an inspection. Almost all of the firms contacted by OSHA have responded with such programs.<sup>114</sup>

When they changed the regulatory paradigm from ticket writing to these cooperative relationships, they identified and reduced 'hazards,' a White House official said. "If you assume the goal is health and safety in these tough workplaces, this is what you want to have a system doing."<sup>115</sup>

Thus, there are ways to target surveillance and inspections, not just to the largest firms, but to the firms or sites most likely to produce the harms the statute or regulation is intended to prevent.<sup>116</sup> This makes inspection threats credible even with limited resources.

### B. *Food Safety Assurance*

The responsibility for the safety of the nation's food supply is vested in two different agencies: one focusing on meat and poultry (the Food Safety and Inspection Service), and the other on all other food items (the Food and Drug Administration). Many programs of cooperative implementation have been tried by these agencies, but both have now focused on a generally accepted method of production regulation known as the Hazard Analysis Critical Control Point (HACCP) method.<sup>117</sup> This section reviews each agency's progress toward HACCP, and then considers whether the HACCP model is a viable candidate for extension into other regulatory areas.

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113. Telephone Interview with Frank Frodyma, Acting Director of Policy, OSHA (June 2, 1995) [hereinafter Frodyma interview].

114. *Id.*; see also BILL CLINTON & AL GORE, THE NEW OSHA: REINVENTING WORKER SAFETY AND HEALTH 4-5 (National Performance Review Report, May 1995).

115. Swoboda & Barr, *supra* note 112, at A16.

116. See *id.* for a description of an OSHA project in the construction industry designed to limit inspectors' primary attention to preventing four types of accidents (falls, electrocution, collapse of structure, and falling items) that account for almost all injuries. This policy allows more and better inspections. Frodyma interview, *supra* note 113.

117. The principles and history of HACCP are discussed *infra* Part II.B.3.

1. *Meat and Poultry Inspection*

Under the Federal Meat Inspection Act of 1907<sup>118</sup> and the Poultry Products Inspection Act of 1957,<sup>119</sup> the Secretary of Agriculture is required to inspect each animal entering a livestock or poultry slaughterhouse before slaughter, to inspect carcasses and parts after slaughter,<sup>120</sup> and to continuously inspect the processing of meat and poultry products.<sup>121</sup> These Acts are enforced and implemented by the Department of Agriculture's Food Safety and Inspection Service (FSIS).<sup>122</sup> FSIS has interpreted each of these statutes as requiring physical inspection of each animal slaughtered, but not physical inspection of each processed meat or poultry product.<sup>123</sup> This distinction between slaughter and processing has produced different regulatory regimes. FSIS' experience in each instance provides evidence of the potential for and limits of cooperative implementation.

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118. Ch. 2907, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. §§ 601-80).

119. Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified as amended at 21 U.S.C. §§ 451-69).

120. 21 U.S.C. § 455 (1995) (poultry), §§ 604-05 (cattle, sheep, swine, goats, horses, mules and other equines).

121. 21 U.S.C. § 455 (poultry and poultry products), § 606 (meat food products).

122. See 9 C.F.R. § 301.2(b) (1995) (meat inspection), § 381.1(b)(3) (poultry inspection).

123. The statutory language, 21 U.S.C. §§ 455, 604-05, clearly requires individual inspection of each animal by a federal inspector both before and after slaughter. FSIS has interpreted its authority under the meat and poultry processing laws, however, as more flexible.

A narrow interpretation of the processing inspection section of the Meat Inspection Act [21 U.S.C. § 606] could mean that a departmental inspector must personally and literally inspect (by some method which the Act does not prescribe) every frankfurter, package of luncheon meat, pork chop, etc., before it could [be approved], and further that a departmental inspector must personally and literally place every label, mark, stamp, or tag on each such item. This language has not been so narrowly interpreted in the administration of the Act. To the contrary, the Department has exercised some discretion regarding its methods of inspection, particularly with regard to processed products with complex formulations. The Department has adhered, however, to the principle that Federal regulators make the determinations as to which products are adulterated and misbranded and which are not, and that the marks of Federal inspection are placed on the products by the inspectors or by establishment employees under that degree of supervision by the inspectors necessary to assure the marks are properly applied only to products eligible therefor.

Similar provisions regarding inspections are contained in the Poultry Processing Inspection Act [21 U.S.C. § 455], although the Secretary has slightly more discretion under this Act with respect to the inspection of "further processing" of poultry products than he has under the Federal Meat Inspection Act with respect to meat food products.

Voluntary Meat and Poultry Plant Quality Control Systems, 45 Fed. Reg. 54,310, 54,317 (1980) [hereinafter Quality Control Systems Rule].

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FSIS is constrained by statute to physically inspect each animal presented for slaughter, despite the inability of such inspection to identify bacterial infestations which are today considered a primary cause of foodborne illnesses.<sup>124</sup> In 1988, FSIS proposed a Streamlined Inspection System (SIS), a modification of its traditional ante- and post-mortem inspections of animals.<sup>125</sup> Under SIS, plant employees would be responsible for certain tasks previously done by federal inspectors, though the inspectors would continue to make the actual inspection and decision whether the item inspected would be passed or condemned.<sup>126</sup> The main advantage of SIS was to increase productivity of slaughterhouses without sacrificing standards of quality. FSIS did not anticipate that SIS would reduce the number of federal inspectors needed or otherwise result in cost savings to the government.<sup>127</sup>

Despite these objectives, SIS was almost universally opposed by consumer and even industry groups.<sup>128</sup> FSIS was ultimately forced to withdraw the SIS proposal<sup>129</sup> after further funding was withdrawn by Congress.<sup>130</sup> FSIS intends to review its proposals to modernize

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124. As noted recently by FSIS Administrator H. Russell Cross: FSIS will continue to inspect every carcass as the law requires. Traditional inspection focuses, as you know, on the defects that can be seen, what we call organoleptic inspection, such as visible contamination and symptoms of animal disease. As we strengthen the scientific basis of our inspection program, focused on bacteria, we must accelerate our . . . efforts against the defects that we cannot see, such as harmful . . . pathogenic bacteria, that cause foodborne illness.

News Conference, June 10, 1992 (Federal News Service, available in Nexis library, Omni file). See also *infra* note 162 and accompanying text (inability of current system to test for pathogenic microorganisms).

125. See Streamlined Inspection System-Cattle and Staffing Standards, 53 Fed. Reg. 48,262 (proposed Nov. 30, 1988) [hereinafter SIS Proposed Rules].

126. See *id.* at 48,264-65 (describing inspection modifications). FSIS has emphasized that SIS would involve no transfer of the actual inspection to plant employees. "Plant employees do not do inspection duties. Our [FSIS] inspectors do 100 percent carcass inspection. They are the ones who inspect the carcasses for disease. They make the decisions. Our veterinarians make the decisions on what gets passed and what gets condemned. The plant is doing the mechanical procedures." News Conference, *supra* note 124 (Remarks of Jill Hollingsworth, FSIS).

127. See SIS Proposed Rules, *supra* note 125, at 48,267-68 (indicating that savings will accrue to the industry); Daniel P. Puzo, *Does Streamlined Beef Inspection Work?*, L.A. TIMES, June 18, 1992, at H37 (quoting FSIS Administrator H. Russell Cross that SIS "will not reduce inspector numbers at all. If we have any say then the numbers are going to go up and so will the inspectors' training.").

128. See Patricia P. Mitchell, *Can USDA Inspectors Do More With Less?*, WASH. POST, Jan. 9, 1991, at E1; Bruce Ingersoll, *New Beef Inspection Would Be So Cursory Even Packers Are Wary*, WALL ST. J., May 16, 1989, at A1.

129. 57 Fed. Reg. 40,623 (1992).

130. The negative public sentiment was ultimately transformed into Congressional disapproval. See Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1993, Pub. L. No. 102-341, 106 Stat. 873, 882 (1992) (providing that "none of the funds [for FSIS] in this Act may be used to carry out the Streamlined Inspection System (for cattle) after April 1, 1993.").

slaughterhouse inspection, however, and remains committed to an effective replacement.<sup>131</sup>

The agency's experience with SIS demonstrates that favorable public and industry predisposition to regulatory reform plays a key part in the success of that reform. Although it is well established that the current method of physical inspection of each animal does not guard against bacterial or chemical contamination, all affected groups universally opposed the reduction of the government's physical inspection proposed under SIS. The perception that dirty or diseased meat was more likely to be placed before American consumers was simply too strong to overcome any efforts by FSIS to implement the SIS system. Critics also contended that SIS, and indeed the FSIS entire inspection system, was not based upon sufficient scientific evidence of what defects in animals actually pose a public health risk.<sup>132</sup> Regardless of the ultimate outcome of the debate, the impression remains firmly rooted in the public and in Congress that physical inspection by federal employees of each animal to be slaughtered, however outdated, should not be compromised.<sup>133</sup>

Although SIS was not considered by FSIS to be any form of cooperative implementation,<sup>134</sup> this experience indicates that any modification of traditional government regulation must be preceded by evidence of effectiveness, as well as significant constituent support. In the case of SIS, promises of increased efficiency and resulting cost reductions to the industry were insufficient to produce industry support, and the evidence of ineffectiveness, though primarily anecdotal, was sufficient to defeat the proposal.

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131. See *FSIS to Withdraw SIS, But Repropose Cattle Inspection Changes*, FOOD CHEMICAL NEWS, Aug. 3, 1992 (available in Nexis library, Omni file).

132. One frequent critic, Carol Tucker Foreman, a former Assistant Secretary of Agriculture, has noted the lack of scientific research. See Mitchell, *supra* note 128 (quoting Foreman's admonition that FSIS must conduct basic research, such as how much bacteria makes people sick); Ingersoll, *supra* note 128. FSIS, on the other hand, maintains that it has conducted significant research into the effects of streamlined inspection. See Mitchell, *supra*, (noting that former FSIS Administrator Lester Crawford maintained "that there is already plenty of data"); News Conference, *supra* note 124 (discussing results of FSIS-sponsored study of SIS).

133. The vitality of this impression was demonstrated by the Department's response to the January 1993 outbreak of illness and deaths apparently linked to contaminated beef sold in Washington fast food restaurants. The initial response was to require additional inspectors in the slaughterhouses, despite the current inability to test for micro-organisms. Some observers believe this impression—that physical inspection remains necessary today—owes its hardness to efforts by meat inspectors who believe that changes to scientific-based methods may mean job losses. See generally, Carole Sugarman, *U.S. Meat Inspections Come Under Scrutiny*, WASH. POST, Feb. 9, 1993, Health section, at 9; Richard Gibson & Scott Kilman, *Tainted-Hamburger Incident Heats Up Debate Over U.S. Meat-Inspection System*, WALL ST. J., Feb. 12, 1993, at B1.

134. FSIS maintained, see *supra* note 126 and accompanying text, that no regulatory functions were being passed to industry.

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Government regulation of the processing of meat and poultry into products, in contrast to slaughterhouse regulation, focuses on the integrity of the process rather than on physical inspection of each product.<sup>135</sup> In this area, FSIS has pursued two different programs involving self-enforcement. Because these programs have been successful at least in part, they provide additional evidence of the components of a successful program.

In the Processed Products Inspection Improvement Act of 1986,<sup>136</sup> Congress authorized FSIS to depart from the previously required continuous presence of federal inspectors at each meat processing establishment.<sup>137</sup> Pursuant to this authority, FSIS adopted a pilot Discretionary Inspection (DI) system.<sup>138</sup> Under DI, FSIS shifted inspectors to priority critical points in each plant or to plants with substandard compliance records.<sup>139</sup> The system relied on a processor's own demonstrated compliance with the processing regulations and internal control systems in determining the scope and frequency of future inspections.<sup>140</sup> In addition, DI was intended to reduce the number of federal inspectors required. FSIS did not consider DI to be a form of self-enforcement,<sup>141</sup> although the Act did provide that plant employees could inspect and pass or condemn processed articles.<sup>142</sup>

FSIS had significant difficulties in implementing DI,<sup>143</sup> resulting in dissatisfaction from its own employees as well as consumer groups.<sup>144</sup> Critics

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135. See *supra* note 123 and accompanying text.

136. Pub. L. No. 99-641, Title IV, 100 Stat. 3567 (1986) (lapsed 1992).

137. Authority to depart from continuous inspection already existed with respect to poultry processing. See 21 U.S.C. § 455(a) (1995).

138. See *Experimentation With Procedures for Determining the Intensity of Inspection Coverage in Processing Establishments; Waivers of Provisions of the Regulations*, 52 Fed. Reg. 10,028 (1987) [hereinafter *DI Rules*].

139. See *USDA's "Discretionary Inspection" Plan for Meat and Poultry Processing Plants: Hearing Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Operations*, 100th Cong., 1st Sess. 168 (1989) [hereinafter *DI Hearings*] (statement of Lester M. Crawford, FSIS Administrator).

140. Criteria for assessing the need and frequency of inspection include: the nature and frequency of processing operations, adequacy and reliability of processing controls and sanitary procedures, and history of compliance with inspection requirements. See *DI Rules*, *supra* note 138, at 10,030.

141. See *DI Hearings*, *supra* note 139, at 170 (statement of Lester M. Crawford, FSIS Administrator) ("In no way do we view the program as 'industry self-policing' nor as an effort to 'de-regulate.'")

142. See § 403(a), 100 Stat. at 3567-68.

143. See *DI Hearings*, *supra* note 139, at 27 (statement of Eduardo Delgado, USDA inspector) ("The . . . system is a program for computers to assign inspectors which plants to cover, when to go there, what to look at and how long to stay there. It turned us into slaves of this computer. It has also been a nightmare . . . . The computer . . . repeatedly sends us to plants that are not open. . . . The computer also skips [quality control] deviations . . . . Inspections are impossible also because plants are not performing the tasks assigned when we show up. Also the tasks that are given are not relevant to that plant.")

144. See *id.* at 29-39 (statement of Eduardo Delgado, USDA inspector), 48-62 (statement of Carol Tucker Foreman, former Assistant Secretary of Agriculture), 67-85 (statement of Thomas

of DI also maintained that plant employees were reluctant to report violations to the inspectors.<sup>145</sup> This widespread discontent with DI ultimately resulted in industry opposition as well.<sup>146</sup> The statutory authority for the DI system expired in November, 1992,<sup>147</sup> and was not renewed.

The difficulties faced by FSIS in implementing the DI system suggest that self-enforcement must be implemented in a manner consistent with the mission perceived by the agency employees who will administer the program. It will be impossible to administer such a program without their cooperation. This requires the design of programs which those employees perceive as workable; DI did not create such a perception among FSIS inspectors.<sup>148</sup> In addition, any program of cooperative implementation must facilitate an environment of honest reporting and correction of violations by the industry; this too was at least perceived by some critics to be lacking in DI.<sup>149</sup>

FSIS has had more success with a different processing cooperative implementation program adopted in 1980. Meat and poultry processors were permitted to apply for approval of a total plant quality control system (QC).<sup>150</sup> Processors desiring approval are required to present their QC system to FSIS, detailing its objectives and operations.<sup>151</sup> Processors with an approved QC system would be entitled to identify their products with a unique logo<sup>152</sup> and, according to amendments to the regulation adopted in

Devine, Legal Director, Government Accountability Project). *See also USDA to Seek Renewal of Discretionary Inspection Bill: Cross*, FOOD CHEMICAL NEWS, June 8, 1992 (available in Nexis library, Omni file) [hereinafter DI Renewal].

145. *See* DI Hearings, *supra* note 139, at 66 (testimony of Thomas Devine, Legal Director, Government Accountability Project) (“[T]he height of this program is an industry honor system. Other witnesses have told you why a conflict of interest compromises that, but I would like to tell you why we can’t live with it because of what it will do to the plant employees who want to be whistleblowers. They will be fired on the spot.”).

146. *See* DI Renewal, *supra* note 144 (“Although it strongly favored the concept of discretionary inspection, the meat industry ultimately joined labor and consumer groups in opposing USDA’s implementing regulations. The American Meat Institute called the proposal ‘overly complex, cumbersome and burdensome to the regulated industry.’”)

147. The implementing legislation, passed on Nov. 10, 1986, applied only for six years following its effective date. *See* § 403(a), 100 Stat. at 3567.

148. *See supra* note 143 and accompanying text.

149. *See supra* note 145 and accompanying text.

150. *See* Quality Control Systems Rule, *supra* note 123.

151. According to the regulation:

Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action—ranging from least to most severe . . . .

9 C.F.R. § 318.4(c)(4) (1995).

152. *See* 9 C.F.R. § 318.4(f) (1995).



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1986,<sup>153</sup> would be entitled to continue in some cases processing approved products without a federal inspector present.<sup>154</sup>

Approved QC systems are being pursued by FSIS in slaughterhouse regulation as well. Under the ill-fated SIS system for cattle, FSIS would have required an approved QC system for larger plants operating under SIS.<sup>155</sup> And a similar SIS for post-mortem inspection of turkeys, approved in 1985,<sup>156</sup> requires establishments participating in this SIS to have an approved QC system.<sup>157</sup> However, the agency's primary use of approved QC systems is currently in the inspection of meat and poultry processing.<sup>158</sup>

As FSIS relies on the QC program as a supplement to its own inspection, this falls within the definition of a program of cooperative implementation. Clearly, it builds on the processors' own incentives to comply with the law, because distribution of unhealthy meat and poultry products will be detrimental to that producer and perhaps the entire industry. The regulated population is applying complex regulations, and is a discrete population still subject to substantial surveillance and inspection. The program was intended to be more effective and cheaper: FSIS projected significant cost savings would be realized because inspectors could be more efficient in their oversight of processors with approved QC systems.<sup>159</sup>

The success of this QC system can be attributed to several factors. First and most importantly, it is available only to processors who already have an exemplary record of production and compliance. Second, it offers those producers marketing and operational incentives (labelling and increased hours of operation). Neither of these advantages existed in the SIS or the DI programs. This experience suggests that cooperative implementation can be successful in an industry previously subjected to substantial direct regulation if it is at first limited to those regulated entities with few problems. Not only does this make initial implementation cost-effective for the agency, but it is less likely to result in reports of regulatory failure linked to the new regulation, thus minimizing the likelihood of political and popular disapproval of the program.

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153. See *Meat and Poultry Inspection; Expansion of Operating Schedules for Total Quality Control Establishments*, 51 Fed. Reg. 32,301 (1986).

154. See 9 C.F.R. § 318.4(h) (1995).

155. See *SIS Proposed Rules*, *supra* note 125, at 48,265-66 (proposing that establishments operating at 275 head/hour or faster be required to have an approved QC system).

156. See *New Turkey Inspection System*, 50 Fed. Reg. 37,508 (1985).

157. See 9 C.F.R. § 381.76(b)(5)(c) (1995).

158. FSIS has proposed extending the QC concept to its regulation of labelling of processed products. See *Total Plant Quality Control for Labeling*, 50 Fed. Reg. 38,824 (proposed Sept. 25, 1985).

159. See *Quality Control Systems Rule*, *supra* note 123 (detailing anticipated cost savings). One of the major selling points of the QC program was that cost savings would accrue not only to processors but to the department as well. See Grumbly, *supra* note 41, at 111-12.

However, the QC program was at best a qualified success. The QC system was probably not more attractive to processors because it lacked significant cost-savings. Implementing a QC system involved a significant extra expense for processors, with the main benefit, longer operating hours, not being sufficiently lucrative. Because a federal inspector was still overseeing the processing most of the time, processors did not see much of a change from the existing program.<sup>160</sup> Thus, although the QC program was FSIS' most successful voluntary program, its success was limited. This reality, along with numerous policy recommendations, has moved FSIS to propose a mandatory HACCP program.<sup>161</sup>

Mandatory HACCP is FSIS' response to increased public concern over the safety of the nation's meat and poultry along with its recognition that the current methods of inspection, though mandated by statute, are incapable of detecting contamination from pathogenic microorganisms.<sup>162</sup> This effort is proceeding parallel to the FDA's proposal for adoption of HACCP in other food production industries.<sup>163</sup>

Briefly defined, HACCP is

[a] system by which meat and poultry establishments can identify and evaluate the hazards that could affect the safety of their products, institute controls necessary to keep these hazards from occurring, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine.

. . . .  
. . . The role of the regulatory agency under HACCP is verification that the establishment is controlling its processes and consistently producing complying products.<sup>164</sup>

HACCP is a good model of cooperative implementation. The need for HACCP first arises because it is impossible to use surveillance and inspection to produce the desired result: meat and poultry products free of pathogenic microorganisms. Conventional inspection fails to identify such microorganisms because it is difficult to take sufficiently large samples, because the dangerous

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160. Telephone Interview with Hal Ruben, Assistant General Counsel, Regulatory Division, Department of Agriculture (Nov. 4, 1994).

161. The QC program drew as participants about 10% of the eligible establishments. Telephone Interview with Robert Savage, Food Technologist, FSIS (May 30, 1995).

162. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6774, 6784 (1995) [hereinafter Meat/Poultry HACCP Release].

163. The FSIS recognizes that "[i]n many important respects, the FSIS and FDA HACCP programs are fully consistent. The same underlying principles of HACCP form the foundation of the two programs." *Id.* at 6816. FDA's HACCP program is discussed *infra* Part II.B.2.

164. Meat/Poultry HACCP Release, *supra* note 162, at 6806.

## Cooperative Implementation of Federal Regulation

quantities of microorganisms are relatively small, and because in many cases it is unknown how much of a particular microorganism constitutes a dangerous level at the production stage.<sup>165</sup> Thus, effective regulation must focus on the process of production, and not on sampling the end products. Because each processing establishment is different, there are different control points in each establishment to prevent introduction of pathogenic microorganisms into the product, and therefore HACCP plans are unique to each line of each establishment. Regulation with HACCP would be impossible without cooperative implementation; the regulated entity designs the compliance method, and the government agency assures that the design is sound and the method is working as designed. FSIS has committed itself to providing guidance to each regulated entity in developing HACCP plans.<sup>166</sup> The proposal also recognizes elements of cooperative implementation discussed in Part I: sufficient expertise must be established both in the agency and the industry,<sup>167</sup> the regulated entity must keep sufficient records of the HACCP program's operation for review by the agency,<sup>168</sup> the agency's role is limited to verifying that the program is working as intended,<sup>169</sup> and traditional enforcement measures are curtailed if possible.<sup>170</sup> Surprisingly, the agency does not view incentives as a problem: the industry wants all its products perceived as safe. Although there are concerns about costs, particularly about short-term costs for smaller establishments,<sup>171</sup> HACCP has a broad base of industry and public support.<sup>172</sup> It has advantages lacking in the prior FSIS programs; unlike SIS or DI, it has a strong scientific basis in programs already

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165. *Id.* at 6799.

166. *Id.* at 6814-15.

167. *Id.* at 6817.

168. *Id.* at 6818.

169. *Id.* at 6820-21.

170. This presents a problem in the case of meat and poultry inspection, because individual inspection is still required by law. *See supra* notes 118-123 and accompanying text. Inspectors will still perform traditional organoleptic inspections in addition to other inspectors reviewing the HACCP program. However, the production of adulterated products will be viewed primarily as a failure of the HACCP process rather than as a separate actionable offense. *See Meat/Poultry HACCP Release, supra* note 162, at 6821-22.

171. *Id.* at 6885. This is part of a larger cost-benefit study showing costs of near-term phase-in of some HACCP principles costing approximately \$360 million with benefits of between \$990 million and \$3.7 billion. *Id.* at 6879-89. *See also* GENERAL ACCOUNTING OFFICE, MEAT AND POULTRY INSPECTION: IMPACT OF USDA'S FOOD SAFETY PROPOSAL ON STATE AGENCIES AND SMALL PLANTS 8 (June 1995) (noting that FSIS intends to compensate for this increased cost in part by assisting small producers in developing HACCP plans).

172. *See Meat/Poultry HACCP Release, supra* note 162, at 6806 ("HACCP has a broad base of support . . . including consumers, the regulated industry, scientists and other professionals, producers, employee representatives, and other Federal and State governmental representatives . . . . Meat and poultry industry representatives have urged the Federal government to institute the mandatory use of a HACCP-based production system for their products.").

in operation in other food safety areas<sup>173</sup> and thus does not result in a public perception of potentially unsafe agency deregulation. In addition, HACCP offers significant cost savings not available under the QC program.

For the reasons outlined above, successful HACCP implementation would provide a good model for other cooperative implementation programs. One other agency, the FDA, has proposed a similar HACCP program, which is outlined in the following section.

## 2. *General Food Safety Regulation*

Under the Federal Food, Drug, and Cosmetic Act,<sup>174</sup> the Food and Drug Administration (FDA) of the Department of Health and Human Services is generally responsible for "the safety . . . of the nation's food supply."<sup>175</sup> In January 1994, the FDA announced proposed rules to implement HACCP for seafood processing establishments.<sup>176</sup> This limited introduction of HACCP in the seafood industry was based in part on the industry's prior experience with a voluntary fee-for-service inspection service offered by the National Marine Fisheries Service (NMFS) since 1992.<sup>177</sup> The FDA acknowledged that traditional methods of endpoint inspection were unable to detect many forms of potential contamination and were too resource intensive to be relied on in the future.<sup>178</sup> The agency noted that HACCP, in contrast, relies primarily on the processor to identify the critical quality control points in processing, to establish preventive measures and standards, to take corrective actions when those measures or standards are exceeded, and to provide effective recordkeeping and verification procedures.<sup>179</sup> The FDA inspectors could then concentrate on the processor's system rather than its products.

A key feature of an inspection system tied to implementation of HACCP is access by Government investigators to the HACCP plan and to monitoring records kept under that plan. In contrast to the "snapshot" provided by current inspections, examination of

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173. *See infra* Part II.B.2.

174. Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-95).

175. Development of Hazard Analysis Critical Control Points for the Food Industry; Request for Comments, 59 Fed. Reg. 39,888, 39,888 (1994) [hereinafter *General HACCP Release*].

176. *See Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products*, 59 Fed. Reg. 4142 (1994) [hereinafter *Seafood HACCP Release*].

177. *See Seafood Inspection*, 57 Fed. Reg. 33,456 (1992). NMFS emphasized that its service, although relying on HACCP principles, "is not a self-certification service. It relies on unannounced system audits by NMFS." *Id.*

178. *See Seafood HACCP Release, supra* note 176, at 4144-47.

179. *Id.* at 4148.

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HACCP records will enable an investigator to see how the processing facility or importer operates over time. It will enable an investigator to determine whether problems have occurred, and how they were addressed. It will also enable an investigator to spot trends that could lead to problems, and thus to help prevent them from occurring. Additionally, it will enable the regulator to review the adequacy of the processor's or importer's preventive control system itself. Under such an inspection system, inadequate preventive controls would warrant remedial or regulatory action regardless of whether the processor's or importer's product is actually contaminated or unsafe.<sup>180</sup>

As with the FSIS proposal, the FDA proposal thus embodies virtually all the elements of cooperative implementation. The FDA has also announced its intention to examine the use of HACCP in processing other foods.<sup>181</sup>

The HACCP program as envisioned relies heavily on the principles of cooperative implementation. Under the existing direct enforcement regime, each individual processor has incentives to lower costs by violating existing food safety standards, so long as the violations remain undetected. This result is made more likely, according to the FDA, because “[t]he sheer number of . . . potential contaminants, the concerns about their toxicity even at very low levels, and the difficulty and expense associated with many of the analytical methods . . . make exhaustive endpoint monitoring of the food supply virtually impossible.”<sup>182</sup> HACCP attempts to avoid these problems by focusing on prevention rather than detection, and by placing primary responsibility for detection and correction on the regulated entity. “Under a HACCP-based inspection system, it would be the responsibility of the company to develop a plan for producing safe food, and the role of Government inspectors would be to verify that the company is carrying out its plan.”<sup>183</sup>

What is not evident in the HACCP proposal is whether the government

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180. *Id.* at 4149.

181. See General HACCP Release, *supra* note 175. The first set of specific proposals were made for seafood because “[t]he body of knowledge and experience on the application of HACCP to food production has not, as far as the agency is aware, been developed for other commodities to the extent that it has for seafood.” *Id.* at 39,891. This proposal is at a much more tentative stage, as evidenced by the nine *Federal Register* pages devoted to solicitation of questions about HACCP for the nation's general food supply, compared with 50 pages of analysis and proposed rules for the FDA's seafood HACCP proposal, and 116 pages for FSIS's meat and poultry HACCP proposal.

182. *Id.* at 39,888. With regard to seafood, the FDA estimates that although recent budget increases allow them to inspect “high risk” processors each year and other processors biennially, product inspections are generally considered inadequate to find, much less prevent, seafood contamination. See Seafood HACCP Release, *supra* note 176, at 4145.

183. General HACCP Release, *supra* note 175, at 39,891.

provides any benefits to the regulated entities offsetting the costs involved in setting up such a quality control program. Granted, food processors have a collective interest in maintaining the public's impression that the nation's food supply is safe; however, each individual processor has just the opposite incentive, as discussed above. How will processors be persuaded to invest the substantial resources required for an effective HACCP program? The FDA has no financial incentive to offer other than reduction of already infrequent endpoint inspections. This same issue has been a significant problem in the implementation of OSHA's program<sup>184</sup> and in similar reforms in meat and poultry inspection.<sup>185</sup>

The incentive with the most potential is the long-term cost savings that HACCP will likely provide. There are initial costs for firms (and the agency) to learn to look at process instead of products. These costs are difficult to quantify, but could conceivably be low, as almost every firm already undertakes some form of quality control.<sup>186</sup>

### 3. *Extending Food Safety Regulatory Reforms*

Could HACCP be applied in other regulatory areas? HACCP programs are based on seven generally accepted characteristics: (1) an analysis of the hazards which result in the production of unacceptable products; (2) critical control points (CCPs) in the process, where those hazards can be reduced or eliminated; (3) critical limits at each CCP; (4) monitoring requirements at each CCP; (5) the requirements that corrective actions be taken when monitoring indicates critical limits have been exceeded; (6) effective record-keeping procedures that document the system; and (7) verification that the system is working correctly.<sup>187</sup> Although these principles originated and have been used exclusively in food safety assurance, there is nothing about these general principles which limits their application to this area. Indeed, HACCP is simply one variant of engineering design known as failure analysis.<sup>188</sup>

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184. See *supra* note 111 and accompanying text.

185. See *supra* note 160 and accompanying text.

186. Telephone Interview with Darrell Schwalm, Assistant for HACCP Policy, Center for Food Safety and Nutrition, Food and Drug Administration (June 1, 1995) [hereinafter Schwalm interview]; accord Telephone Interview with Robert Savage, Food Technologist, Food Safety and Inspection Service, Department of Agriculture (May 30, 1995) [hereinafter Savage interview]. FSIS is considering broad-based HACCP programs in meat and poultry production similar to FDA's. See *supra* Part II.B.1.

187. See SARA MORTIMORE & CAROL WALLACE, HACCP: A PRACTICAL APPROACH 4-6 (1994); Meat/Poultry HACCP Release, *supra* note 162, at 6807-11; General HACCP Release, *supra* note 175, at 39,889-90; Seafood HACCP Release, *supra* note 176, at 4147-48.

188. MORTIMORE & WALLACE, *supra* note 187, at 188. One example is the renowned effort by W. Edwards Deming to reform quality control in businesses generally. See Schwalm interview, *supra* note 186. The third of Deming's famous "Fourteen Points for Management" states:

## Cooperative Implementation of Federal Regulation

Although HACCP may be generally applicable, its history is in food safety. The FSIS HACCP proposal originated in 1989. The FDA's examination of HACCP's applicability to all food products grew out of its seafood program, which in turn developed from a fee-for-service program offered in conjunction with the National Marine Fisheries Service pursuant to legislation enacted in 1986.<sup>189</sup> Each set of proposed rules is based on exhaustive scientific and policy study.<sup>190</sup> Private industry has been applying HACCP since the early 1960s.<sup>191</sup> Regulators to date have resisted expansion beyond food safety, fearing it will "water down" the HACCP concept and begin to make it look more like traditional inspection. Also, the industry and the scientific community believe that food safety issues are currently more important.<sup>192</sup>

However, the voluntary HACCP program adopted for seafood extended to food quality and labelling standards,<sup>193</sup> and

[t]he seafood industry found it useful to include sanitation and economic fraud in their training for a HACCP approach to a regulatory program. By treating all CCPs the same, they found there was less confusion during training and employees could understand that "this point is critical because it resulted in a product that was not in compliance with the law," (i.e. not safe, unwholesome, or mislabeled).<sup>194</sup>

Thus other concerns besides food safety have been included in HACCP programs. By altering the concept of the "product" and the "hazard," HACCP

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Cease dependence on mass inspection. Routine 100 per cent inspection to improve quality is equivalent to planning for defects, acknowledgement that the process has not the capability required for the specifications.

Inspection to improve quality is too late, ineffective, costly. When product leaves the door of a supplier, it is too late to do anything about its quality. Quality comes not from inspection, but from improvement of the production process.

W. EDWARDS DEMING, *OUT OF THE CRISIS* 28-29 (1986).

189. See Catherine E. Adams et al., *HACCP System in Regulatory Inspection Programs: Case Studies of the USDA, USDC and DOD*, in *HACCP PRINCIPLES AND APPLICATIONS* 115-23 (Merle D. Pierson & Donald A. Carlett, Jr. eds., 1992). NMFS began offering HACCP-based inspection services in 1992. See *supra* note 177 and accompanying text.

190. See *Seafood HACCP Release*, *supra* note 176, at 4142-46, 4191; *Meat/Poultry HACCP Release*, *supra* note 162, at 6783-84.

191. See Howard E. Bauman, *Introduction to HACCP*, in *HACCP PRINCIPLES AND APPLICATIONS*, *supra* note 189, at 1-4; *Seafood HACCP Release*, *supra* note 176, at 4147.

192. Schwalm interview, *supra* note 186; Savage interview, *supra* note 186.

193. See *Seafood Inspection*, *supra* note 177, at 33,456 (1992) (noting that inspection program includes "Economic Fraud—illegal or misleading actions that defraud consumers, including species substitution, short weight, overglazing, and short fill"). The inspection program also includes review of product labels. NMFS FISHERY PRODUCTS INSPECTION MANUAL I, Ch. 9, § 02, part VII.D (Oct. 20, 1993).

194. Adams et al., *supra* note 189, at 120-21.

principles could be widely extended. In pollution control, for example, could the product be considered clean wastewater and the hazards identified and controlled in this manner? In other safety-related areas, could the product be considered a safe workplace or a safe airplane?<sup>195</sup> Indeed, “you can use identical procedures to those which we have described for safety HACCP but will need to redefine ‘hazard’ as a non-compliance with legal requirements.”<sup>196</sup> Doing so transforms HACCP to cooperative implementation. Thus, it is probably unwise to suggest applying HACCP to other regulatory programs under the same name, though the same concepts are at the root of all cooperative implementation.<sup>197</sup>

### C. *Pollution Abatement*

Pollution abatement through alternatives to classical “command and control” regulation has been the subject of debate among economists, lawyers, and legislators unparalleled in any other regulatory area. The theoretical and empirical literature on the general use of market-based incentives for pollution control is vast and wide-ranging,<sup>198</sup> and the policies in just one area—air pollution reduction credits—are now approximately twenty years in the making.<sup>199</sup> The prototype for regulation by cooperative implementation in

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195. See MORTIMORE & WALLACE, *supra* note 187, at 189-90 (suggesting that HACCP principles could be applied in areas such as prevention of malicious tampering, plant design, preventative maintenance, cleaning procedures, and general health and safety assessments).

196. *Id.* at 190.

197. Consider, for example, the problem of fraudulent financial reporting by companies whose securities are publicly-traded. In 1987, the “Treadway Commission” (so named for its chair, former SEC Commissioner James C. Treadway, Jr.), a private-sector initiative sponsored by accounting industry membership and interest groups, recommended that company management adopt, to prevent fraudulent financial reporting, a framework that consists of three steps: (1) identify and understand the factors that can lead to fraudulent financial reporting; (2) assess the risks that these factors create; and (3) design and implement internal controls to provide reasonable assurance that fraudulent financial reporting will be prevented or detected. REPORT OF THE NATIONAL COMMISSION ON FRAUDULENT FINANCIAL REPORTING 33 (1987). A follow-up report added “monitoring” as an explicit step in that framework. 3 COMMITTEE OF SPONSORING ORGANIZATIONS OF THE TREADWAY COMMISSION, INTERNAL CONTROL—INTEGRATED FRAMEWORK 14 (1992). These factors clearly resemble the seven HACCP principles.

198. One study estimates (without listing) that at least 100 articles “endorsing market-based approaches to achieving regulatory goals” had been written in the 1976-88 period. See Daniel J. Dudek & John Palmisano, *Emissions Trading: Why is this Thoroughbred Hobbled?*, 13 COLUM. J. ENVTL. L. 218 (1988). The pace does not appear to have slowed since then. Major research texts devoted exclusively to emissions trading summarize and significantly add to lifetimes of scientific, economic and legal research. See, e.g., THOMAS H. TIETENBERG, EMISSIONS TRADING (1985); R. SHEP MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT (1983); RICHARD A. LIROFF, AIR POLLUTION OFFSETS: TRADING, SELLING, AND BANKING (1980).

199. See Michael H. Levin, *Getting There: Implementing the “Bubble” Policy, in SOCIAL REGULATION*, *supra* note 32, at 59, 68 (dating the origins of the “bubble” concept at 1972-73); RICHARD A. LIROFF, REFORMING AIR POLLUTION REGULATION 26, 37 (1986) (noting that “netting” regulations were first issued in 1974, the “genesis of the bubble policy” was in 1977);



this area is the permit program of water pollution control, currently being adapted for use in air pollution prevention as well.

1. *Water Pollution*

Under the Clean Water Act,<sup>200</sup> it is unlawful to discharge any pollutant without a permit.<sup>201</sup> Permits are issued under the National Permit Discharge Elimination System (NPDES)<sup>202</sup> either by the Environmental Protection Agency (EPA) or, in most cases, by the states under permit programs approved by the EPA.<sup>203</sup> Reports of discharges, indicating compliance or noncompliance with the permit, are required from each permit holder at least annually.<sup>204</sup> These reports, along with the permit terms, quickly indicate whether the permittee has complied with the Act.<sup>205</sup> Penalties for violation of permit provisions are assessable by the EPA in an administrative action,<sup>206</sup> by any person in a civil action,<sup>207</sup> or in a criminal action.<sup>208</sup> Thus, the holder of a Clean Water Act permit may be compelled in some cases to confess in a required report that a violation of law has occurred and could thereby be subjected to significant fines in an action by the government or virtually any member of the public.<sup>209</sup>

Obviously, such a system of self-reporting creates some incentive on the

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TIETENBERG, *supra* note 198, at 9 (dating the inception of the program at 1975). The general idea of using economic-based incentives for pollution control originated a few years earlier with J.H. DALES, *POLLUTION, PROPERTY AND PRICES* (1968). See Richard B. Stewart, *Economics, Environment, and the Limits of Legal Control*, 9 HARV. ENV. L. REV. 1, 12 n.33 (1985); see also James E. Krier, *The Tragedy of the Commons, Part Two*, 15 HARV. J.L. & PUB. POL'Y 325, 325 (1992) ("The idea . . . is by now almost old hat. The intellectual history dates back at least to the 1930s, when the British economist . . . Pigou is thought to have suggested the imposition of taxes on pollution emissions.").

200. Pub. L. No. 95-217, § 2, 91 Stat. 1566 (1977).

201. Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, § 301(a), 86 Stat. 816, 844 (1972) (codified at 33 U.S.C. § 1311(a)). The "deceptive simplicity" of § 301(a) is embellished by definitions of each critical term used. 2 LAW OF ENVIRONMENTAL PROTECTION § 12.05[1] (Sheldon M. Novick et al. eds., 1993).

202. Clean Water Act § 402, 33 U.S.C. § 1342 (1994).

203. See 51 Fed. Reg. 36,806, 36,808 (1986) (listing 36 states and the Virgin Islands as having certified NPDES programs).

204. 40 C.F.R. §§ 122.44(2) (1995) (EPA-administered permit programs), 123.25 (state-administered permit programs).

205. "The permit, in short, defines compliance for the discharger and eases the task of government enforcement." William L. Andreen, *Beyond Words of Exhortation: The Congressional Prescription for Vigorous Federal Enforcement of the Clean Water Act*, 55 GEO. WASH. L. REV. 202, 204 (1987).

206. Clean Water Act § 309(g), 33 U.S.C. § 1319(g) (1994).

207. 33 U.S.C. §§ 1319(d), 1365.

208. 33 U.S.C. § 1319(c).

209. In order to bring a suit for a violation of the Act, a citizen must be "adversely affected." 33 U.S.C. § 1365(g). Such an injury, however, is not difficult to show. See 2 LAW OF ENVIRONMENTAL PROTECTION, *supra* note 201, § 12.08[3][b][i].

part of the source to comply with the permit before a report is due rather than to confess noncompliance. On the other hand, the system also creates perhaps more powerful incentives not to report noncompliance at all. However, the penalties for willful false reporting under the Act can be as severe as the penalties for the substantive violation.<sup>210</sup> In addition, each state program is required to have systems to review reports filed, search for required reports not filed, comprehensively survey and individually inspect each source, and receive and act upon public complaints.<sup>211</sup>

Comparing the program's features to the theories of cooperative implementation, it appears that this system of self-reporting under the Clean Water Act will be effective only if there is sufficient incentive to comply imposed on sources by the federal and state governments. There is no more onerous alternative avoided by sources that receive permits, since permits are universally required; nor is it in a firm's economic self-interest (independent of the Act's fines and penalties) to obtain a permit. Rather, the universe of regulated and potentially-regulated sources is sufficiently small to enable a credible enforcement presence to exist,<sup>212</sup> which provides the main incentive for effective self-reporting. The Act implores, if not commands, the EPA to bring enforcement action for violations,<sup>213</sup> and in 1987, Congress increased fines and penalties under the Act and authorized the EPA to impose administrative fines.<sup>214</sup> In addition, citizen suits are a credible deterrent. The cases are not difficult to prove, and there are many interested parties willing to litigate.<sup>215</sup> One reviewer of recent citizen suits concluded that "permittees cannot afford a casual attitude toward their monitoring and reporting obligations, and can no longer assume that compliance which satisfies the regulatory authorities will necessarily insulate them from suit."<sup>216</sup>

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210. For example, a first-time negligent violation is criminally punishable by a fine of at least \$2500, but not more than \$25,000 per day of violation, or two years' imprisonment. Clean Air Act § 309(c)(1), 33 U.S.C. § 1319(c)(1) (1994). A first-time knowingly false report is criminally punishable by a fine of up to \$10,000 or two years' imprisonment. 33 U.S.C. § 1319(c)(4).

211. See 40 C.F.R. § 123.26(a)-(c) (1995). All of this activity must be conducted in a manner "that will produce evidence admissible in an enforcement proceeding or in court." 40 C.F.R. § 123.26(d).

212. Telephone Interview with Steven Sweeney, Office of the General Counsel, Water Division, Environmental Protection Agency (July 19, 1994). If the EPA were to move to a broader program of regulating pollution from "nonpoint sources" (other than from the end of wastewater pipes), monitoring and enforcement problems would likely multiply. Esther Bartfeld, *Point-Nonpoint Source Trading: Looking Beyond Potential Cost Savings*, 23 ENVTL. L. 43, 95-96 (1993).

213. Clean Water Act § 309(a)-(b), 33 U.S.C. § 1319(a)-(b) (1994); See also Andreen, *supra* note 205, at 242-59 (arguing that better interpretation of § 309 is that EPA has mandatory and judicially enforceable duty to bring enforcement action once violation is identified).

214. See LAW OF ENVIRONMENTAL PROTECTION, *supra* note 201, § 12.08[1][c].

215. See *id.* § 12.08[1][a].

216. Frank M. Thomas, Jr., *Citizen Suits and the NPDES Program*, 17 ENVTL. L. REP. (Envtl. L. Inst.) 10,050, 10,055 (1987).

2. *Air Pollution*

Under the Clean Air Act,<sup>217</sup> the EPA establishes standards of air quality and regulates emissions from some sources directly, while in other areas it delegates responsibility to the states for attainment and enforcement of EPA-mandated standards.<sup>218</sup> In both its direct regulation and approval of state efforts, EPA has relied on cooperative implementation through economic incentives given to regulated entities for compliance.

The EPA has adopted a program of “emissions reduction credits,”<sup>219</sup> which are various economic incentives made available to regulated entities under four different provisions of the Act.<sup>220</sup> First, under Section 111 of the Act, new sources of certain pollutants require approval by permit before construction.<sup>221</sup> Those sources are manufacturing or processing facilities or other sources listed by the EPA, which also sets emissions standards for each separate type of source.<sup>222</sup> Second, under Section 172 of the Act, in any “nonattainment area” which exceeds EPA maximum levels of certain air pollutants,<sup>223</sup> major<sup>224</sup> stationary sources of these pollutants may be built or modified only under permit.<sup>225</sup> Third, under Section 165 of the Act, even

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217. Ch. 360, 69 Stat. 322 (1955) (codified as amended at 42 U.S.C. §§ 7401-7671q (1994)).

218. See DAVID P. CURRIE, *AIR POLLUTION: FEDERAL LAW AND ANALYSIS* § 4.01 (1981 & Supp. 1992); David Schoenbrod, *Goals Statutes or Rules Statutes: The Case of the Clean Air Act*, 30 UCLA L. REV. 740, 756-59 (1983).

219. The term was coined by the EPA. See Emissions Trading Policy Statement, 51 Fed. Reg. 43,814, 43,814 (1986). Prior to the adoption of this Policy Statement, these credits were known (and are often still known) variously as “bubbles,” “offsets,” “netting” or “banking” programs. LIROFF, *supra* note 199, at 4 n.\*. For definitions of these terms, see *infra* notes 232-36 and accompanying text.

220. This listing of four different types is not meant to imply that each is a distinct regulatory scheme. On the contrary, the overlap of different EPA requirements upon a single industrial project has a complexity “that cannot be overstated.” LIROFF, *supra* note 199, at 32; see *id.* at 32-34 (detailing six different variations and combinations of these requirements applicable to a single hypothetical project).

221. See Clean Air Act § 111(e), 42 U.S.C. § 7411(e) (1994). “New source” is defined as the construction or modification of a stationary (as opposed to a mobile) source of air pollutants. 42 U.S.C. § 7411(a)(2).

222. 42 U.S.C. § 7411(b). The EPA has promulgated standards of emission levels of air pollutants for 61 different industries or other sources. See 40 C.F.R. § 60 (1995).

223. The EPA is authorized to establish national ambient air quality standards for air pollutants “reasonably . . . anticipated to endanger public health or welfare” and which emanate “from numerous or diverse mobile or stationary sources.” Clean Air Act § 108(a)(1), 42 U.S.C. § 7408(a)(1) (1994). There are currently standards for six such pollutants: sulfur dioxide, particulate matter, carbon monoxide, ozone, nitrogen dioxide and lead. See 40 C.F.R. pt. 50 (1995). A “nonattainment area” is an area of a state which does not meet these standards. See Clean Air Act § 107(d)(1)(A)(i), 42 U.S.C. § 7407(d)(1)(A)(i) (1994).

224. A major source is one that emits “or has the potential to emit one hundred tons per year or more of any air pollutant . . .” Clean Air Act § 302(j), 42 U.S.C. § 7602(j) (1994).

225. See 42 U.S.C. § 7502(c)(5).

in an "attainment" area, which meets the EPA ambient air requirements,<sup>226</sup> major sources may be built or modified only if any increase in the amounts of these pollutants is within statutory limits.<sup>227</sup> Under these three permitting requirements, even though a particular new source results in an increase in pollutant emissions, it may nonetheless be allowed if there are compensating reductions in emissions from other sources.<sup>228</sup> Fourth, in the 1990 amendments to the Act, Congress established a system of tradable permits for emissions of sulfur dioxide,<sup>229</sup> a major contributor to "acid rain."<sup>230</sup>

The emissions reduction credits granted under these provisions of the Clean Air Act are, in turn, denoted as four different programs: "bubbles," "offsets," "banking" and "netting." The use of these terms among the different programs varies,<sup>231</sup> but there are generally accepted definitions. "Bubbles" are generally credits used to avoid the permit requirements for modifications of existing sources of particular types or industries under Section 111 of the

226. See 42 U.S.C. § 7407(d)(1)(A)(ii).

227. See 42 U.S.C. § 7475(a)(3). The maximum allowable increases are set forth at 42 U.S.C. § 7473(b).

228. See 40 C.F.R. § 51.165 (1995). "Source" is used here not in its finest legal sense, but only for its ordinary meaning. A lot of freight rides on this one word. For a map of the tortured path of definition of the statutory terms "source" and "facility" to implement these offset rules, see CURRIE, *supra* note 218, at § 3.05 and Laurens H. Rhinelander, *The Bubble Concept: A Pragmatic Approach to Regulation Under the Clean Air Act*, 1 VA. J. NAT. RESOURCES L. 177, 198-218 (1981), both discussing the principal cases of *Asarco, Inc. v. EPA*, 578 F.2d 319 (D.C. Cir. 1978), *Alabama Power Co. v. Costle*, 606 F.2d 1068 (D.C. Cir. 1979) and *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Liroff notes that "[f]ederal appellate judges have made herculean but largely unpersuasive attempts to reconcile appeals court opinions that sometimes have approved trading and other times have not," but that the Supreme Court in *Chevron* "lifted much of the pall the appeals courts had cast over trading." LIROFF, *supra* note 199, at 13.

With respect to permits in nonattainment areas, the 1977 amendments to the Act provided statutory offset rules. See Clean Air Act Amendments of 1977, Pub. L. No. 95-95, sec. 129(a), § 173(c), 91 Stat. 685, 748-50 (1977) (codified at 42 U.S.C. § 7503(c) (1978)).

229. See Clean Air Act Amendments of 1990, Pub. L. No. 101-549, §§ 401-416, 104 Stat. 2399, 2584-2634 (1990) (codified at 42 U.S.C. §§ 7651-7651o).

230. See H.R. Rep. No. 490, 101st Cong., 2d Sess. 355 (1990).

231. See, e.g. Currie, *supra* note 218, § 3.05 (describing the § 111 credits variously as "bubbles," "offsets" and "netting"), § 6.10.50 (describing the § 172 credits as "netting" or "bubbles"), § 7.06 (describing the § 165 credits as "netting"). The term has a generally accepted intuitive meaning although it may apply in several different specific situations.

The term "bubble" describes the treatment of an air-polluting plant or other facility as if it were enveloped in a plastic bubble with only one outlet of pollutant emissions. Instead of placing emission limitations on each outlet within a single plant, only the total amount of a particular pollutant emitted from a plant is regulated. Reduction in pollution from one outlet, e.g., a stack within that plant, may be used to offset an increase in emissions from another outlet.

The bubble concept is thus one of several complementary variants of the conceptually broader "offset" or "controlled trading" theory. Each variant reflects a common theme: a firm should be allowed to offset a reduction in emissions from one outlet against current or future pollution emitted from another outlet.

Rhineland, *supra* note 228, at 178.

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Act.<sup>232</sup> “Netting” is the use of credits to offset emissions increases in order to avoid classification as a “major” source and the attendant more stringent permit requirements.<sup>233</sup> “Offsets” are uses of credits to offset emissions increases otherwise prohibited in nonattainment areas or to bring the increases within the allowable limits in attainment areas.<sup>234</sup> “Banking” permits firms to save credits not currently used for later “bubbling,” offset, netting, or sale to other firms.<sup>235</sup> The “acid rain” provisions in the 1990 amendments to the Act provide for “allowances” for sulfur dioxide emissions, and for transfer of these allowances.<sup>236</sup>

Numerous researchers claim that this type of regulation will be more efficient<sup>237</sup> and will lower compliance costs significantly.<sup>238</sup> This is in

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232. Emissions Trading Policy Statement, *supra* note 219, at 43,830; CURRIE, *supra* note 218, § 7.06 n.5.50; LIROFF, *supra* note 199, at 4; TIETENBERG, *supra* note 198, at 8; Robert W. Hahn and Gordon L. Hester, *Where Did All the Markets Go? An Analysis of EPA's Emissions Trading Program*, 6 YALE J. ON REG. 109, 123 (1989); Levin, *supra* note 199, at 67-68; Dudek & Palmisano, *supra* note 198, at 227 & n.16.

233. See Emissions Trading Policy Statement, *supra* note 219, at 43,830; Tietenberg, *supra* note 198, at 8; Hahn & Hester, *supra* note 232, at 132 & n.125; Dudek & Palmisano, *supra* note 198, at 225-26. Liroff notes the distinction between bubbles and netting:

Netting and the bubble are conceptually similar, in that increased controls at one point are traded for decreased controls at another. However, the bubble initially was developed to ease the obligations of companies to reduce emissions from existing sources. Netting, in contrast, was intended to reduce the administrative and pollution reduction obligations of sources being modified.

LIROFF, *supra* note 199, at 6.

234. See Emissions Trading Policy Statement, *supra* note 219, at 43,830-31; Tietenberg, *supra* note 198, at 7-8; Hahn & Hester, *supra* note 232, at 119; Dudek & Palmisano, *supra* note 198, at 224. The offset program was significant in nonattainment areas which otherwise would have faced a ban on new construction or modification in 1979. See Hahn & Hester, *supra*, at 119. The construction ban was repealed by the 1990 amendments to the Act. Clean Air Act § 110(a)(4), added by the Clean Air Act Amendments of 1970, Pub. L. No. 91-604, § 4(a), 84 Stat. 1676, 1680 (1970) (codified at 42 U.S.C. § 7410(a)(4), repealed by the Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 101(d)(2), 104 Stat. 2399, 2409 (1990).

Offsets differ from netting in that they can be applied both to new sources and to modifications of existing sources, and an offset requires a reduction in total emissions, while netting only requires that there be no net increase. See LIROFF, *supra* note 199, at 7.

235. See TIETENBERG, *supra* note 198, at 8-9; Hahn & Hester, *supra* note 232, at 129-30 & nn.108-109; Dudek & Palmisano, *supra* note 198, at 227-28. Banking is permitted only if a state provides for it in a plan which meets EPA requirements. Emissions Trading Policy Statement, *supra* note 219, at 43,832-34.

236. See Clean Air Act Amendments of 1990, Pub. L. No. 101-549, § 401, 104 Stat. 2399, 2589 (1990) (codified at 42 U.S.C. § 7651b (1995)).

237. See generally, Marshall J. Breger, et al., *Providing Economic Incentives in Environmental Regulation*, Speech to the Administrative Conference of the United States (Apr. 23, 1990) in 8 YALE J. ON REG. 463 (1991); Stewart, *supra* note 199; Robert W. Hahn and Roger G. Noll, *Designing a Market for Tradable Emissions Permits*, in REFORM OF ENVIRONMENTAL REGULATION 119-46 (Wesley A. Magat ed. 1982); Douglas M. Costle, *Environmental Regulation and Regulatory Reform*, 57 WASH. L. REV. 409 (1982); LIROFF, *supra* note 199; Rhinelander, *supra* note 228.

contrast to the inefficient “command and control” style of the Act generally.<sup>239</sup> However, critics of this alternative regulatory approach claim that the economic theory is too flawed in practice to be touted as a clear improvement. There are significant problems in establishing permissible levels of pollution<sup>240</sup> and in measuring levels of emissions from certain sources.<sup>241</sup> Measurement problems aside, there are significant disputes about the “baseline” amounts against which to begin measuring credits, and the measurement of the impact of a changing mix of emissions on human health.<sup>242</sup> And calculation problems aside, it has proved difficult to establish

238. The issue of cost savings is complex in the case of emissions reduction credits as with any area of supervised self-regulation. Virtually all estimates, however, have shown significant cost savings, though the estimates vary widely. See Hahn & Hester, *supra* note 232, at 134-36; LIROFF, *supra* note 199, at xvii; Breger, et al., *supra* note 237, at 474-75. For a thorough catalogue of cost savings studies, see TIETENBERG, *supra* note 198, at 38-59 (summarizing 19 studies).

239. See generally, Schoenbrod, *supra* note 218, at 756-59. See also John D. Graham, *The Failure of Agency-Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act*, 1985 Duke L.J. 100 (criticism of program of EPA regulation of particularly hazardous pollutants under § 112 of the Act, 42 U.S.C. § 7412 (1995)).

240. See Howard Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and “Fine Tuning” Regulatory Reforms*, 37 Stan. L. Rev. 1267, 1283 (1985) (“Many important environmental uncertainties . . . stem from inadequate scientific understanding rather than merely from inadequate data.”). Latin continues that the lack of scientific knowledge often requires a political judgment by Congress that “prompt injury prevention [must prevail] over the need for an optimal balance between benefits and costs.” *Id.* at 1283-84. Though Latin uses this argument to justify continued reliance on “command and control” regulation, the legislative history of the emissions allowance trading system adopted in the 1990 amendments to the Act indicate that Congress recognized the scientific uncertainty and chose to adopt a market-based incentive system. See H.R. REP. NO. 490, 101st Cong., 2d Sess., pt. 1 at 361 (1990) (“Scientists can give Congress guidance as to roughly how protective they think different control programs would be of the different resources, but it is up to Congress to decide how risk-averse it wants to be. No magic number emerges purely from the scientific data. . . . Clearly, the longer Congress waits, the more environmental degradation will occur.”).

241. See Latin, *supra* note 240, at 1322-23 (asserting that self-reporting by firms is very unreliable, citing numerous examples of incomplete, inaccurate or even falsified reports to EPA); Marc J. Roberts, *Some Problems of Implementing Marketable Pollution Rights Schemes: The Case of the Clean Air Act*, in REFORM OF ENVIRONMENTAL REGULATION 99-101 (Wesley A. Magat ed. 1982) (citing problems in determining what is a “source,” what source “offsets” another, and relevant geographic areas and time periods); *id.* at 106 (potential need for supervision of emissions reports and trades makes it unclear “whether or not devices like offsets and the bubble policy will increase or decrease the need for regulatory agency expenditures”); Robert W. Hahn & Gordon L. Hester, *Marketable Permits: Lessons for Theory and Practice*, 16 *ECOLOGICAL L.Q.* 361, 403 (1989) (noting that “[q]uestions about the ability to monitor emissions have played an important role in the [limited] design of emissions trading policies”).

These difficulties exist under the current law as well. “The Act’s enforcement . . . requires more data about pollution effects and controls than science can provide, thereby allowing manipulation that undercuts achievement of the Act’s goals, wastes resources, and creates inequities.” Schoenbrod, *supra* note 218, at 743.

242. LIROFF, *supra* note 199, at 15-17; TIETENBERG, *supra* note 198, at 113-15.

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functioning markets for trading of credits.<sup>243</sup> Moreover, there are external social costs to be considered,<sup>244</sup> as well as the difficulty of making technically “optimal” decisions in a political environment.<sup>245</sup> This uncertainty makes it impossible to assure that these new approaches are an improvement over traditional “command and control” regulation,<sup>246</sup> which, even if imperfect, has a track record of producing significant reductions in pollution levels.<sup>247</sup>

The response to these critics has generally been to recognize the existing limits of market-based incentives, and then to suggest strategies for successful implementation given those limits.<sup>248</sup> These programs need to be

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243. See Hahn & Hester, *supra* note 232, at 140-41 (citing uncertainty of rights and difficulty of transfer as reasons for the relative inactivity of emissions trading under current EPA rules); see generally Evan Goldberg, Comment, *The Design of an Emissions Permit Market for RECLAIM: A Holistic Approach*, 11 UCLA J. ENVTL. L. & POL'Y 297 (1993) (discussing issues and problems in market design). But see Dudek & Palmisano, *supra* note 198, at 236-44; Adam J. Rosenberg, Note, *Emissions Credit Futures Contracts on the Chicago Board of Trade: Regional and Rational Challenges to the Right to Pollute*, 13 VA. ENVTL. L.J. 501 (1994).

244. See Latin, *supra* note 240, at 1291-92 (criticizing proponents of market-based incentives for failing to consider social costs of dislocation and the like, concluding that “[a] contention that ‘fine-tuning’ approaches will perform better than command-and-control standards ought to be clearly distinguished from a contention that the legislature should have reached a different balance between competing interests”) (emphasis in original). See also TIETENBERG, *supra* note 198, at 95-96 (concluding that command-and-control regulation may have reduced costs from dislocation, but imposed costs on consumers by raising prices with a disproportionate impact on poorer families).

245. See Latin, *supra* note 240, at 1293 (“No realistic appraisal of competing control strategies can simply assume a benign, cooperative regulatory climate, but that is what proponents of ‘fine-tuning’ [market-based incentives] have often done.”).

246. See *id.* at 1304 (concluding that “theoretically ‘efficient’ regulatory strategies require more data, more sophisticated scientific and economic analysis, more agency expertise and resources, and more cooperation from regulated parties. These requirements ensure that [these] strategies cannot be implemented effectively in many environmental protection contexts.”).

247. See Breger et al., *supra* note 237, at 467 (remarks of Richard B. Stewart) (“What we see after 20 years is that the system has achieved gains. Certainly the problems without these controls would have been much worse.”); LIROFF, *supra* note 199, at 32 (“The command-and-control system of the Clean Air Act does have significant accomplishments to its credit.”).

Command-and-control regulation can yield more benefits than incentive programs because it can result in reductions of harmful pollutants below the “threshold” level, where incentive-based systems lose their incentives and are ineffective. See Wallace E. Oates et al., *The Net Benefits of Incentive-Based Regulation: A Case Study of Environmental Standard-Setting*, 79 AM. ECON. REV. 1233 (1989). In Oates’ study, an incentive program compared to a command-and-control system thus resulted in achievement of higher standards, but not necessarily cleaner air. See *id.* at 1236-38. But see Dudek & Palmisano, *supra* note 198, at 237-38 (“As to the claim that emissions trading results in missed opportunities for more controls, while that may be true in the short run, it is false in the long run. If regulators adopt an attitude that every emission reduction should go toward improved air quality, the incentives to industry to produce extra emission reductions, in the real world, are antagonistic to long run regulatory objectives—more controls, sooner, with less intrusions and fewer public sector resources.”).

248. Liroff provided a general assessment in 1986, in light of expected congressional action, which remains true even after the 1990 amendments to the Act:

Even though emissions trading has not yet produced some of the wonderful results

implemented gradually to overcome industry and agency inertia and resistance.<sup>249</sup> Technology must exist to permit functioning cooperative implementation, in this case, the measurement of emissions<sup>250</sup> and efficient trading of credits and allowances.<sup>251</sup> The program of statutory regulation must consist of clear and definite standards from Congress or the agency.<sup>252</sup>

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that its most enthusiastic promoters once expected, it continues to hold promise as a device for promoting more cost-effective pollution control. For Congress to kill emissions trading, after all these years of trying to make it work, and with evidence that it sometimes does produce results not attainable by conventional controls, would send the wrong signal to would-be innovators in the public and private sector.

Trading has been the victim of unduly high expectations. Fine-tuning the rules governing it has been extremely difficult. But it has produced some noteworthy benefits, and further benefits will be lost if it is abandoned.

LIROFF, *supra* note 199, at 145. See also TIETENBERG, *supra* note 198, at 215 (“In no way should [flaws in emissions trading] overshadow the program’s very positive accomplishments. On balance, the current emissions trading program reflects a remarkably astute compromise between the desire to promote cost-effectiveness on the one hand and the desire to have an administratively simple, yet politically acceptable program on the other.”). For a similar assessment of the potential for this approach for controlling nonpoint source pollution under the Clean Water Act, see Bartfeld, *supra* note 212, at 104-05.

249. See Levin, *supra* note 199, at 66-68. See also Stewart, *supra* note 199, at 22 (noting the need for “incremental changes that will demonstrate both the feasibility of economic-based incentives and the benefit that they can provide to all affected interests”). The emissions trading program has followed this path to date. Its enduring role “can be directly attributed to the manner in which it was implemented. It was not only compatible with the traditional command-and-control approach, it was implemented to make the transition as smooth as possible.” TIETENBERG, *supra* note 198, at 213.

250. Liroff notes the fundamental problems underlying evaluation of either command-and-control or market incentive regulations:

Although emissions trading is an effort to overcome some of the Clean Air Act’s faults, it has stumbled over the harsh reality that, after all these years, regulators still are unable to answer some basic questions about air pollution in the United States today. They have only a rough sense of how much pollution dischargers are emitting and of how much progress is being made in cleaning the air.

LIROFF, *supra* note 199, at 143.

251. See Hahn & Hester, *supra* note 232, at 149-51 (proposal for more effective markets for trading and banking of credits); Hahn & Hester, *supra* note 241, at 405 (suggesting that market-based approaches must initially be limited to relatively simple programs relating to a small number of pollutants and a small number of sources). Again, in the 1990 amendments to the Act creating sulfur dioxide allowance trading, Congress indicated that the program was designed to facilitate tradeability of allowances. See H.R. REP. NO. 490, 101st Cong., 2d Sess., pt. 1, at 365-66 (1990). Creation of an efficient market for allowances, however, may defeat the ability of such a trading system to produce an overall reduction in pollution; for rights to be tradeable, they must be certain, that is, not subject to arbitrary confiscation. See Jeanne M. Dennis, Comment, *Smoke for Sale: Paradoxes and Problems of the Emissions Trading Program of the Clean Air Act Amendments of 1990*, 40 UCLA L. REV. 1101, 1118-27 (1993).

Tietenberg demonstrates that, in economic theory, cost-effective trading systems can be designed in many areas, but the regulatory information burden varies greatly with the type of pollutant to be regulated. See TIETENBERG, *supra* note 198, at 16-36. The adoption of marketable rights in a limited area for a limited number of pollutants is consistent with the suggestion of Hahn & Hester, *supra* note 241.

252. Latin, *supra* note 240, at 1300-01, faults proponents of market-based incentives for their inability to decide whether Congress or the agency should be the source of specific rules.



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Perhaps most importantly, a political consensus must exist that cooperative implementation, here in the form of economic-based incentives for pollution control, can work, and can be trusted in implementing even the most important regulatory goals.<sup>253</sup>

Emissions reduction credit and trading programs serve as good models of cooperative implementation programs. They rely on the industry's motivation to adopt the most cost-effective means of compliance with emissions standards, an exceedingly complex if not intractable problem under direct regulation. Apart from measurement and reporting problems, which remain significant,<sup>254</sup> it is clear that the industry has the requisite economic incentive to comply with self-enforced rules.<sup>255</sup> Congress in particular has become more assertive, reclaiming some delegation given to the EPA.<sup>256</sup> Congress has shown a willingness to make some of the more difficult policy decisions itself, leaving the agency the complex but more workable problems of implementation.<sup>257</sup> Recognizing that expertise may be difficult to acquire, the

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Schoenbrod, *supra* note 218, at 807-09, responds to critics' contentions that Congress lacks the expertise and time to deal with these issues competently by noting the enormous investments of congressional time and study under the current Act.

253. One of the most difficult problems in implementing emissions trading programs is the politically unacceptable label of a "right to pollute." See Hahn & Hester, *supra* note 232, at 143 (terminology explicitly avoids any "notion that rights to emit pollutants are being exchanged"). In adopting transferrable emissions allowances in the 1990 amendments to the Act, Congress came very close to authorizing such "rights to pollute." However, Congress made it clear that it does not believe these allowances to constitute property rights. See Clean Air Act § 404(f) (42 U.S.C. § 7651b(f) (1995)); see also H.R. REP. NO. 490, 101st Cong., 2d Sess., pt. 1, at 374 (1990).

Stewart notes that the first steps include educating policymakers and implementing incremental systems that produce results to build popular confidence in strategies offering economic incentives to private industry. Stewart, *supra* note 199, at 20-22. Levin suggests that such types of regulatory reform "must be structured to produce quick real-world success stories. Legislatures, regulatory agencies, and industry tend to act more on anecdotes than on analytic data. Nothing succeeds like success . . ." Levin, *supra* note 199, at 91. Many of these problems, particularly the reluctance of agency employees and Congress to depart from traditional methods of regulation, are similar to those that FSIS faces in meat and poultry inspection discussed *supra*, Part II.B.1.

254. See *supra* notes 240-241 and accompanying text.

255. See Costle, *supra* note 237, at 431 ("The bubble policy encourages industry's capacity for technological innovation to meet a performance standard; it thus relies on the carrot of lower operating costs as distinct from the stick of regulatory sanctions to be applied if complex, rigid design standards are not followed.").

256. Congress has not expressly revoked EPA authority, but has legislated specific standards in several areas rather than relying on the EPA to set those standards. See, e.g., Clean Air Act § 112(b), 42 U.S.C. § 7412(b) (1995) (list of hazardous air pollutants), § 7651c (initial sulfur dioxide allowances by specific plant and generator).

257. See Schoenbrod, *supra* note 218, at 803-18 (emphasizing the value of "rules-based" statutes in effective self-regulation). The passage of the Clean Air Act Amendments of 1990 suggests a breakthrough of sorts in disproving the pessimistic "public choice" theories that public regulation must remain bureaucratic, self-interested and inefficient. "[S]hifts in the interest group alignment [in the 1990 amendments] surrounding environmental policy suggest that more responsible regulatory structures are now possible, at least within some areas of environmental policy." Peter S. Menell, *Institutional Fantasylands: From Scientific Management to Free Market*

EPA has begun programs in the areas where there is the most implementation experience: conventional pollutants and stationary sources of emissions.<sup>258</sup> In sum, it is still impossible to state categorically that the EPA's program of emissions reduction credits will succeed or fail.<sup>259</sup> However, "it seems fair to say that [it] provides a good model for implementing other . . . incentive-based reforms that cut across whole programs or groups of regulations and are meant to change how industry complies and how much compliance costs."<sup>260</sup>

In addition to the informal program of transferrable credits under "bubble" and similar rules and the permitting program for sulfur dioxide emissions, Congress has sought to overhaul the Clean Air Act permitting system generally in a fashion consistent with cooperative implementation criteria. In Title V of the Act, added by the 1990 amendments,<sup>261</sup> Congress provided for the first time a general permitting requirement, similar to that in existence for many years under the Clean Water Act.<sup>262</sup> The new permit program was intended to consolidate and clarify the disparate regulations for each source of pollution, resulting in "[i]ncreased source accountability and better enforcement."<sup>263</sup> In addition, Congress intended the program to provide more flexibility in means to comply with the permit requirements,<sup>264</sup> and to lay the groundwork for market-based incentives, that is, transferable allowances similar to those created under Title IV of the Act.<sup>265</sup>

The Title V implementing regulations, establishing the requirements for permitting systems to be adopted under the Act, include each of the elements

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258. The pollutants regulated in the emissions reduction credit and allowance trading programs are the "criteria" pollutants in § 108 of the Act, 42 U.S.C. § 7408 (1995). The EPA established air quality standards for most of these pollutants in 1971. See CURRIE, *supra* note 218, at § 4.02.

259. See Latin, *supra* note 240, at 1331 ("It would be relatively easy to improve environmental regulation if the major inefficiencies stemmed from stupidity, venality, and agency capture by extremist factions . . . [b]ut this characterization is simplistic. Many critical problems result from inherent limitations on environmental decisionmaking and from conflicts between the legitimate but incompatible interests of diverse parties.").

260. Levin, *supra* note 199, at 89.

261. See Clean Air Act Amendments of 1990, Pub. L. No. 101-549 § 501, 104 Stat. 2399, 2635-48 (1990) (codified at 42 U.S.C. §§ 7661a-f (1995)).

262. See H.R. REP. NO. 490, 101st Cong., 2d Sess. pt. 1, at 342 (1990); Operating Permit Program; Proposed Rules, 56 Fed. Reg. 21,712, 21,713 (1991). Although the previous set of permit requirements under the Clean Air Act were formidable, they were not universal. There was, until the 1990 amendments, no provision in the Act comparable to the general prohibition of pollution without a permit in § 301(a) of the Clean Water Act, see *supra* text accompanying note 201. Once a Clean Air Act permit program is effective, the Act prohibits, in a fashion similar to the Clean Water Act, operation of a source without a permit. 42 U.S.C. § 7661a(a) (1995).

263. Operating Permit Program, Proposed Rules, 56 Fed. Reg. 21,712, 21,713 (1991); Operating Permit Program, Final Rules, 57 Fed. Reg. 32,250, 32,251 (1992).

264. Operating Permit Program, Proposed Rules, 56 Fed. Reg. 21,712, 21,714-15 (1991).

265. *Id.* at 21,714; Operating Permit Programs, Final Rules, 57 Fed. Reg. 32,550, 32,551-52 (1992). See also *supra* text accompanying note 236 (sulfur dioxide emissions allowances).

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necessary for a program of effective cooperative implementation. Permittees are required to monitor emissions and report on these monitoring programs at least semiannually, and these reports must be certified by a “responsible official” of the permittee.<sup>266</sup> The permitting authority (the state or the EPA) has the right to inspect all facilities and records,<sup>267</sup> and must have enforcement powers including at least the right to seek civil injunctions and civil and criminal fines.<sup>268</sup> The EPA recommends the ability to proceed administratively and to seek incarceration as a criminal penalty as well.<sup>269</sup> However, if the regulated entity complies with the permit, it is deemed to be complying with the law.<sup>270</sup>

The main difficulty in making Title V comprehensive air pollution permits work is deciding to what extent the permits reflect performance or output standards. The regulations specify changes in operations a source of pollution can make without having to change the permit at all,<sup>271</sup> changes that can be made with relatively minor procedural hurdles,<sup>272</sup> and all other changes that require the same notice to the EPA, the state(s) and the public as do original permits or renewals.<sup>273</sup> Exceptions to this last requirement, as well as determinations of what changes do not require permit modifications at all, have been the source of most of the recent controversy over the Title V program.<sup>274</sup> The reactions to the Title V permitting program demonstrate some of the difficulties anticipated with a cooperative implementation program: assuring the public that the agency remains vigilant in assuring compliance

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266. 40 C.F.R. § 70.6(a)(3)(iii)(A).

267. 40 C.F.R. § 70.6(c)(2).

268. 40 C.F.R. § 70.11. These enforcement requirements are intended to parallel those applicable to permitting authorities under the Clean Water Act. *See Operating Permit Program, Final Rules*, 57 Fed. Reg. 32,250, 32,293 (1992).

269. *Id.* at 32,293.

270. 40 C.F.R. § 70.6 (1995). This is known as the “permit shield.”

271. 40 C.F.R. § 70.4(b)(14), known as “off-permit provisions.”

272. 40 C.F.R. § 70.4(b)(12), known as “operational flexibility provisions.” The eligible changes may be made by the source upon seven days’ notice to the EPA and state permit administrator; however, the changes are not covered by the “permit shield” unless these changes were contemplated in the original permit. *Id.*

273. 40 C.F.R. § 70.7(e)(4)(ii). There are exceptions with more limited notice and faster processing requirements for “minor permit modifications,” defined at 40 C.F.R. § 70.7(e)(2)(i). However, minor modifications are still more difficult to make than changes pursuant to the “operational flexibility” provisions discussed *supra* at text accompanying note 271.

274. Nearly one-third of the issues raised in litigation challenging the Title V rules involved these flexibility provisions. *See Operating Permits Program Rule Revisions*, 59 Fed. Reg. 44,460, 44,461 (1994). EPA’s proposed revisions would clarify the extent of off-permit revisions permitted and the reach of the “operational flexibility rules.” *See id.* at 44,463-72. The agency also proposed significantly expanding what would be “minor” permit revisions not requiring the full procedures as upon permit issuance or renewal, increasing both the scope of changes permitted to be called “minor” as well as providing for public notice in that process. *See id.* at 44,474-75.

with the regulation<sup>275</sup> while providing meaningful incentives for cooperative implementation in the form of operational flexibility for the regulated entities.

### 3. *Toxic Substance Control*

The Toxic Substances Control Act<sup>276</sup> regulates the production and distribution of hazardous chemical substances.<sup>277</sup> The Act prohibits import into the United States of chemicals and chemical mixtures not in compliance with the Act.<sup>278</sup> Rather than rely solely on physical inspection of each shipment presented for import, the Treasury Department and the EPA require each importer of a chemical substance to certify that the shipment complies with the Act or that the Act does not apply.<sup>279</sup>

Applying the theories of cooperative implementation to this program, it seems that it should be successful because the shippers have an interest in compliance. If the Act does actually promote safe shipment of dangerous substances, compliance will lower costs for all shippers.<sup>280</sup> However, because any individual shipper would, with any given shipment, find it cheaper to violate the Act, monitoring is essential. Under the Act, the Customs Service retains the authority to detain nonconforming shipments or shipments for which no certification is made,<sup>281</sup> and the EPA can separately pursue violations of the Act's reporting provisions.<sup>282</sup> The regulation is complex in that it is wide-ranging, and the regulated population, though technically discrete and observable (shippers of imports), is large enough to be host to toxic smugglers. Thus, the EPA's separate enforcement of the Act was held necessary to

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275. "These petitioners were primarily concerned that the flexibility provisions are vague, fail to provide for public participation, or inadequately provide for State or local permitting authority review." *Id.* at 44,461-62.

276. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-2692 (1995)).

277. *See, e.g.*, § 6(a) of the Act, 15 U.S.C. § 2605a-a(1) (1995), which permits the EPA Administrator, upon finding that a chemical substance "presents or will present an unreasonable risk of injury to health or the environment," to, among other things, "prohibit the manufacturing, processing, or distribution in commerce of such substance."

278. *See* § 13(a) of the Act, 15 U.S.C. § 2612(a) (1995).

279. *See* 19 C.F.R. § 12.121 (1995).

280. This incentive would be similar to that of shippers of agricultural products potentially infested with dangerous pests, since these shippers are usually agents of the growers. *See infra* Part II.D.2.

281. *See* § 13(a)(2) of the Act, 15 U.S.C. § 2612(a)(2) (1995) and 19 C.F.R. § 12.122 (1995).

282. Section 15(3) of the Act, 15 U.S.C. § 2614(3) (1995), makes it unlawful to fail to "submit reports, notices, or other information . . . as required by this Act or a rule thereunder," and Section 16(a)(2), 15 U.S.C. § 2615(a)(2), gives the EPA Administrator the authority to levy civil fines for violations of Section 15. The reporting requirements for importers have been held to be "reports, notices, or other information" under § 15(3). *See ALM Corp. v. EPA*, 974 F.2d 380, 384-85 (3d Cir. 1992).

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legitimize the “self-policing” features of the Act.<sup>283</sup> The certification requirement assists in monitoring, but is also intended to affect compliance itself, by sensitizing shippers to the Act’s requirements.

### 4. *Other Voluntary Compliance Programs*

The EPA has recently proposed or adopted several programs encouraging voluntary participation in cooperative implementation. These programs apply to regulations under all laws subject to the EPA’s jurisdiction. At first blush, the voluntariness seems to make these programs radically different from traditional regulation, which is by definition non-voluntary. Nonetheless, they remain relevant examples. The voluntary nature of the program is not an essential element of the regulatory scheme or a necessary condition of success, rather it is simply one way to experiment with novel regulatory techniques. Thus, the distinction between voluntary and mandatory programs is not critical for purposes of this review. Moreover, if the agency is results-focused, it should be irrelevant what type of regulatory technique is used to achieve the policy goals in question.

In 1993, the agency announced it was considering development of an “Environmental Leadership Program” or ELP.<sup>284</sup> This was intended as a kind of “model citizen” program for businesses.<sup>285</sup> Beginning from that point, the agency would seek out those firms with a commitment to pollution prevention. In developing this program, the EPA follows the principles of cooperative implementation. The ELP program would recognize achievement of goals, regardless of methods used.<sup>286</sup> The program would initially seek to set goals for the reduction of pollutants that are high risk or “difficult to control through conventional approaches.”<sup>287</sup> Most importantly, the proposal recognizes that it is important to offer incentives to encourage firms to participate. Although the EPA would use public recognition as the main

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283. The *ALM Corp.* court approved of the EPA’s argument:

It is at least impractical and perhaps impossible for the Customs Service to identify every non-complying shipment at the port because of the large volume of imports and the inefficiency and inconvenience of physical searches of every import by Customs Service officials or importers. The certification requirements are a form of self-policing. When violations may not be discovered until after entry, as is the case here, a post-entry procedure for penalizing violators is necessary.

*ALM Corp.*, 974 F.2d at 385-86. The court upheld an administrative fine of \$19,500 against the petitioner for violation of the Act’s reporting requirements.

284. See Environmental Leadership Program, 58 Fed. Reg. 4802 (1993).

285. *Id.* at 4803.

286. *Id.* at 4805. “National environmental goals offer the advantage of setting clear expectations for Program participants, so that companies are not ‘second-guessed’ by EPA during the application process or on subsequent review. The goals also would provide a basis for the public to evaluate the progress of this new voluntary program.” *Id.*

287. *Id.*

incentive,<sup>288</sup> the proposal suggests a varied menu of incentives as alternatives.<sup>289</sup>

In mid-1995, the EPA announced an open-ended regulatory reform initiative, "Project XL." The agency is seeking innovative pilot projects which yield better results than traditional regulation and provide credible monitoring to allow the agency and the public to judge the projects' success.<sup>290</sup> These are intended to be programs following the principles of cooperative implementation, as is apparent from the EPA's background statement:

Over the last two years, the Environmental Protection Agency has charted a course designed to demonstrate that environmental goals can best be achieved by providing regulatory and policy flexibility while maintaining accountability, that flexibility can also provide greater protection at a lower cost, that better decisions result from a collaborative process with people working together, and that environmental solutions are often achieved by focusing efforts at the facility or place where protection is being sought. EPA has found that allowing facilities, communities, and other entities to explore non-traditional pollution control solutions can result in regulated entities achieving environmental protection results beyond those anticipated by current regulations or policies. Often these alternative approaches can produce cheaper, more efficient results as well.<sup>291</sup>

At about the same time, EPA announced an interim policy of elimination

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288. See *id.* at 4811-12. EPA notes that participants at OSHA's Voluntary Protection Program conference placed the highest value on public recognition as an incentive for voluntary cooperative implementation. *Id.* at 4811. OSHA's program is discussed in Part II.A above.

289. The other possible incentives are: faster permitting, faster registration, recognition of environmental leadership in product labelling, compliance credit in enforcement actions, reduced monitoring or reporting requirements, multimedia permits, access to an EPA "ombudsman", and credit for voluntary actions against future regulatory requirements. *Id.* at 4812. In a subsequent request for pilot projects, the agency reaffirmed this preference for public recognition and willingness to consider other incentives, within reason. Environmental Leadership Program, Request for Pilot Project Proposals, 59 Fed. Reg. 32,062-63 (1994).

Proposals should focus on incentives that can be offered by [EPA] under existing law using administrative authority or policies that lie clearly within [its] jurisdiction. Proposals to change statutory deadlines, amend environmental standards, or that require actions by other agencies are not appropriate for this program.

*Id.* at 32,063.

290. See Regulatory Reinvention (XL) Pilot Projects, 60 Fed. Reg. 27,282, 27,287 (1995) (listing project criteria).

291. *Id.* at 27,283; accord BILL CLINTON & AL GORE, REINVENTING ENVIRONMENTAL REGULATIONS 36 (National Performance Review, Mar. 16, 1995) (describing Project XL), 14 ("By providing flexibility—with accountability—we will spark technological innovations that will demonstrate that economic and environmental goals can be achieved simultaneously.")

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of punitive penalties assessed under environmental laws for companies “that voluntarily identify, disclose and correct violations.”<sup>292</sup> As with Project XL, this policy is based almost entirely on the principles of cooperative implementation. The agency recognizes that detection of violations is difficult, because of scientific limitations and the limited resources available to the agency.<sup>293</sup> Violations that are discovered must be corrected in order for cooperative implementation to have any public credibility.<sup>294</sup> The agency must provide incentives for such conduct, which it does by lowering the costs of compliance (fines, criminal referrals, and agency investigations).<sup>295</sup>

### D. *Other Examples*

Other federal programs involving more discrete issues or industries have adopted cooperative implementation approaches. These include the major examples of current efforts outside of the health and safety areas.<sup>296</sup>

#### 1. *Transportation Safety*

The Department of Transportation (DOT) is responsible for the safe operation of commercial airplanes and airlines, commercial motor vehicles, and railroads.<sup>297</sup> In many instances, DOT safety requirements are implemented not through agency inspection and surveillance but through approval of plans of compliance prepared by the carriers and approved by the Department. Alcohol testing programs are primarily the responsibility of each carrier. DOT regulations specify the types of tests to be used, the qualifications of testing technicians, and the records to be produced and kept.<sup>298</sup> Medical

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292. Voluntary Environmental Self-Policing and Self-Disclosure Interim Policy Statement, 60 Fed. Reg. 16,875, 16,875 (1995). The agency also commits, under these circumstances, not to refer the violation to the Justice Department for possible criminal prosecution, nor to initiate its own enforcement investigation. *Id.* at 16,876.

293. “Self-policing by regulated entities can play a crucial role in finding, fixing and preventing violations.” *See id.* (Principle for Voluntary Compliance No. 1).

294. *See id.* (Principle No. 2).

295. *See id.* (Principles No. 3-6). However, Principle No. 7 states that EPA must recover any economic benefit realized from the violation in order “[t]o preserve a level playing field.” *Id.* (Principle No. 7).

296. *See also* AYRES & BRAITHWAITE, *supra* note 6 (discussing mine safety programs in the United States, Australia and the United Kingdom). The U.S. program, Ayres & Braithwaite later concluded, is “[p]erhaps the most highly developed version of . . . enforced self-regulation. . . .” *Id.* at 116.

297. *See* 49 U.S.C. §§ 20103(a) (railroads), 31136 (commercial motor vehicles), 44701 (aircraft and air carriers) (1994).

298. *See* Procedures for Transportation Workplace Drug and Alcohol Testing Programs, 59 Fed. Reg. 7,340 (1994). Although DOT settled on one method of alcohol testing in almost all cases, it did so primarily because of performance constraints in the statute. Otherwise, DOT said it would be willing to consider other methods of testing in order to provide maximum flexibility.

examinations for pilots would be made less frequent under proposed rules,<sup>299</sup> and the FAA is considering dispensing with some required physical examinations completely and having pilots self-certify their fitness.<sup>300</sup> Rail carriers are required to report, within 30 days, on remedial actions taken in response to certain cited safety violations.<sup>301</sup> The purpose of the reporting requirement is to increase the frequency and timeliness of remedies and hence to prevent further accidents.<sup>302</sup> As the agency may use the report in assessing the penalty amount,<sup>303</sup> the report serves a purpose not unlike the EPA voluntary reporting program<sup>304</sup> (though the railroad's reports are not voluntary).

In each area, the motivations are consistent with those predicted by cooperative implementation: direct inspection would be impossible since causes of failure are innumerable and unique to each carrier or operator, or the regulated entities are too numerous to inspect. However, the level of program detail specified by the agency varies according to the need for uniformity.<sup>305</sup> In addition, DOT must focus on prevention rather than failure analysis in safety regulation. Although these programs rely on the regulated entities, the Department maintains monitoring and surveillance as a matter of policy

*Id.*

299. See Revision of Medical Standards and Certification Procedures and Duration of Medical Certificates, 59 Fed. Reg. 53,226 (1994).

300. Interview with Neil Eisner, Assistant General Counsel, DOT. (May 30 and June 16, 1995).

301. See Remedial Actions Reporting, 59 Fed. Reg. 43,666 (1994) (to be codified at 49 C.F.R. pt. 209).

302. 49 C.F.R. § 209.401(a) (1994).

303. Remedial Actions Reporting, *supra* note 301, at 43,668.

304. See *supra* notes 291-94 and accompanying text.

305. For example, when the Federal Railroad Administration (FRA) promulgated rules for licensing of locomotive operators, it allowed railroads to compile their own programs and submit them to FRA for approval. This allowed FRA to rely on existing programs to a great degree.

FRA also has decided to retain the "certification" option provided by the statute and not resort to a more traditional licensing scheme. FRA is opting for certification in large measure because it permits all parties to continue to rely on the promptness and efficiency of existing programmatic structures. These structures, which have evolved over many years on the individual railroads, have familiar procedures and are administered by experienced and knowledgeable personnel. Licensing, on the other hand, would generate a need to duplicate or replace, to some degree, the existing private sector system with a governmental system that might or might not operate with the same degree of promptness or economic efficiency.

Qualifications for Locomotive Engineers, 56 Fed. Reg. 28,228, 28,229 (1991). In contrast, the FRA's proposed rules for brake inspection are more stringent, although each railroad is still responsible for program adoption and implementation. See Power Brake Regulations, 59 Fed. Reg. 47,676 (1994) (to be codified at 49 C.F.R. § 229). FRA rejected the locomotive-operator approach, although it would provide "significant flexibility," because it "would require complex and timely evaluation of a potentially large number of disparate plans" from over 600 railroads and other contract facilities; FRA determined to rely on detailed performance standards instead. *Id.* at 47,701.



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because it recognizes that many feel the regulated entities lack compliance incentives. Although normally safe operations are lower-cost operations, many carriers are unaware of data proving the correlation, and many other carriers are smaller, marginal operations which cannot afford to pay large current costs of regulation and await the long-run benefits.<sup>306</sup>

### 2. *Agricultural Quarantines*

Under the Federal Plant Pest Act<sup>307</sup> and the Plant Quarantine Act,<sup>308</sup> the Secretary of Agriculture has broad authority to prohibit or restrict the transportation of plants and plant products into and throughout the United States to prevent the introduction or spread of plant pests.<sup>309</sup> Absent the Secretary's approval, transportation of plants, plant products and plant pests into or throughout the United States is generally prohibited.<sup>310</sup>

In implementing several such quarantines, the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has followed cooperative implementation principles by allowing shippers to conduct inspection, treatment and other requirements through "compliance agreements." These agreements are between APHIS or a state authority and a person moving affected items in which the person agrees to comply with those requirements. These compliance agreements are used in place of direct inspection of the articles to be moved and issuance of a certificate for each movement by the APHIS. These agreements are provided for in the regulations governing fourteen different plant pests and diseases.<sup>311</sup> The earliest compliance agreements were authorized almost thirty years ago,<sup>312</sup> and they have been authorized repeatedly since that time, whenever various quarantines were adopted. Although each provision authorizing compliance agreements varies in language from the others, generally these agreements are

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306. Eisner interview, *supra* note 300.

307. Pub. L. No. 85-36, 71 Stat. 31 (1957) (codified at 7 U.S.C. §§ 147a, 149, 150aa-150jj (1994)).

308. Ch. 308, 37 Stat. 315 (1912) (codified principally at 7 U.S.C. §§ 151-54, 156-164a (1994)).

309. *See* 7 U.S.C. §§ 150bb, 150dd, 160-61 (1994).

310. *See* 7 U.S.C. §§ 150bb, 154, 161.

311. 7 C.F.R. §§ 301.38-6 (black stem rust), 301.45-6 (gypsy moth), 301.50-6 (pine shoot beetle), 301.52-5 (pink bollworm), 301.64-6 (Mexican fruit fly), 301.75-13 (citrus canker), 301.78-6 (Mediterranean fruit fly), 301.80-5 (witchweed), 301.81-5 (imported fire ant), 301.85-5 (golden nematode), 301.87-6 (sugarcane diseases), 301.90-6 (corn cyst nematode), 301.91-6 (European larch canker), 301.93-6 (Oriental fruit fly).

312. *See* 32 Fed. Reg. 9496, 9498 (1967) (amending witchweed quarantines, adding 7 C.F.R. § 301.80-5 to permit compliance agreements). The Department did not specify in its adopting release the rationale for use of compliance agreements. It is implicit that these voluntary agreements were designed as a less cumbersome alternative to the formal inspection and licensing requirements.

discretionary and may be cancelled for cause at any time, with an opportunity for a hearing on material issues of fact.<sup>313</sup>

Through these agreements, APHIS effectively delegates to the private shipper the responsibility for primary compliance with the inspection and treatment requirements of each regulation governing each plant or plant pest. The shipper implements and supervises the compliance, subject to review by the APHIS and cancellation of the agreement or legal action in the event of a violation. These agreements are widely used and are generally effective because the people agreeing to comply are those with the primary financial stake in the proper regulation of the plant pests, namely the shippers and growers of affected crops and other articles regulated under the Acts.<sup>314</sup>

### 3. *Federally-funded Scientific Research*

The federal government produces substantial amounts of scientific research, both directly and by contract with others. The prevention and detection of scientific fraud has involved significant self-enforcement by recipients of federal grants, under programs developed by the Public Health Service of the Department of Health and Human Services (PHS) and the National Science Foundation (NSF).<sup>315</sup> The PHS program was formalized in the late 1980s<sup>316</sup> and was legislatively mandated in 1993.<sup>317</sup> The NSF has stated, citing its general administrative authority,<sup>318</sup> that “awardee institutions bear primary responsibility for prevention and detection of misconduct.”<sup>319</sup>

This simple arrangement is a model of a cooperative implementation program. Awardee institutions probably are in the best position to detect and prevent scientific fraud. They are closer to (if not directly involved with) the research, and thus have better access to relevant facts; they are probably more cost-effective in their investigations; and they can impose a fuller and more

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313. See, e.g., 7 C.F.R. § 301.80-5 (1995).

314. Telephone Interview with Ron Cipolla, Assistant General Counsel, Regulatory Division, Department of Agriculture (Nov. 4, 1992).

315. See generally, Robert M. Andersen, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 J.L. & TECH. 121 (1988).

316. See Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 54 Fed. Reg. 32,446, 32, 446 (1989) (noting first interim policies were published in 1986 and became part of PHS manual in 1988) (codified at 42 C.F.R. pt 50) [hereinafter PHS Final Rules].

317. Pub. L. 103-43, §161, 107 Stat. 122, 140 (1993) (codified at 42 U.S.C. 289b(b) (1994)) requires the Secretary of Health and Human Services to require that each entity receiving financial assistance must (1) provide assurance to the Secretary that it has a process to review reports of scientific misconduct; (2) agree to report any investigation of misconduct in connection with a funded project to PHS; and (3) agree to abide by other PHS regulations.

318. 45 C.F.R. pt. 689 (1995) (citing 42 U.S.C. § 1870(a) in Statement of Authority).

319. 45 C.F.R. § 689.3(a).

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effective range of sanctions.<sup>320</sup> The institution's inherent conflict of interest is dealt with by protection of complainants,<sup>321</sup> as well as complete oversight by the agencies. Both NSF and PHS require reports on any investigation being conducted by an awardee,<sup>322</sup> and each retains full investigative authority.<sup>323</sup> The comprehensive reporting requirements were opposed when each set of rules was proposed, but both NSF and PHS maintained that complete reports while investigations were in progress, as well as final reports when those investigations were concluded, were necessary for effective oversight of federal grant monies.<sup>324</sup>

### 4. *Rangeland Grazing*

The Taylor Grazing Act<sup>325</sup> and the Federal Land Policy and Management Act (FLPMA)<sup>326</sup> govern the use of federally-owned western rangeland. These laws are administered by the Department of the Interior's Bureau of Land Management (BLM). An innovative but ultimately extra-statutory program used by BLM in the mid-1980s involved cooperative implementation by those permitted to graze cattle on federal land.

Permits or leases are required in order to graze animals on federal rangeland.<sup>327</sup> Each such permit or license carries a limited term, although with preference for renewal,<sup>328</sup> and a number of required conditions for its

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320. Andersen, *supra* note 315, at 134-36.

321. NSF regulations provide that "[t]o the extent possible the identi[t]y of informants who wish to remain anonymous will be kept confidential." 45 C.F.R. § 689.4(b) (1995). PHS awardees are required to prevent retaliation against their employees who make allegations of misconduct. 42 U.S.C. § 289b(e) (1994).

322. See 45 C.F.R. § 689.3(b) (1995) (listing requirements for an institution investigation if an NSF investigation is to be deferred); 42 C.F.R. §§ 50.103(d)(4)-(15), 50.104 (1994) (listing requirements for an applicant's policies and procedures regarding investigations and reporting requirements to PHS regarding investigations actually opened).

323. See, e.g., 42 C.F.R. § 50.104(a)(5) (1994) ("If satisfactory progress is not made in the institution's investigation, the [PHS] may undertake an investigation of its own."); 45 C.F.R. § 689.4(d)(3) (1995) (NSF may "[a]t any time proceed with its own inquiry").

324. See PHS Final Rules, *supra* note 316, at 32,448 ("The PHS believes the reporting requirements . . . are necessary in order for the Department to carry out its responsibility under the statute for the stewardship of Federal funds. . . . [A]n active monitoring role is important and . . . the reports required under the regulation are essential to that role."); Misconduct in Science and Engineering Research, 52 Fed. Reg. 24,466, 24,467 (1987) ("We cannot accept the suggestion that NSF be notified only after an investigation has been completed . . . . This would be a serious abrogation of our responsibility to protect Federal property and to oversee the proper administration of awards of public funds.").

325. Taylor Grazing Act of 1934, ch. 865, 48 Stat. 1269 (1934) (codified as amended at 43 U.S.C. §§ 315-315o-1 (1994)).

326. Pub. L. 94-579, 90 Stat. 2743 (1976) (codified principally at 43 U.S.C. §§ 1701-1782 (1994)).

327. See 43 U.S.C. §315b (1994).

328. 43 U.S.C. §§ 315b & 1752(c).

grant and use.<sup>329</sup> In 1984, as part of a program to streamline its regulations,<sup>330</sup> BLM adopted Cooperative Management Agreements (CMAs) as part of the permitting program. CMAs were available to a permittee “who has demonstrated exemplary rangeland management practices” to receive the equivalent of a ten-year permit, subject only to BLM’s periodic evaluation of the cooperating party’s performance.<sup>331</sup> This is in contrast to ordinary permits or leases which are subject to modification throughout their terms if conditions change.<sup>332</sup>

The CMAs were intended to “provide for greater incentives for private investments in practices that will improve rangeland productivity.”<sup>333</sup> Critics contended, however, that without incorporating into the CMAs the explicit requirements of federal law, self-interest would overwhelm the public interest and “grazing management [would return] to near-total rancher control.”<sup>334</sup> These statements indicate the tension in rangeland management between those who view the federal law broadly and those who view it as an intrusion on private rights.<sup>335</sup> The CMAs were an attempt to provide that ranchers, in the furtherance of their private rights, that is, the continued right to receive

329. See 43 U.S.C. § 315b (1995) (preferences for neighboring landowners or users); 43 C.F.R. §§ 4130.6 - 4130.6-3 (1995) (required and optional conditions of lease or permit).

330. See Amendments to the Grazing Regulations; Proposed Rulemaking, 48 Fed. Reg. 21,820, 21,820 (1983) [hereinafter Proposed Rules].

331. See Grazing Administration, Exclusive of Alaska; Final Rules, 49 Fed. Reg. 6440, 6451 (1984) (codified at 43 C.F.R. § 4120.1 (1995)).

332. See 43 U.S.C. § 1752(d)-(e) (1995) (FLPMA provisions for leases and permits).

333. Proposed Rules, *supra* note 330, at 21,820. In theory, the CMA could be used to encourage multiple uses of rangeland, as it “could include discretionary objectives such as improvements to wildlife habitat or watershed.” D. Bernard Zaleha, Note, *The Rise and Fall of BLM’s “Cooperative Management Agreements”*: A Livestock Management Tool Succumbs to Judicial Scrutiny, 17 ENVTL. L. 125, 140 (1986).

334. George Cameron Coggins, *The Law of Public Rangeland Management V: Prescriptions for Reform*, 14 ENVTL. L. 497, 499 n.8 (1984). See also Zaleha, *supra* note 333, at 149-50 (concluding that the theory underlying the CMA program is flawed because ranchers lack the economic motivation to take nonranching uses into account in their rangeland management).

335. For the viewpoint that rangeland management has been the captured province of the stockmen, see generally Coggins, *supra* note 334. Professor Coggins’ four preceding articles in the series present similar arguments and together these articles present a comprehensive history of rangeland management in the United States. See George Cameron Coggins, *The Law of Public Rangeland Management IV: FLPMA, PRIA, and the Multiple Use Mandate*, 14 ENVTL. L. 1 (1983); George Cameron Coggins, *The Law of Public Rangeland Management III: A Survey of Creeping Regulation at the Periphery, 1934-1982*, 13 ENVTL. L. 295 (1983); George Cameron Coggins & Margaret Lindeberg-Johnson, *Public Rangeland Management II: The Commons and the Taylor Act*, 13 ENVTL. L. 1 (1982); George Cameron Coggins et al., *The Law of Public Rangeland Management I: The Extent and Distribution of Federal Power*, 12 ENVTL. L. 535 (1982). For a contrary historical presentation, see WAYNE HAGE, *STORM OVER RANGELANDS: PRIVATE RIGHTS IN FEDERAL LANDS* (3d. ed. 1994). Hage notes in his preface his long concern with “the incessant attack on the western range livestock industry.” *Id.* at xi. See also Frank J. Falen & Karen Budd-Falen, *The Right to Graze Livestock on the Federal Lands: The Historical Development of Western Grazing Rights*, 30 IDAHO L. REV. 505 (1993-94).

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federally-subsidized grazing land,<sup>336</sup> would in turn use that land in an environmentally responsible manner. However, the CMA rule failed to explicitly require anything from ranchers, other than a preexisting demonstration of “exemplary management practices,” which do not necessarily relate to protection of the rangeland or nongrazing uses as required by the Taylor Act and FLPMA. Thus, the CMAs were ultimately held by a District Court to be unauthorized by those Acts.<sup>337</sup> The court reasoned that there was no compulsion retained by BLM over the ranchers to follow the statutory requirements.<sup>338</sup>

BLM acquiesced in the scuttling of CMAs, rather than amend the terms of the regulation to comply with the District Court’s opinion.<sup>339</sup> The proposed rangeland grazing reform regulations contain only a hint of the CMA idea—using the permittee’s self-interest as a means to ensure proper rangeland management—by taking into account an applicant’s “demonstrated stewardship of the public lands” when reviewing competing applications.<sup>340</sup>

### 5. *Indian Gaming*

The Indian Gaming Regulatory Act<sup>341</sup> established a comprehensive scheme of federal-state-tribal regulation of gaming permitted on federally-recognized Indian lands and administered by the National Indian Gaming Commission.<sup>342</sup> The Act divides all games into three categories subject to

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336. Federal grazing fees are far below private fees. In 1993, the federal fee was \$1.98 per animal unit month, while statewide averages for private fees ranged from \$5.72 to \$12.60. 59 Fed. Reg. 14,314, 14,315 (1994) (comprehensive revision of rules and policies known as Rangeland Reform '94) [hereinafter Rangeland Reform '94 Proposed Rules]. BLM has proposed to raise the federal fee to \$3.96, still well below private rates. *See id.* at 14,316.

337. *See* Natural Resources Defense Council, Inc. v. Hodel, 618 F. Supp. 848, 868-71 (E.D. Cal. 1985).

338. The court notes specifically that:

Permittees must be kept under a sufficiently real threat of cancellation or modification in order to adequately protect the public lands from overgrazing or other forms of mismanagement. Any other interpretation . . . is inconsistent with the dominant purposes expressed in the Taylor Grazing Act [and the] FLPMA . . . [I]t is the public policy of the United States that the Secretary and the BLM, not the ranchers, shall retain final control and decisionmaking authority over livestock grazing practices on the public lands.

*Id.* at 871.

339. *See* Grazing Administration; Effects of Court Order Enjoining Certain Regulations in 43 CFR Group 4100, 50 Fed. Reg. 51,522 (1985).

340. *See* Rangeland Reform '94 Proposed Rules, *supra* note 336, at 14,334 (discussing proposed changes to 43 C.F.R. § 4130.1-2).

341. Pub. L. No. 100-497, 102 Stat. 2467 (1988) (codified at 25 U.S.C. §§ 2701-2720 (1994)).

342. The impetus for the legislation was the Supreme Court’s decision in *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987), holding that state laws regulating gambling did not apply on Indian lands. “[I]f the decision had been implemented Nationwide, the

regulation by tribal governments only (Class I gaming),<sup>343</sup> by tribal and federal governments (Class II gaming),<sup>344</sup> or by tribal and federal governments pursuant to a compact between the tribe and state government (Class III gaming).<sup>345</sup> Class II gaming may be regulated solely by the tribe operating the gaming activity if it applies for a certificate of self-regulation, has operated the activity for at least three years, and meets the operating requirements set forth in the Act.<sup>346</sup> Any such self-regulated activity is not subject to most direct federal regulation and is assessed a lower fee by the federal government.<sup>347</sup>

The intent of this limited individual cooperative implementation was to provide a method to respect the sovereignty of a tribe which chooses to operate its own facility.<sup>348</sup> The Act's provisions include elements necessary for

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result would have been chaotic. There would have been almost no control or administration of gaming activities in the various jurisdictions." *Implementation of the Indian Gaming Regulatory Act: Hearings Before the Senate Select Comm. on Indian Affairs*, 102d Cong., 2d Sess. 1 (1992) (statement of Sen. Daniel K. Inouye).

343. See 25 U.S.C. § 2710(a)(1). Class I gaming is defined as games with minimal values or those conducted as part of tribal ceremonies. See 25 U.S.C. § 2703(6).

344. 25 U.S.C. § 2710(b). The distinction between Class II and Class III games is critical because only the latter require a compact with the state government. Although the Act defined these classes of games, see 25 U.S.C. § 2703(7)-(8), distinctions between them remained unclear. The National Indian Gaming Commission, an agency created by the Act in 1988, recently issued regulations defining Class II and Class III games. See 57 Fed. Reg. 12,382 (1992). States do maintain a limited role in that neither Class II nor Class III games are permitted on Indian lands within a state which prohibits any form of gambling altogether. See 25 U.S.C. § 2710(b)(1)(A) & (d)(1)(B).

345. See 25 U.S.C. § 2710(d). Subsection (d)(7) provides a cause of action to tribes for a state's failure to negotiate in good faith toward a compact permitting Class III gaming on the tribe's lands. Notwithstanding this language, some courts have held that the Eleventh Amendment bars suit against the state or that individual state officials may not be required to negotiate. See 784 F. Supp. 1549 (S.D. Ala. 1992) (prohibiting suit against state officials); *Sault Ste. Marie Tribe of Chippewa Indians v. Michigan*, 800 F. Supp. 1484 (W.D. Mich. 1992) (prohibiting suits against state and state officials); and *Poarch Band of Creek Indians v. Alabama*, 776 F. Supp. 550 (S.D. Ala. 1991) (prohibiting suit against state) *But see* *Kickapoo Tribe of Indians v. Kansas*, 818 F. Supp. 1423 (D. Kan. 1993) (permitting suit against state); *Seminole Tribe of Florida v. Florida*, 801 F. Supp. 655 (S.D. Fla. 1992) (permitting suit against state and state officials); and *Spokane Tribe v. Washington*, 790 F. Supp. 1057 (E.D. Wash. 1991) (prohibiting suit against state but permitting suit against state officials). See generally, *Implementation of the Indian Gaming Regulatory Act: Hearing Before the Senate Select Committee on Indian Affairs*, 102d Cong., 2d Sess. 40-88 (1992).

346. See 25 U.S.C. § 2710(c)(3)-(4). The requirements include effective accounting of revenues, safe operation, lack of evidence of criminal activity, and adequate systems for accounting, investigation of employees, and enforcement of the tribal gaming ordinances and regulations.

347. See 25 U.S.C. § 2710(c)(5). Fees assessed on self-regulated Class II gaming activities are limited to 0.25% of assessable gross revenues, *id.*, but fees assessed on directly regulated activities are as high as 5%. 25 C.F.R. § 514.1(a)(4) (1995).

348. See 25 U.S.C. § 2701(5) (Congressional finding that "Indian tribes have the exclusive right to regulate gaming activity on Indian lands if the gaming activity is not specifically prohibited by Federal law and is conducted within a State which does not . . . prohibit such gaming activity."

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effective oversight. The Commission must initially certify the gaming operation as in compliance with the act and then receives annual reports on the gaming operation.<sup>349</sup> In addition, the Commission retains the authority to investigate alleged violations of the Act or regulations,<sup>350</sup> to revoke the tribe's self-regulatory authority,<sup>351</sup> and to close the gaming operation for "substantial violation of the provisions of this Act."<sup>352</sup> And although the Commission's investigative power is broad, its enforcement power extends only to the operators of a self-regulated gaming activity.<sup>353</sup>

The self-regulation of Class II gaming meets the definition of cooperative implementation. It would be difficult to specify for each separate gaming operation what would be required to comply with the Act; the game operators, if sufficiently expert and motivated, would be likely to implement the regulations more effectively. The monitoring and residual direct enforcement programs create a credible compliance incentive. The arrangement to date, however, has not been widely used because the economic incentives are lacking. The games subject to self-enforcement are not those that are most profitable, nor are the fee differentials for self-regulated gaming sufficient to generate a significant economic incentive.<sup>354</sup>

### III. Recommendations for Adoption of Cooperative Implementation Programs

It is now time to put the theory of Part I and the practice of Part II together. A broad-based generalized conclusion would be comprehensive but not helpful. It is reasonable to conclude, therefore, that cooperative implementation should be considered as a viable regulatory alternative according to the characteristics identified in Part I. It offers the potential for the federal government to develop more efficient and less costly regulatory programs.

The theories of cooperative implementation in Part I are general, and the

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349. 25 U.S.C. § 2710(c)(4)-(5).

350. See 25 U.S.C. § 2715.

351. 25 U.S.C. § 2710(c)(6).

352. 25 U.S.C. § 2713(b).

353. See 25 U.S.C. § 2713(a) (extending the power of the Commission to levy civil fines only to "the tribal operator of an Indian game or a management contractor.") See also 25 U.S.C. § 2706(a) (limiting enforcement to civil fines in the enumeration of the Commission's powers).

354. Most tribes do not operate their own casinos and games, but do so by contract with management firms; most tribes also desire to engage in the more lucrative Class III gaming activities. Telephone interview with Anthony J. Hope, Chairman, National Indian Gaming Commission (July 12, 1993) [hereinafter Hope interview]. Self-regulation is not available in either of these cases. See 25 U.S.C. § 2710(c)(3), (d)(1) (1994). Furthermore, the fee differential for self-regulated gaming operations is not as great as originally anticipated. See 25 C.F.R. § 514.1(a)(4) (1995). The fees imposed on directly-regulated gaming operations are currently 0.7% of gross revenues, far below the 5% authorized by the Act. Hope interview, *supra*.

specific applications listed in Part II could be extended beyond their current focus. Given that the realities of complex regulatory reform require an agency to address only one program, industry or statute at a time,<sup>355</sup> what do these general principles and specific examples suggest about where an agency might begin?

The regulatory program that would be a good candidate for cooperative implementation is one in which complex regulations are applied to complex organizations in order to prevent harms from occurring, rather than merely to identify and punish violations. The major cooperative implementation programs in place today, as discussed in Part II, involve primarily health, safety and protection of the environment. The other programs discussed in Part II (voluntary food product labelling regulation and supervision of federally-funded scientific research) are directed toward prevention of fraud. The first place for an agency to begin, therefore, would be to examine its programs (if any) dealing with health, safety, protection of the environment, and prevention of fraud. These are the areas in which the most robust cooperative implementation models have been developed and in which agencies have the most experience.

If agencies consider cooperative implementation in other areas, they would likely be most successful if related to these four areas. For example, perhaps a cooperative implementation model based on health or safety could be extended to economic regulation if one of the purposes of that regulation is the economic health of a regulated entity. Because cooperative implementation to date has been a theory of production quality control, such programs should be able to identify a "product" whose production is to be controlled. This need not be the firm's main product; a program might consider clean wastewater as the "product" for purposes of its regulation. And it need not be an actual "product" at all; a program might consider a financially stable financial institution or common carrier as its product in designing a cooperative implementation program. Although these are areas with little or no current experience, they are potential candidates if the subject matter of the regulation can be so categorized.

The potential subject of a cooperative implementation initiative must also be selected with political requirements in mind. Any such initiative develops initially in an environment of suspicion, and perhaps rightly so; a credible

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355. Justice Breyer notes:

[O]ne is forced to question whether the "generic" proposals are likely to provide, or to generate, sufficient impetus for reform. If the "generic" efforts are indeed insufficient, should we not examine the "candidates" for major regulatory change—the environment, worker safety, and natural gas—by undertaking the type of detailed investigative work that I have described? This is the direction that meaningful regulatory reform ought to take.

Stephen Breyer, *Reforming Regulation*, 59 TUL. L. REV. 1, 23 (1984).



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agency monitoring program is crucial to the success of any cooperative implementation.<sup>356</sup> Nonetheless, it may be impossible to overcome present notions or proclivities. For example, meat inspection reform operates in a political environment still wedded to individual organoleptic examination of each carcass by a government inspector.<sup>357</sup> And using HACCP principles outside the food industry may be difficult simply because everyone familiar with HACCP has always applied it only in that area.<sup>358</sup>

Any program of regulation would be better if it were founded on good research of the causes and cures of the harms the regulation is to prevent. This is true even if the agency is pursuing traditional “command-and-control” regulation, but it is essential if the agency is to turn over design of the compliance program to the regulated entities.

There must be a knowledge base which permits the industry to identify a “product” whose quality is to be controlled. There must be evidence suggesting what the components of that quality are so that harms or hazards can be identified, and there must be a relationship between quantifiable data and those components of quality. For example, it was initially difficult for FSIS to propose a HACCP program for meat and poultry without a scientific basis for determining what pathogenic microorganisms pose the greatest public health threat, how they are introduced into the slaughter and processing systems, and most importantly, how they can be controlled. Each of these elements is essential to the design of any cooperative implementation program.

The agency, of course, must be sufficiently expert in the substantive area involved, but expert as well in program design and review, so that it can recognize the components of a good self-regulatory program. This is good news and bad news. The bad news is that many agencies must learn an entirely new way of regulation. For example, a critical element of FSIS’ adoption of HACCP is the ability to train inspectors in review of HACCP plans when their primary focus to date has been organoleptic inspection of carcasses and supervision of product processing lines.<sup>359</sup> The good news, however, is that there is a lesser requirement for substantive knowledge of the processing system, which makes it possible for the agency, through a cooperative implementation program, to adapt its regulations to a wide variety of subjects. For example, one feature of HACCP particularly attractive to the FDA is that the inspectors can concentrate their expertise on review of HACCP plans rather than the virtually unlimited methods and types of food production in the United States. Expert knowledge in such diverse fields is difficult to acquire.<sup>360</sup>

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356. See *supra* Part I.B.3.

357. See *supra* note 132 and accompanying text.

358. See *supra* notes 192-97 and accompanying text.

359. See Meat/Poultry HACCP Release, *supra* note 162, at 6829-30.

360. Schwalm interview, *supra* note 186.

A characteristic which makes cooperative implementation stand out as the regulatory technique of choice is that surveillance, inspection and detection is often impossible. This is ordinarily the case where inspection through reliable sampling would destroy the product, where the inspection sites are too numerous to reliably sample with the limited agency resources at hand, where there is imperfect knowledge about what the “baseline” amounts should be, where it is difficult for the agency to inspect, test, sample or reproduce the regulated entity’s efforts, or where waiting for failures to occur is unacceptable public policy, as well as bad management.<sup>361</sup> In other words, the agency with limited resources may simply not have the ability to operate an enforcement program which provides a credible deterrent effect.

Determining success or failure of traditional enforcement is not a simple, binary evaluation. Success comes in varying degrees, and portions of a program may, for the reasons discussed above, be more susceptible to cooperative implementation than others. However, the more of the above-listed characteristics that an agency’s program possesses, the more likely it is that cooperative implementation will yield better results.

## Conclusion

The examples in Part II demonstrate a willingness to experiment with self-enforcement across several apparently unrelated regulatory programs. Successful programs operate in conformity with the model suggested in Part I, and those programs which do not meet all of the requirements of the model were limited in their usefulness. These efforts, successful at least in part in most programs, are being made in programs which have complex problems, large regulated populations and ambitious policy goals—pollution prevention, worker health, food safety—and therefore stand at the frontier of regulatory reform.

As was the case with audited self-regulation, it is unlikely that mandating the consideration of cooperative implementation across-the-board would have any beneficial effects.<sup>362</sup> However, Part III suggests some useful generalizations for future regulatory approaches depending upon a proper evaluation of the regulatory program, the state of knowledge about causes and prevention of harms, and the relative success of a traditional enforcement program. The most promising candidates for cooperative implementation are those in or closely related to health, safety, and protection of the environment, where there is sound science supporting generally accepted harm prevention

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361. See generally DEMING, *supra* note 188.

362. See Michael, *supra* note 6, at 246-48 (discussing the futility of mandatory regulatory analysis).

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methods, where traditional “product” or “end-of-the-pipe” inspection is inadequate to prevent these harms, and where it is essential public policy that harms be prevented as well as punished.

Unfortunately, it is impossible to specify or even suggest, at a broad policy level, any specific programs that are ideal candidates for cooperative implementation approaches. This Article has identified many potential areas of regulation which might be responsive to cooperative implementation; however, a realistic decision that cooperative implementation is even worthy of further study in any particular area is a question that itself requires detailed analysis.<sup>363</sup> In many cases, however, that analysis may already have been done. Agencies know their industries. The cost savings and increased efficiency which could result from more widely-applied programs of self-regulation would provide agencies with adequate motivations. In addition, it is possible that there could be overall cost savings, as the private enforcement structure may cost less to administer than the government inspectorate it partially supplants. There are important political factors to be considered in determining when regulatory reform is likely to succeed.<sup>364</sup> But as with audited self-regulation, potential reforms can be analyzed now, in preparation for a politically opportune moment.<sup>365</sup> This Article has attempted to provide that analysis by reviewing the literature and actual regulatory experience. Since meaningful regulatory reform proceeds best one agency or program at a time, analytical tools must be made available to agencies without delay, so that regulatory reform can begin at its proper starting point.

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363. See *supra* note 355 and accompanying text. In discussing the application of HACCP analysis to regulatory problems generally, examples were given such as workplace safety, airplane construction integrity and financial reporting. See *supra* notes 195, 197 and accompanying text. Part III.A included examples of common carrier or financial institution regulation. However, even cursory examination of these theories by staff of OSHA, FAA, SEC, FRA, FCC, OCC or FDIC (to name a few), or by researchers in those fields, would be far more productive than further development of any of those examples here.

364. See Robert W. Hahn & Robert N. Stavins, *Incentive-Based Environmental Regulation: A New Era From an Old Idea?*, 18 *ECOLOGICAL QUARTERLY* 1, 31-41 (1991) (discussing the political factors that made reform of air pollution regulation a reality in 1990).

365. See Michael, *supra* note 6, at 248-50.

