Chapter 10 Principles-Based Regulation and Emerging Technology

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Innovations in emerging technologies are changing "every aspect of human life" at an unprecedented pace (NanoAction 2007). The companies trying to apply these advancements and the regulatory agencies trying to oversee these technologies are struggling to keep up the speed of development of new technologies, and need new approaches to be able to adapt to the complexity and rapid pace of innovation (U.S. Dep't of Treasury 2008). One possible mechanism to allow both innovators and regulators to remain more flexible and adaptable to rapidly changing technologies is to replace the current rules-based regulatory system with a principles-based approach. A principle-based approach has the potential to reward companies for acting ethically while encouraging innovativeness, efficiency, and competition in developing areas of technology. At the same time, a principles-based approach raises a number of difficult legal, policy and political challenges that would need to be overcome for such a system to succeed. This chapter will explain the background, objectives and experience of principles-based regulation, review the strengths and weaknesses of such an approach, and consider the applicability of principles-based regulation for the oversight of emerging technologies.

10.1 What Is Principles-Based Regulation?

There is a long-standing tension in regulatory theory between rules-based approaches and standards-based approaches to regulation (Kaplow 1992). Briefly, rules-based approaches set forth the specific acts or behaviors a regulated party is expected to achieve with some specificity (e.g., discharge no more than 0.45 pounds of pollutant X per hour) whereas a standards-based approach sets forth a more general goal that the regulated party must strive to achieve (e.g., discharge pollutant X at a level that will be safe for human health and the environment). Both approaches have their relative strengths and weaknesses – the key ones being that rules provide

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more certainty but are also more rigid, whereas standards are more subjective and subject to different interpretations, but provide greater flexibility for adapting to shifting circumstances (Coglianese et al. 2003). In the legally-oriented regulatory system of the U.S. and increasingly other industrial nations, rule-based systems have been the preferred approach, often described as the "command and control approach." Under this approach, regulation is described as "the promulgation of rules by government accompanied by mechanisms for monitoring and enforcement" (Black 2002).

Principles-based regulation goes one step beyond standards and instead of specifying specific requirements (rules) or general obligations (standards), it focuses on desired outcomes (Barrass 2007; Black 2008). This approach uses guiding principles that are broad, general, and abstract (Cunningham 2007). Principles-based regulation is a "complex form of regulation" where expectations are expressed using qualitative terms and the underlying reason for them is given (Black 2008). Using principles, rather than rules, gives each company the discretion to determine how they can best apply them to their practices (Freshfields Bruckhaus Deringer 2007). As such, principles-based regulation is sometimes referred to as "light touch" oversight (Gray 2009).

As the principles are applied to new situations, they become more developed and transparent. (Schwarcz 2008). These principles not only provide companies greater flexibility to comply with their current expectations, they also provide greater agility for adapting to new situations and contexts that arise in rapidly changing areas of activity (Better Regulation Task Force 2003). By being outcome-focused, principles-based regulation can, encourage more collaborative approaches and focus on finding solutions to problems instead of being overburdened by attempts to stay in compliance with an inflexible rules-based system (Ford 2008; Hopper and Stainsby 2006).

Under a principles-based approach, the regulatory agency identifies the general principles that companies are expected to comply with, and then each company develops its own interpretation, framework, and best practices for adhering to the applicable principles (Kovacevich et al. 2008). In other words, companies are expected to be self-reflective in determining how the principles should be applied to their practices to ensure compliance (Black 2008). Principle-based regulation is most applicable where it would be unduly burdensome if not impossible to create specific rules for every possible scenario (Ford 2008). They should thus be used when "the regulator 'knows the result [he] is trying to achieve but does not know the means for achieving it, when circumstances are likely to change in ways that the [regulator] cannot predict, or when the [regulator] does not even know" the specific result it desires (Ford 2008).

Because principles are usually worded very generally and thus may be subject to different interpretations, a key prerequisite of a principles-based approach is that the regulatory and regulated parties are well-intentioned and prepared to trust and cooperate with each other. The shift from rules-based to principles-based regulation requires a significant change in how companies interact with their regulators (FSA 2007). Instead of the regulator unilaterally deciding if the company is following the rules, the regulator and the company must work together to "determine how the regulatory outcomes envisage in a principle are to be reached." (Barrass 2007). Principles-based regulation thus requires a "close engagement" between the regulator and the company that is more intimate than traditional inspection and supervision (Black 2008; FSA 2007). Conversely, the regulator should articulate the guiding principles in a "flexible and dynamic" manner and has the responsibility to clearly communicate the goals and outcomes companies are expected to achieve (Ford 2008; FSA 2007). Moreover, the regulator should direct its energy toward the most pressing problems rather than enforcing against technicalities or minor disagreements (Better Regulation Task Force 2003). The regulator is also expected to regulate consistently, which allows companies to be more innovative without violating the principles (Better Regulation Task Force 2003).

Although a principles-based system gives companies more flexibility than a rulebased approach, the regulator continues to settle disputes, take enforcement actions, and administer sanctions when principles are breached (FSA 2008; Ford 2008; U.S. Dept. of Treasury 2008). The regulator always has the responsibility for ensuring that companies are complying with the applicable principles (Cunningham 2007). The regulator distinguishes between companies who occasionally make mistakes from those with more serious problems, and direct their resources to the latter (Ford 2008).

Principles-based regulation is a relatively new concept that received much governmental and scholarly interest recently after being adopted to regulate financial institutions, most prominently the United Kingdom and Canada (Black 2008; Cunningham 2007). In the United Kingdom, financial regulation, conducted by the Financial Services Authority (FSA), is based on eleven broad principles, such as conducting business with integrity, observing proper standards of market conduct, treating customers fairly, protecting client's assets, and dealing with regulators in an open and cooperative way (FSA 2008). These broad principles are then supplemented with some specific rules, as well as some illustrative examples provided by FSA as guidance of good and bad practices (Hopper and Stainsby 2006). The FSA only brings enforcement action when one of the eleven principles is "clearly breached" (Hopper and Stainsby 2006). The U.K.'s. principles-based regulatory approach to financial regulation came under considerable criticism with the recent high-profile failure of Northern Rock Bank even though the institution seemed to be complying with the regulators' principles, and resulted in an enhanced reliance on back-up rules to reinforce the general principles (Gray 2009). Similarly, financial regulations in Canada are based on broad principles such as prohibiting "unfair practices," but this principles-based approach begins to resemble rules when it provides specific definitions, clarifications, and requirements (Cunningham 2007). Officials in the European Union and United States have expressed interest and support for adopting a similar principles-based approach for financial regulation in their jurisdictions, although the recent economic crisis has moved consideration of such changes to the back burner (Black 2008).

10.2 Benefits of Principles-Based Regulation

A number of potential benefits are attributed to principles-based regulation, although there has been a tendency to exaggerate some of these benefits. Notwithstanding some hyperbole, there are some important potential benefits associated with principles-based regulation.

10.2.1 Regulatory Objectives More Important than the Letter of the Law

The most significant benefit of principles-based regulation is that it puts the overall objective of regulation before the letter of the law, and thus may increase the likelihood that the regulatory objective will be achieved while reducing the risk of becoming embroiled in technicalities that are not critical to the overall goal of the regulation (Cunningham 2007). Principles-based regulation encourages more effective regulation by discouraging "loophole behavior and checklist style approaches" (Ford 2008). Under traditional rule-based regulation, companies have incentives to engage in "creative compliance" whereby they technically comply with the letter but not spirit of the regulation (Black 2008; Cunningham 2007; Ford 2008). Even the best-drafted rules can never prevent or anticipate all possible misconduct, and so there will inevitably be gaps between the wording and spirit of the rule that a company could exploit (FSA 2007). Additionally, regardless of how carefully a rule is written, it will always be "both under- and over-inclusive in relation to the original principle" (Kershaw 2005, p. 605). Finally, "the more precise the rules, the more complex they become ... the greater the potential for internal inconsistencies in their application, and the more uncertain their application becomes in any particular circumstance" (Black 2008, p. 438). In contrast, because the focus of principlesbased regulation is on the overall objectives of the regulation rather than specific wording and detailed regulatory prescriptions, the focus is more clearly on the desired outcome. Complying with high-level principles, instead of being distracted by the minutiae of rigid rules, reduces misconduct, distraction, and misdirection by regulated entities (Hopper and Stainsby 2006).

10.2.2 Greater Flexibility for Companies

A principles-based regulatory system puts the responsibility on each company to determine the best way to apply the principles to their objectives to ensure that they are compliant (FSA 2008; Black 2008; Ford 2008). Each company has the flexibility to determine how each principle applies to their products, practices and businesses, which if approached in good faith should permit more creative, effective and efficient compliance (Freshfields Bruckhaus Deringer 2007; U.S. Dept. of Treasury 2008; Kershaw 2005). A principles-based approach gives companies more options

for conducting business and accomplishing both their and the regulatory goals (FSA 2008; Black 2008). Not only will this allow companies to be more efficient and creative in their compliance, but the additional freedom should also make companies more cooperative and willing to comply with the regulatory objectives (Ford 2008; Black 2008).

10.2.3 More Dynamic and Adaptive Regulation

Another key advantage of principles-based regulation, of particular relevance to the topic of this book, is that principles-based regulation can better and more quickly adapt to changing circumstances than can traditional rules-based regulation (Black 2008). Because they are written in broad general terms, principles are usually resilient and maintain their relevance even as the regulated activities and their context change in response to evolving technologies and other factors (Cunningham 2007). In contrast, more detailed rules are often made obsolete or inapplicable by even relatively minor changes in circumstances. Rules are also unable to keep up with innovations and changes in the industry, and can easily become outdated (FSA 2007). Because rules require very specific and detailed language, supported by adequate legal and evidentiary analysis and process, rules take much longer to promulgate than principles and cannot be changed fast enough to effectively regulate industries that are constantly developing and changing (Cunningham 2007; Better Regulation Task Force 2003). The relative dynamism of principles-based regulation make it particularly well-suited for fast-changing regulatory subjects such as emerging technologies.

10.2.4 Better Relationship Between Regulators and Regulated Parties

The greater flexibility and reduction in detailed obligations provided by principlesbased regulation may make companies more willing to accept regulation as "an integral part of business decision-making" (FSA 2008). Companies view the principles as something to internalize into their metrics of success instead of an obstacle to circumvent. Moreover, regulators are perceived more as an ally to accomplish mutual objectives together than an adversary to be feared and fought. Enforcement is cooperative, as the regulator considers reasonable efforts to apply the principles to each company's situation as substantial compliance, rather than bringing enforcement actions based on technical violations and paperwork discrepancies (FSA 2008; Barrass 2007). Multiple rules can be consolidated under one principle, making it easier for companies and regulators to understand what the expectations are and to ensure that compliance is occurring (Ford 2008). Furthermore, problems are resolved more efficiently because they are addressed more proactively and with input from the regulator (Kovacevich et al. 2008). From the perspective of regulators, the principles-based approach also provides greater flexibility as they only have to take enforcement action when a principle has been clearly violated (Black 2008).

10.3 Limitations of Principles-Based Regulation

Principles-based regulation is not a panacea, and has some important limitations, discussed next.

10.3.1 Uncertainty

One of the biggest drawbacks of principles-based regulation is the level of uncertainty associated with what is expected by applying the general principles to a wide variety of different situations (FSA 2008; Hopper and Stainsby 2007; Black 2008; Cunningham 2008). As they seek to apply the guiding principles to their own operations and activities, companies will be uncertain if their actions are in compliance with the regulator's understanding of the principles (Black 2008; Schwarcz 2008). The vagueness and flexibility of principles can lead to multiple interpretations in a particular context (Black 2008). Since the principles are open to interpretation, it will also be more challenging to identify when a principle has been breached (Barrass 2007), and there will be uncertainty how tolerant regulators will be of a company's divergent interpretation. One fear is that companies will be blamed in hindsight for actions that may have seemed like reasonable and good-faith interpretation of the principles at the time the decision was made (Gray 2009; Cunningham 2007). Alternatively, a regulator may feel constrained from taking enforcement action against a company that takes a self-serving approach to the principles that technically complies with the wording but not spirit of the principle (Gray 2009).

Using a principles-based system can lead to communication problems between the regulator and the regulated company (Black 2008). Companies will want to minimize their risk by requesting more direction and clear boundaries from the regulator (Black 2008). Yet, regulators will want to avoid undercutting the benefits of having broad principles by issuing too many interpretations and guidance on construing the principles. Alternatively, if the company receives too many communications from the regulator, they may be uncertain about what their expectations are (Black 2008).

10.3.2 Compliance Problems

Principles-based regulation relies heavily on companies being honest and open with their regulator (FSA Internal Audit Div. 2008). They are required to keep their regulator informed about changes and risks related to their endeavors. The regulator needs to provide sufficient supervision and conduct ongoing assessments on the

companies' functions. In order to do this, the regulator requires more information than he would need in a rules-based system (FSA 2007). The regulator needs enough information and knowledge to fully understand the risks and choices each company is making (U.S. Dep't of Treasury 2008). Without such access and information, the government may not have enough knowledge about an industry, particularly when emerging technology is involved, to be able to identify when a company is not being compliant, the cause of the problem, or what solutions will resolve it (Black 2002). It is well-known that the "government cannot know as much about [an] industry as [the] industry does about itself." (Black 2002, p. 3). Hence, there may be a greater risk of non-compliance with principles than with a rule-based system.

A related compliance concern is that regulated companies must be motivated to perform beyond the minimal level of compliance to achieve the objectives of principles-based regulation (Black 2008). For at least some companies, this is likely to be a problem. Without detailed rules, it is harder for the regulator to convince recalcitrant companies to comply with regulations, and it is more difficult for the regulator to say "no" to companies' questionable practices (Black 2008).

In addition, the close relationship between companies and regulators necessary for principles-based regulation to thrive can lead to complacency or exploitation of the relationship. The regulator must be leery of companies that abuse the principles or their relationship with the regulator (Ford 2008). There is a risk that companies will attempt to use their relationship with the regulator to avoid punishments when they breach principles or commit fraud (Kovacevich et al. 2008). The closer relationship between the company and the regulator can result in the regulator becoming overly familiar with the company and can overlook breaches that he would have seen had he been more impartial (FSA Internal Audit Div. 2008). The principles-based system allows the regulator to provide less oversight to companies that have demonstrated compliance (Ford 2008). This can lead to an increase in abuse by companies. Adopting principles, rather than rules, results in fewer norms applying to an industry, which further opens the door for abuse by companies that can convince a regulator that their indiscretions are still in compliance with the guiding principles (Schwarcz 2008).

The bottom line is that a principles-based system can facilitate trust between the regulator and the company, but it cannot create it (Black 2008). "Compliance systems can be empowered under principles-based regulation, but only if they are strong already" (Black 2008, p. 427). If trust between the regulator and regulated does not already exist, a principles-based system can "never be operationalized." (Black 2008, p. 456).

10.3.3 Changes in the Industry's Culture

Changing to principles-based regulation requires a dramatic and perhaps risky shift in the culture of the industry (FSA 2007). Each company will shoulder more responsibility for how they meet their regulatory obligations (FSA 2007; Gray 2009). They will be "required to think through the application of the provisions to particular situations to a far greater degree than they are with respect to a detailed rule" (Black 2008, p. 440). There will be an increased need to exercise judgment by multiple levels of management to be in compliance with the guiding principles (FSA 2007). Companies will no longer be able to solely rely on their regulator for compliance information, but will have to make their own judgments regarding their ideas to create new technologies (FSA 2007). The pressure, freedom, and fear of setbacks due to compliance issues could lead companies to being overly cautious regarding the projects they take on (Schwarcz 2008; Cunningham 2007). This could potentially hamper innovation and stifle competition if companies are unwilling to take risks or are unwilling to do the research that will make their experiments and proposed products comply with the principles (Schwarcz 2008).

10.3.4 Principles Can Erode into Rules

There is a risk with principles-based regulation that, over time and through their application, the principles can begin to resemble rules (Gray 2009). Once the principles have begun to be applied, there can be a decrease in using them innovatively. Companies become conservative and only use the principles in limited ways that have been deemed to be in compliance in previous applications (Schwarcz 2008). They restrict their use of the principles rather than risk using them in more innovative ways that might be rejected by the regulator (Schwarcz 2008). If the regulator only accepts certain practices as complying with the principles or if companies treat the principles like detailed rules, the companies' application of the principles becomes homogenous (Black 2008). This canalization of principles into more rule-like requirements is especially likely when a regulator is highly punitive and inflexible in its enforcement policies (Black 2008). As the principles become more rule-like, the flexibility and innovation offered by a principles-based approach is lost.

10.4 Principles-Based Regulation for Emerging Technologies?

Although principles-based regulation has both significant benefits and limitations, a principles-based approach may have particular promise for regulating emerging technologies. Emerging technologies can arise and be deployed quickly, evolve and change at a rapid pace, and create a wide diversity of applications and contexts. Traditional rule-based regulation is hard-pressed to respond to all three of these challenges, whereas principles-based regulation provides the flexibility, speed and dexterity to deal with fast-moving and diverse regulatory situations. Some of the principles used in financial regulation could also apply to emerging technologies, such as conducting business with integrity and diligence (FSA 2007). Other relevant principles that have been used or proposed in other regulatory contexts include the need to promote innovation, increase efficiency, and enhance competition between

companies (U.S. Dept. of Treasury 2008). Maintaining the safety of employees and consumers are also crucial principles for any company involved in emerging technologies (Kovacevich et al. 2008). Another potential principle that might apply to companies in emerging technology fields might be conducting business with a high degree of transparency (Better Regulation Task Force 2003).

A principles-based approach might be particularly apt as an interim regulatory approach for emerging technologies that can be instated relatively quickly and provide some oversight until a more traditional rule-based system can be developed. This can help to fill the oversight gap that often exists for emerging technologies while the government is developing the sufficient evidentiary base and knowledge needed to promulgate traditional rules (Marchant et al. 2008). For example, the European Union has adopted a code of practice for nanotechnology researchers that is based on general principles, and serves as a gap-filling measure until more concrete regulations can be adopted (European Commission 2008). Over time, the principles could be strengthened and "filled-out" into more of a rule-based system with increasing knowledge and experience (Better Regulation Task Force 2003). Nevertheless, a principles-based approach for emerging technologies would likely face many challenges, such as overcoming the culture of litigation that pervades the U.S. regulatory system (Black 2008).

10.5 Conclusion

Principles-based regulation for emerging technologies in the United States may help address the existing problem that rules-based regulation cannot keep up with the pace of new developments. Particularly if implemented as an interim approach while regulators develop more traditional rule-based approaches, principles-based regulation can serve in a flexible, adaptable, and dynamic gap-filling role. However, implementing a principles-based approach will not be without its challenges and problems. New technologies are being developed in various industries that are supervised by numerous, and sometimes overlapping, agencies. Applying a principles-based approach might require the creation of a separate agency that would be devoted solely to new technologies; which comes with the additional problem of determining when a technology or method is no longer considered "emerging." Otherwise numerous agencies will have to change to a principles-based approach to accommodate every industry where technology is advancing rapidly. Engineers who are developing new technologies will appreciate the freedom that comes with adhering to principles, but ultimately they may want the certainty that comes with having to adhering to rules.

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