


Principles Based Regulation

Professor Julia Black, LSE

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Outline

- What is principles-based regulation?
 - PBR in the rule books and guidance
 - PBR in operation
- Why have PBR?
- What are the risks of PBR?
- What is necessary for the successful implementation of PBR?

Context

- Broad context of the 'better regulation' debate: how to deliver effective, proportionate and targeted regulation without compromising the achievement of social and economic objectives
- Debates on PBR are on-going in a number of regulatory sectors
- In the UK context, PBR is also running alongside the implementation of the Hampton principles, in particular risk based regulation

PBR in the rule books

- The presence in the rule books / codes of practice of general, broadly stated rules, or ‘principles’, to set the standards by which regulated firms must conduct business
- Principles express the fundamental obligations that all should observe
- In particular
 - they are drafted at a high level of generality
 - they contain terms which are qualitative not quantitative
 - they are purposive and outcome orientated

PBR and regulatory practices

- Rule book PBR can be associated with a number of additional regulatory practices
 - an orientation to outcomes
 - an explicit and developed reliance on firms' internal management
 - a revised approach to inspection and enforcement
 - a reallocation of responsibilities for working out the practical application of the regulatory provisions

Why have rule book PBR?

- To facilitate and enhance
 - *Communication* by stating clearly the purpose of the rules
 - *Effectiveness* by focusing on purposes and outcomes
 - *Durability* of the rules, facilitating response to changing contexts
 - *Substantive compliance* by blocking loopholes and requiring compliance with the spirit of the law not the letter
 - *Integration and embedding* of the purposes and outcomes of the regulation with the goals and processes of regulated firms

PBR and Regulatory Practices:

(1) Outcome orientation

- Focus on why is the rule there? What is it trying to achieve?
- Implications for firms / centres:
 - flexibility (and responsibility) for firms / licensees to develop their own ways of achieving the outcomes specified
- Implications for regulators:
 - identifying what the important outcomes are and developing methods to assess them

(2) Reliance on firm's internal management

- Focus on internal management and controls
- Link with risk based inspection regimes: evaluation of management and controls as risk mitigators or risk enhancers
- Implications for firms / centres:
 - enhanced procedures and demonstration that achieving outcomes
- Implications for regulators:
 - move away from 'tick-box' compliance assessments to deeper analysis of firm's activities and the exercise of judgement

(3) Revised approach to inspection and enforcement

- Move to risk based inspection regimes; Hampton principles
 - Focus on risks to outcomes rather than process based
 - Selection and prioritisation of issues for regulatory attention
- Implications for firms / centres
 - More data collection by regulator
 - More analytical approach to inspections
 - Less frequent inspections in low risk areas, but more intensive inspection in high risk ones
- Implications for regulators
 - Risk based regulation means not doing things – regulators take a risk
 - Implies significant cultural and organisational changes for regulators

(4) Reallocation of responsibilities

- With flexibility comes responsibility
- Implications for firms and regulators: principles can remove the 'prop' of detailed rules, though rules often remain
- Implications for regulators
 - Role for guidance and clarity from the regulator
 - Requirements to exercise judgements and make commitments
- Implications for firms
 - Requirements to exercise judgement and 'think through' the application of the regulatory requirements
- New 'regulatory bargain' but
 - Firms' requirements are contradictory – to have 'light touch' regulation but to know just what they have to do
 - Terms of the 'bargain' are endlessly contested as to what the balance of responsibilities should be between regulators and firms

Risks and PBR

- Risks for firms
 - ‘interpretive risk’ – that firms / centres don’t interpret the requirements in the same way as the regulator and will be subject to enforcement action as a result
- Risks to consumers / patients
 - ‘backsliding risk’ – that firms / centres will be allowed to ‘backslide’ on their regulatory responsibilities, and regulators won’t be kept in check by detailed rules

Addressing the risks

- Interpretive risk
 - Probability & impact analysis
 - Regulators can reduce the probability of interpretive risk by working with the regulated population and issuing guidance, but they cannot, and arguably should not, reduce it altogether
 - Regulators can address the impact of interpretive risk through their enforcement policy
 - ‘defences’ of due diligence by firms, reasonable endeavours
 - Graduated response to infractions, starting at the base of the enforcement pyramid

Addressing the risks continued

- Backsliding risk
 - Regulators can reduce the probability of backsliding risk by
 - Focusing on issues that pose a high risk to their objectives, such as patient safety, not on peripheral issues or ‘easy wins’
 - Building a culture of risk awareness and substantive compliance in firms
 - Regulators can reduce the impact of backsliding risk by
 - Giving additional supervisory attention to high impact areas
 - Developing policies for how to respond when risks crystallise
 - Having a clear enforcement policy that is not afraid to use sanctions where these are needed
 - Paying attention to compensatory or restorative policies if risk crystallises

Summary

- PBR in the rule books can be accompanied by a number of other changes in regulatory practices
- These changes can be far reaching for firms and regulators and take time to achieve
- Ultimately, the effectiveness of PBR depends on trust
- Paradox is that PBR can facilitate the development of mutual trust but cannot create it, yet trust needs to exist before PBR can work