

Better Regulation Delivery Office

Ethical Business Regulation: Understanding the Evidence

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In November 2015, the Better Regulation Delivery Office (BRDO) commissioned Professor Christopher Hodges to produce a brief introduction to the key concepts explored in his recently published book, 'Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Compliance and Ethics', which examines the theories and practice of how to control corporate behaviour through regulatory techniques, drawing on the principal theories of deterrence, economic rational acting, responsive regulation, and the findings of behavioural psychology.

The aim of this paper is to provide regulators and others with an interest in developments in regulatory delivery with an overview of the research theories and empirical evidence noted in the book, and of the author's proposition of a new theory of 'ethical regulation'.

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Executive summary

This report summarises the current evidence that supports how public regulators in a contemporary Western European democracy should seek to affect the market behaviour of traders. It draws especially on the findings of behavioural psychology, shared ethical values, and economic and cultural incentives. The basic idea is one of a collaborative approach between businesses, their stakeholders and public officials, based on a shared ethical approach. It recognises a series of points. First, that compliant behaviour cannot be guaranteed by regulation alone, and that ethical culture in business is an essential component that should be promoted and not undermined. Second, that regulatory and other systems need to be designed to provide evidence of business commitment to ethical behaviour, on which trust can be based. Third, that systemic learning has to be based on capture of information, and that maximising the reporting of problems requires a no blame culture. Fourth, that regulation will be most effective where it is based on the collaborative involvement of all parties. Fifth, that society needs to be protected from those who seek to break laws, and that people expect that wrongdoing deserves proportionate sanctions.

Wide powers and discretion: what should be used when?

Officials who are responsible for enforcing regulatory law now have a very considerable variety and range of enforcement measures in their toolbox (ranging from inspection to support and advice), backed by criminal, civil and reputational sanctions, and in some cases the ability to achieve redress. How should officers aim to use these powers?

This paper aims to summarise the fundamental basis on which an enforcement or regulatory officer should select particular powers from the toolbox, so as to achieve regulatory outcomes, recognising the importance of professional competence in exercising regulatory discretion. The UK is regarded as a world leader in innovative approaches to regulation.² Developing an effective general approach to 'enforcement' is regarded internationally as an area that is undeveloped but highly important.³ Empirical evidence from behavioural psychology and regulatory practice suggests the regulatory approach that is summarised here.

Fundamental values

The essence of a modern democracy is based on respect for others, expressed through support for fundamental human rights. Applying that political policy to a vibrant market economy produces the result that society supports mutual exchange through honest trade so as to improve the common good. Trade and harmonious society function on the basis of trust. So the purpose of regulation of business activity is to enable widespread trust in traders, on the basis of which a healthy, sustainable and growing economy can exist, which in turn supports employment, social stability and innovation.

Regulation evolved from a historical model in which a powerful individual 'commanded and controlled' the actions of his inferiors, exercising unfettered authority through enforcement by fear of imposing harsh punishments on those who did not obey, with or without justification. In contemporary society, that vertical authoritative model is replaced by a more horizontal model of mutual trust. Even if regulatory bodies hold significant power to enforce the law, they must act fairly, proportionately, following due process, and be accountable for their actions. Enforcement agencies may hold significant power and sometimes instigate major sanctions, but are subject to constraints. This paper aims to suggest how a 21st century public officer should approach 'enforcement', at least in the context of the regulatory structures that exist in the UK.

How people make decisions: fairness, proportionality, morality

Decisions are made by people rather than by organisations, although the structures, systems, objectives, culture and incentives that operate within organisations can affect the decisions made by the people who work in them. The focus of affecting compliance with laws should therefore be on affecting both the behaviour of individuals and the organisational environment.

Empirical research has found that people obey rules where:4

- a. the rule corresponds to their internal moral value system;
- b. the rule has been made fairly; and
- c. the rule is applied fairly.⁵

Individuals do not need to be familiar with every legal rule, but generally operate on a broad sense of justice. When faced with a particular situation, the individual may draw on examples of a social norm or custom as a means of guiding social compliance and normative orientation. So learning and remembering graphic situations will be a useful tool, as will reminders.

We now know a lot about how people make decisions, including why they may irrationally break rules, or make predictable mistakes. Human behaviour is strongly *responsive to social influences*: people want to conform to the perceived behaviour of other people, and that influence can overcome known facts or one's own ideological worldview. Such influence supports findings that motivating factors for directors to engage with health and safety requirements included fear of loss of reputation. People can be influenced by *how information is presented or 'framed'*, so that information that is vivid and salient can have a larger impact on behaviour than information that is statistical and abstract. People often display *loss aversion*: they may well dislike losses more than they like corresponding gains. People have *difficulties in assessing probability*: people often show unrealistic optimism, may neglect or disregard the issue of probability, especially when strong emotions are triggered, and when emotions are strongly felt, may focus on the outcome and not on the probability that it will occur. Judgments about probability are often affected by whether a recent event comes readily to mind. People's respect for all rules and for the system generally will be undermined where they see that rules are not being enforced evenly and fairly.

A substantial body of empirical research supports the 'soft enforcement' approach of supporting compliance, in areas such as in care homes for the elderly, ¹⁸ water pollution, ¹⁹ occupational health and safety, particularly on railways, ²⁰ environmental protection, ²¹ the mining industry, ²² manufacturing in Thailand, ²³ food businesses, ²⁴ the activities of a range of Australian agencies, ²⁵ Danish farming, ²⁶ and UK fish protection. ²⁷ There is little in this work that supports enforcement practices based on deterrence or a theory that people make decisions based on economic calculations – in most situations.

An inquiry by the UK National Audit Office found that UK businesses, in particular SMEs, often lack clarity about *how* to comply.²⁸ Research by different agencies found that SMEs believe that they are complying until a person they respect points out that they could improve, after which they usually follow the advice.²⁹ This evidence influenced official thinking that much behaviour is affected by information, advice, support, and reminders – consistent with psychological research.

Primary Authority builds on this by harnessing the relationships that organisations such as trade associations have with their members to identify current regulatory issues for those businesses and disseminate robust guidance to them, providing the regulator with an efficient means of supporting improvements in compliance. For example, the National Federation of Meat and Food Traders works in partnership with its primary authority, Horsham District Council, to get authoritative guidance to its membership of small, independent butchers.

The use of advice and persuasion as the first step for enforcement officers was set out in the Hampton Report of 2005. The first objective of the six Sentencing Principles set out by Richard Macrory is to aim 'to change the behaviour of the offender', and accompanied a similar broadening in the purposes of the criminal justice system. Similarly, the UK Government's statutory code of practice for regulators, the Regulators' Code, stresses the need for regulators to adopt a positive and proactive approach towards ensuring compliance, requiring that:

- regulators should carry out their activities in a way that supports those they regulate to comply and grow; and
- regulators should ensure clear information, guidance and advice is available to help those they regulate meet their responsibilities to comply.³⁴

As an example of this approach, the addition of 'enhanced consumer measures' to the toolbox of enforcement powers for consumer protection legislation in the Consumer Rights Act 2015 aims to empower enforcers to achieve fair outcomes through compliance, redress and choice.³⁵

Consequences of the findings of behavioural psychology

The findings of behavioural psychology noted above suggest the following conclusions in relation to regulatory action.

- 1) The regulatory system will be most effective in affecting the behaviour of individuals where it supports *ethical* and *fair* behaviour.
- 2) Businesses should demonstrate constant evidence of their commitment to fair and ethical behaviour that will support the *trust* of regulators and enforcers, as well as of all levels of management and employees, customers, suppliers, investors and other stakeholders.
- 3) A blame culture will inhibit learning and an ethical culture, so businesses and regulators should support an essentially *open* collaborative culture.
- 4) Regulatory systems need to be based on *collaboration* if they are to support an ethical regime, as well as maximising performance, compliance and innovation.
- 5) Where people break rules or behave immorally, people expect to see a *proportionate* response.

We will now examine how each of these five points can be realised in practice:

1. Supporting ethical and fair behaviour

If the regulatory *system* is to encourage and support ethical behaviour by traders, regulators/enforcers have a critical role to play. They should adopt the right incentives and actions that support, and do not hinder, efforts by individuals and businesses to behave ethically. For example, regulators should adopt published enforcement policies that recognise business commitment to an ethical approach. Imposing a punitive response to non-compliance that arises despite ethical behaviour would be counter-productive.

It will be important to influence both individual and group behaviour. The culture of an organisation is a vital component. Many reports following the financial services crisis in 2008 noted the inadequacy of responding by imposing a multitude of rules whilst ignoring the need to create and nurture an ethical culture within banks. Since then, however, the extensive imposition of new regulation has prompted a demand for increased certainty through *more* rules, reducing the ability of individuals on the front line to think for themselves and diminishing their power and responsibility of acting responsibly.

Studies into successful businesses have consistently pointed to their adoption of a culture based upon values in which everyone is aligned to focus on the achievement of desired outcomes – especially if the goals and means are ethical. Such a culture will generate ideas for improvement (innovation), in which complaints are treated as gifts, ³⁷ lessons are applied, and things put right when they have gone wrong.

2. Ethical business

How can businesses behave ethically? The requirement is for a business to adopt ethical business practices in everything that is done throughout the organisation. Codes on individual aspects, such as production, waste, marketing or social responsibility, are not enough: the approach has to be holistic. It has to be led from the top, but to exist at every level of the social groups within an organisation. Studies on the causes of sustained long-term business success have concluded that it is critical to establish clear *core values*, which are shared by *all* members of the workforce, form an ideology that is enduring and able to be applied consistently in different trading and geographical circumstances, whilst operational goals are constantly examined and developed.

It is essential to provide *evidence of trust* that an organisation operates with ethical values, to support independent judgment on whether an expectation of ethical behaviour is warranted. ⁴⁰ Mere claims by a company that it can be trusted will clearly not suffice. Mechanisms should be designed to produce reliable evidence of trust. This may include aspects such as: a deep and consistent adherence to ethical principles; a high proportion of satisfied customers; consistent application of compliance systems and audits; transparency; ethical governance structures; belonging to an external professional structure that has high ethical principles and provides ongoing training, help lines, auditing and sanctions; effective use of internal Ethics Ambassadors; ⁴¹ and structures enabling decisions to be debated to test ethical compliance, evaluated against external views, and made transparent. These sources of evidence will be mutually reinforcing, so as to provide density. ⁴²

3. An open culture

Transparency is one of the features of ethical environments. The regulatory systems in which learning and maintenance of performance is critically important – such as civil aviation, ⁴³ pharmacovigilance, and workplace health and safety – approach 'regulation' as a behavioural system to support people making the right decisions through constant learning.

The approach is based on the recognition that both human error and system error are unavoidable, ⁴⁴ and that multiple descriptions of events are plausible, so that finding truth in relation to making changes in how things are done requires multiple inputs. ⁴⁵ A critical issue is to identify *why* a hazard occurred, what factors (environmental, organisational, human, cultural, etc.) were potential causative factors, and how the risk of a similar event occurring again can be reduced. This recognises that no system will be able to prevent every adverse event from occurring. The focus should be on constant monitoring and learning from events so as to improve performance and reduce risk.

However, individuals will not volunteer information if they fear attracting criticism or blame. ⁴⁶ So it is essential – in the absence of obvious or serious wrongdoing – to encourage an 'open culture' of sharing and questioning, rather than a 'blame culture'. ⁴⁷ Such an approach could have been applied in financial services by triggering a review of simple questions such as 'Is this practice ethical?', 'Is this product in the best interests of the customer?', or 'Does this customer need this product?' It is an approach that could transform the NHS. If a no blame culture is to be successful, blame has to be removed from *all* of the relevant contexts within which people work: regulation (of entities, systems and professionals), employment, liability and social. Essentially, blame is replaced by a collaborative approach to problem-solving, rather than an adversarial relationship between individuals in the organisation as well as with regulators.

An approach based on learning and improvement supports a coordinated intra-company and external-regulatory response to problems that – instead of blaming – proceeds through the following steps: openly clarifying all the facts; full investigation to identify what went wrong and how to reduce the risk that any human in a similar situation would repeat the undesired behaviour; implementing such responsive measures by all relevant actors; redressing any harm caused; and imposing professional, employment and public sanctions that respond to the degree of moral fairness.

4. A collaborative regime

It is important that regulators and businesses *collaborate*, rather than having an adversarial and distanced relationship, and that such collaboration is transparent to outsiders, who can see that lessons are constantly being learned. Both systems for business management, compliance and risk, ⁴⁸ and for regulation, involve essential mechanisms based on circulation of information so as to monitor performance, identify risks and make improvements. Examples of regulatory information systems are the pharmacovigilance system for medicines, ⁴⁹ the RAPEX system for general product safety, ⁵⁰ the 'safeguard procedure' and post-marketing surveillance system for engineered products, ⁵² and the 'RIDDOR' legislation for workplace health and safety. ⁵³

The objective here should be to improve outputs through combining public and business regulatory systems in structured, supervised co-regulatory structures. Many examples of co-regulation already exist in the UK, such as in advertising, pharmaceutical promotion, financial lending, franchising, and the business codes of many sectors.⁵⁴

In respect of local authority regulation, Primary Authority embeds collaboration through individual agreements within which the separate and complementary efforts of business and regulator are recognised. Such co-regulatory structures can be developed to include commitment to ethical behaviour and mechanisms that generate the evidence to support a relationship of trust.

Agreements can include commitments by businesses or trade associations to share information and shoulder responsibility for significant elements of inspection and education, so that the regulator is better informed and may act in a supervisory or strategic oversight role, whilst still retaining the abilities to intervene and impose behavioural controls and sanctions if necessary. The existence and operation of the collaborative relationship must be fully transparent, allowing workers, customers, suppliers and others to see evidence of how the system operates, and monitoring the accurate and reliable performance of each task.

5. Fair and proportionate responses

An ethical and fair culture, whether within an organisation or in a regulatory enforcement regime, has to be seen to respond to problems and wrongdoing by distinguishing between people who are basically trying to do the right thing and those who are not – essentially an issue of motivation. It is important that enforcement responses should be *fair and proportionate*. Part of this is ensuring that the responsibility is attributed to the highest relevant level of management within an organisation, rather than the foot soldier who may be a victim of the system or of wilfully blind or 'immoral' management. This approach accords with the concept of 'responsive regulation'. Thus, if people engage in activity that is criminal, people expect to see the law upheld and for there to be a proportionate response. But where people have been trying to do the right thing, or have been generally, but not wilfully, ignorant about how to do things, adopting a punitive response would be seen as unfair, and hence would undermine general willingness to comply.

Successive UK governments have based their approaches to enforcement on the proposition that 'most people try to do the right thing most of the time', and that what is needed is to *support* good performance, innovation and economic growth through information, education advice, encouragement and appreciation.⁵⁵ In most situations, the focus needs to be on improving the behaviour of the people who may make mistakes, but also on the structures, systems, objectives, culture and incentives of traders' organisations that affect the actions and decisions made by the people who work in them.

That approach can be contrasted with an approach that is repressive, deterrent or heavy-handed. The latter approach is now rarely adopted by UK enforcement agencies, at least for businesses that are basically 'trying to do the right thing'. The idea that a person will obey the law because of fear that a breach will be punished, so it is better to conform than suffer, has been shown to be effective only where individuals *perceive* there to be a high risk of identification, from which they will suffer embarrassment and loss of reputational esteem. (In addition, we know from the research mentioned earlier that individuals are not skilled at assessing risk.) Achieving that *perception* on a widespread basis may be prohibitively expensive. Ruling by fear in a modern democracy is an unattractive and arguably unconstitutional policy. Further, behavioural psychology does not support the idea that future compliance (deterrence) is increased by imposing a stronger penalty.

Conclusions

The evidence outlined above suggests the following conclusions:

1. Regulation is often about affecting behaviour

In order to be effective regulation should be viewed as producing desirable *behaviour* by the people involved. The norms of the working groups should be aligned with those of the wider society in which they operate. In a democratic society, this means they should be ethical. Where such values are shared and are ethical, compliance and performance will be maximised. The same conditions should support commercial success through demonstrating a reputation for ethical practice that can be trusted.

2. Ethical culture and collaboration

Businesses should be encouraged to adopt ethical practice throughout their organisations and activities. Regulatory systems and actions should support and incentivise this. Collaborative agreements such as the Primary Authority model could include requirements that support business ethics.

Supporting ethical commercial behaviour requires leadership and support from all stakeholders, including staff, customers, suppliers, investors, competitors and commentators – and regulators, politicians and the media. There should be a culture not just of achieving the relevant regulatory and behavioural standards but also of continuous learning and improvement. The culture should involve accountability to share all relevant information on a no-blame basis, so that the data on which performance, improvement and innovation can be based will be maximised. If a no-blame culture is to be effective, it must exist across all relevant aspects, including employment relationships, systemic regulation, professional regulation, and business units.

The culture should be based on regular questioning and evaluation of whether decisions and actions are in fact 'doing the right thing'. This will involve structures and behaviours, which enable transparent and verifiable certainty, internally and externally. What is ethical should be subject to debate, and updated as opinions change.

3. Response to adverse events

In most cases, where people are acting in good faith, the appropriate response to adverse events is to support them to analyse and learn rather than to blame. Failures should be noted and acknowledged, rather than ignored, and an appropriate response made.

Where actions are immoral, or accountability as described above has not been observed, a proportionate response should be made. Enforcement policies should generally avoid the concept of deterrence, since it has limited effect on behaviour, conflicts with a learning-based performance culture, and is undemocratic.

Where sanctions are imposed, the totality of the sanctions should be proportionate to the degree of moral culpability involved. That requires an equalisation as between all of the various factors: social response, reputational and public response, employment discipline response, civil redress response, and regulatory or criminal response.

4. Better regulation impact

Adoption of a robust and evidenced ethical business regulatory system would enable the regulatory architecture to be rationalised to consist of:

- a. high level general principles, such as to trade fairly, respect human rights;
- b. providing detail at a lower tier, in guidance at sectoral (trade association), internal (group or corporate), or area (Chambers of Commerce for SMEs) levels.

End notes

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Better Regulation in Europe: United Kingdom (OECD, 2010); OECD Regulatory Policy Outlook 2015 (OECD, 2015).

Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections (OECD, May 2014).

⁴ L Friedman, *The Legal System: A Social Science Perspective* (Russell Sage Foundation, 1975), 105-13; RA Kagan, N Gunningham and D Thornton, 'Fear, duty, and regulatory compliance: lessons from three research projects' in C Parker and VL Nielsen (eds), *Explaining Compliance: Business Responses to Regulation* (Edward Elgar, 2012).

J Darley, TR Tyler and K Bilz, 'Enacting justice: the interplay of individual and institutional perspectives,' in M Hogg and J Cooper (eds), The SAGE Handbook of Social Psychology (Sage, 2003); TR Tyler, Why People Obey the Law (Yale University Press, 2006); TR Tyler and SL Blader, Cooperation in Groups: Procedural Justice, Social Identity, and Behavioral Engagement (Psychology Press, 2000).

A Bandura, Social Foundations of Thought and Action: A Social Cognitive Theory (Prentice-Hall, 1986), 103; JR Anderson, Learning and Memory: An Integrated Approach (Wiley, 2000), 348.

C Engel, 'Learning the Law' (2008) 4(3) Journal of Institutional Economics 275; FC Bartlett, Remembering: A Study in Experimental and Social Psychology (Cambridge University Press, 1932), 204, 206; JR Anderson, Learning and Memory: An Integrated Approach (Wiley, 2000), 285.

See generally T Gilovich, D Griffin, and D Kahneman (eds), Heuristics and Biases: The Psychology of Intuitive Judgment (Cambridge University Press, 2002); D Kahneman and A Tversky (eds), Choices, Values,

and Frames (Cambridge University Press, 2000).

See e.g. D Hirshleifer, 'The Blind Leading the Blind: Social Influence, Fads, and Informational Cascades', in M Tommasi and K Ierulli, (eds), *The New Economics of Human Behavior* (Cambridge University Press, 1995), 188, 189; E Duflo and E Saez, 'The Role of Information and Social Interactions in Retirement Plan Decisions: Evidence from a Randomized Experiment' (2003) 118 *Quarterly Journal of Economics* 815, 839; H Allcott, 'Social Norms and Energy Conservation' (MIT Center for Energy and Environmental Policy Research Working Paper No 09-014, Oct 2009); SE Carrell, M Hoekstra, and JE West, *Is Poor Fitness Contagious? Evidence from Randomly Assigned Friends* (NBER Working Paper No 16518, Nov 2010); AV Banerjee and E Duflo, *Poor Economics: A Radical Rethinking of the Way to Fight Poverty* (Public Affairs, 2011) 267-268.

SE Asch, 'Effects of Group Pressure Upon the Modification and Distortion of Judgments' in H Guetzkow (ed), Groups, Leadership and Men (1951) 177, 186; GL Cohen,' Party Over Policy: The Dominating Impact of

Group Influence on Political Beliefs' (2003) 85 Journal of Personal & Social Psychology 808, 819.

M Miller, Director Leadership of Health and Safety (Health & Safety Laboratory, 2005), iv.

See RH Thaler, D Kahneman, and JL Knetsch, 'Experimental Tests of the Endowment Effect and the Coase Theorem', in RH Thaler, *Quasi Rational Economics* (Russell Sage, 1991), 167, 169; AP McGraw, et al, 'Comparing Gains and Losses' (2010) 21 *Psychological Science* 1438, 1444; D Card and GB Dahl, 'Family Violence and Football: The Effect of Unexpected Emotional Cues on Violent Behavior' (2011) 126 *Quarterly Journal of Economics* 103, 105–06, 130–35.

See C Jolls, 'Behavioral Economics Analysis of Redistributive Legal Rules' (1998) 51 Vanderbilt Law Review 1653, 1659. See generally T Sharot, The Optimism Bias: A Tour of the Irrationally Positive Brain (Knopf,

2011).

See GF Loewenstein, et al, 'Risk as Feelings', (2001) 127 Psychology Bulletin 267, 280.

See Y Rottenstreich and CK Hsee, 'Money, Kisses, and Electric Shocks: On the Affective Psychology of Risk' (2001) 12 Psychological Science 185.

See A Tversky and D Kahneman, 'Availability: A Heuristic for Judging Frequency and Probability' (1973) 5

Cog Psych 207, 221.

- TR Tyler and HJ Smith, 'Social Justice and Social Movements' Chap. 101, in DT Gilbert, ST Fiske and G Lindzey (eds), *The Handbook of Social Psychology*, 4th Edition. Vol. II, 595-629 (New York, NY: Oxford University Press, 1998); TR Tyler and P Degoey, 'Trust in Organizational Authorities: The Influence of Motive Attributions on Willingness to Accept Decisions' in RM Kramer and TR Tyler (eds), *Trust in Organizational Authorities*, 331 (Thousand Oaks, CA: Sage Publications Inc., 1996); K Murphy, "Trust Me, I'm the Taxman": The Role of Trust in Nurturing Compliance' (2002) *Centre for Tax System Integrity Working Paper no. 43* 1-31.
- See I Ayres and J Braithwaite, Responsive Regulation: Transcending the Deregulation Debate (Oxford University Press, 1992).

K Hawkins, Environment and Enforcement: Regulation and the Social Definition of Pollution (Clarendon Press, 1984); K Hawkins, Law as Last Resort (Oxford University Press, 20902).

H Genn, 'Business responses to the regulation of health and safety in England' (1993) 15 Law and Policy 219; BM Hutter, Compliance: Regulation and Environment (Clarendon Press, 1997); BM Hutter, Regulation and Risk: Occupational Health and Safety on the Railways (Oxford University Press, 2001).

MA PhD FSALS. Professor of Justice Systems, and Supernumerary Fellow of Wolfson College, University of Oxford. Head of the Swiss Re/CMS Research Programme on Civil Justice Systems, Centre for Socio-Legal Studies, Oxford. Honorary Professor 2013-2016, the China University of Political Science and Law, Beijing. Research funding is received from the Swiss Reinsurance Company Limited, the European Justice Forum and international law firm CMS.

- P Grabosky, 'Beyond the Regulatory State' (1994) 27(2) Australian and New Zealand J of Criminology 192; P Grabosky, 'Green Markets: Environmental Regulation by the Private Sector' (1994) 16(4) Law and Policy 419-48; N Gunningham and P Grabosky, Smart Regulation. Designing Environmental Policy (Oxford University Press, 1998).
- ²² F Haines, Corporate Regulation: Beyond 'Punish or Persuade' (Clarendon Press, 1997).
- F Haines, 'Regulatory Reform in Light of Regulatory Character: Assessing Industrial Safety Change in the Aftermath of the Kader Toy Factory Fire in Bangkok, Thailand' (2003) 12 Social and Legal Studies 461.
- BM Hutter and C Jones, 'From government to governance: external influences on business risk management' (2007) 1 Regulation & Governance 27.
- J Braithwaite and P Grabosky, Of Manners Gentle: Enforcement Strategies of Australian Business Regulatory Agencies (Oxford University Press, 1987).
- PJ May and S Winter, 'Regulatory Enforcement and Compliance: Examining Danish Agro-Environmental Policy' (1999) 18(4) *Journal of Policy Analysis and Management* 625.
- J Black and R Baldwin, 'Really Responsive Regulation' (2008) 71(1) Modern Law Review 59.
- Delivering regulatory reform. Report by the Comptroller and Auditor General (National Audit Office, 2011).
- R Fairman and C Yapp, Making an impact on SME compliance behaviour: An evaluation of the effect of interventions upon compliance with health and safety legislation in small and medium sized enterprises (Health and Safety Executive, 2005), Research Report 366; The Anderson Review of Government Guidance on Regulation. Business Perspectives of Government Guidance. Research Study Conducted for Department for Business, Enterprise and Regulatory Reform. Final Report (Ipsos MORI, 2008); The Anderson Review. Summary of views from meetings with small and medium sized enterprises (SMEs) (Department for Business, Enterprise and Regulatory Reform, 2009); How Your Business Can Achieve Compliance: Guidance (Office of Fair Trading, 2010) OFT1278.
- P Hampton, Reducing administrative burdens: effective inspection and enforcement (HM Treasury, 2005).
- R Macrory, Regulatory Justice: making sanctions effective (HM Treasury, 2006). Implementation was in the Regulatory Enforcement and Sanctions Act 2008..
- 32 Criminal Justice Act 2003, s 142.
- Regulators' Code, (Department for Business Innovation and Skills, Better Regulation Delivery Office, 2014), made under the Legislative and Regulatory Reform Act 2006, s 22(1).
- Regulators' Code, provisions 1 and 5.
- Enterprise Act 2008, s 219A, inserted by the Consumer Rights Act 2015, Sch 7, art 8.
- Toward Effective Governance of Financial Institutions (Group of 30, 2012); Investing in Integrity. The Lord Mayor's Conference on Trust and Values (City Values Forum, 2012); A New Paradigm. Financial Institution Boards and Supervisors (Group of 30, 2013); The FCA's approach to advancing its objectives (FCA, 2013); The Salz Review of Barclays' Business Practices report to the Board of Barclays PLC. (2013), para 2.4; A report on the culture of British retail banking (New City Agenda and Cass Business School, 2014).
- K Evans, "Using the Gift of Complaints": A Review of Concerns (Complaints) Handling in NHS Wales (Welsh Government, 2014).
- 38 C Hodges, Law and Corporate Behaviour: Integrating Theories of Regulation and Enforcement (Hart Publishing, 2015).
- J Collins and JI Porras, *Built to Last: Successful Habits of Visionary Companies* (12th ed, HarperCollins, 2005); R Barrett, *The Values-Driven Organization* (Routledge, 2014).
- O O'Neill, 'Trust, Trustworthiness, and Accountability' in N Morris and D Vines (eds), Capital Failure; Rebuilding Trust in Financial Services (Oxford University Press, 2014), 178; TM Jones, 'Ethical Decision Making by Individuals in Organizations: An Issue-Contingent Model' (1991) 16(2) Academy of Management Review 366.
- ⁴¹ R Steinholtz, 'Ethics Ambassadors: Getting under the skin of the business' (2014) *Business Compliance* 16.
- ⁴² CA Heimer, 'Explaining variation in the impact of law: organizations, institutions, and professions' (1996) 15 *Studies in Law, Politics and Society* 29, 37.
- The transformation to performance-based regulation (Civil Aviation Authority, 2014), 1.
- D McCune, C Lewis and D Arendt, 'Safety Culture in Your Safety Management System' in AJ Stolzer, CD Halford and JJ Goglia (eds), *Implementing Safety Management Systems in Aviation* (Ashgate, 2011), 138.
- S Dekker, Just Culture. Balancing Safety and Accountability (Ashgate Publishing, 2007), ix.
- ⁴⁶ Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid (Royal College of Surgeons of London, 2014).
- Regulation (EU) No 996/2010. See RL Helmreich, 'Building safety on the three cultures of aviation' in Proceedings if the IATA Human Factors Seminar (Bankkok, 1999), 39; D McCune, C Lewis and D Arendt, 'Safety Culture in Your Safety Management System' in AJ Stolzer, CD Halford and JJ Goglia (eds), Implementing Safety Management Systems in Aviation (Ashgate, 2011).
- BJ Schoordijk, 'Risk management alshoeksteen van corporate governance' in SHA Dumoulinea (ed), *Tussen Themis en Mercurius*, BedrijfsjuridischebijdragenaaneenEuropesebeleidsconcurrentie, Lustrumuitgave-NederlandsGenootschap van Bedrijfsjuristen (Kluwer, 2005), 309-329; DAMHW Strik, 'Deel II Aansprakelijkheidvoorfalendrisicomanagement', in *Ondernemingsbestuur en risicobeheersing op de drempel van eennieuw decennium: eenondernemingsrechtelijkeanalyse*, Preadvies van de Vereeniging 'Handelsrecht' 2009 (Kluwer, 2009); J Eijsbouts, *Corporate responsibility, beyond voluntarism. Regulatory options to reinforce the licence to operate* (Inaugural lecture, Maastricht University, 2011).

- Directive 2001/83/EC on the Community code relating to medicinal products for human use. Extensive guidelines see are at Volume 9A of the Rules Governing Medicinal Products in the European Union: Guidelines on Pharmacovigilance for Medicinal Products for Human Use, which includes guidelines for competent authorities and the EMEA at Part II.
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.
- Decision No 768/2008/EC, Annex I, art R32.
- Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, COM(2013) 77, 13.2.2013, para 2.3.
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013, SI 2013/1471.
- The Advertising Standards Authority and its Advertising Codes; Code of Practice for the Pharmaceutical Industry; the Lending Standards Board; the Lending Standards Board; Consumer Codes Approval Scheme: Core Criteria and Guidance, at http://www.tradingstandards.gov.uk/advice/ConsumerCodes.cfm.
- A Fair Deal for All. Extending Competitive Markets: Empowered Consumers, Successful Business (Department for Trade and Industry, 2005); How Your Business Can Achieve Compliance. Guidance (Office of Fair Trading, 2010), OFT1278, October 2010; Statement of consumer protection enforcement principles (Office of Fair Trading, 2010), OFT1221, revised 2012; A better deal: boosting competition to bring down bills for families and firms (HM Treasury, December 2015), Cm 9164.

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