



Risk Regulation and Compliance: Food Safety in the UK

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Table of Contents

List of Abbreviations 3
Introduction..... 4
Regulating Food Safety in the UK in 21st Century 4
Principles and Philosophies of Risk Regulation 6
Responses to state regulation: issues of compliance..... 7
Risk based approaches to regulation 9
The regulatory practices of 'state' regulators..... 11
Risk regulation and food: regulation beyond the state 14
Discussion 15
Bibliography..... 17
Notes 23

List of Abbreviations

BERR	Department for Business, Enterprise and Regulatory Reform
BRE	Better Regulation Executive
BRTF	Better Regulation Task Force
EHOs	Environmental Health Officers
FBOs	Food Business operators
FSA	Food Standards Agency
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis and Critical Control Point
IGD	Institute of Grocery Distribution
MHS	Meat Hygiene Service
NAO	National Audit Office
RBR	Risk-based regulation
SMEs	Micro, small and medium-sized enterprises
TSOs	Trading Standards Officers
UWIC	University of Wales Institute, Cardiff

Introduction

1. This paper was produced at the request of the Public Inquiry into the outbreak of E. coli O157 that occurred in South Wales in September 2005. Its purpose is to set out the key principles of food hygiene regulation in the UK and to consider issues of enforcement and compliance. We will highlight some of the main tensions running through risk regulation in this area and particular note will be made of how these issues relate to small businesses.

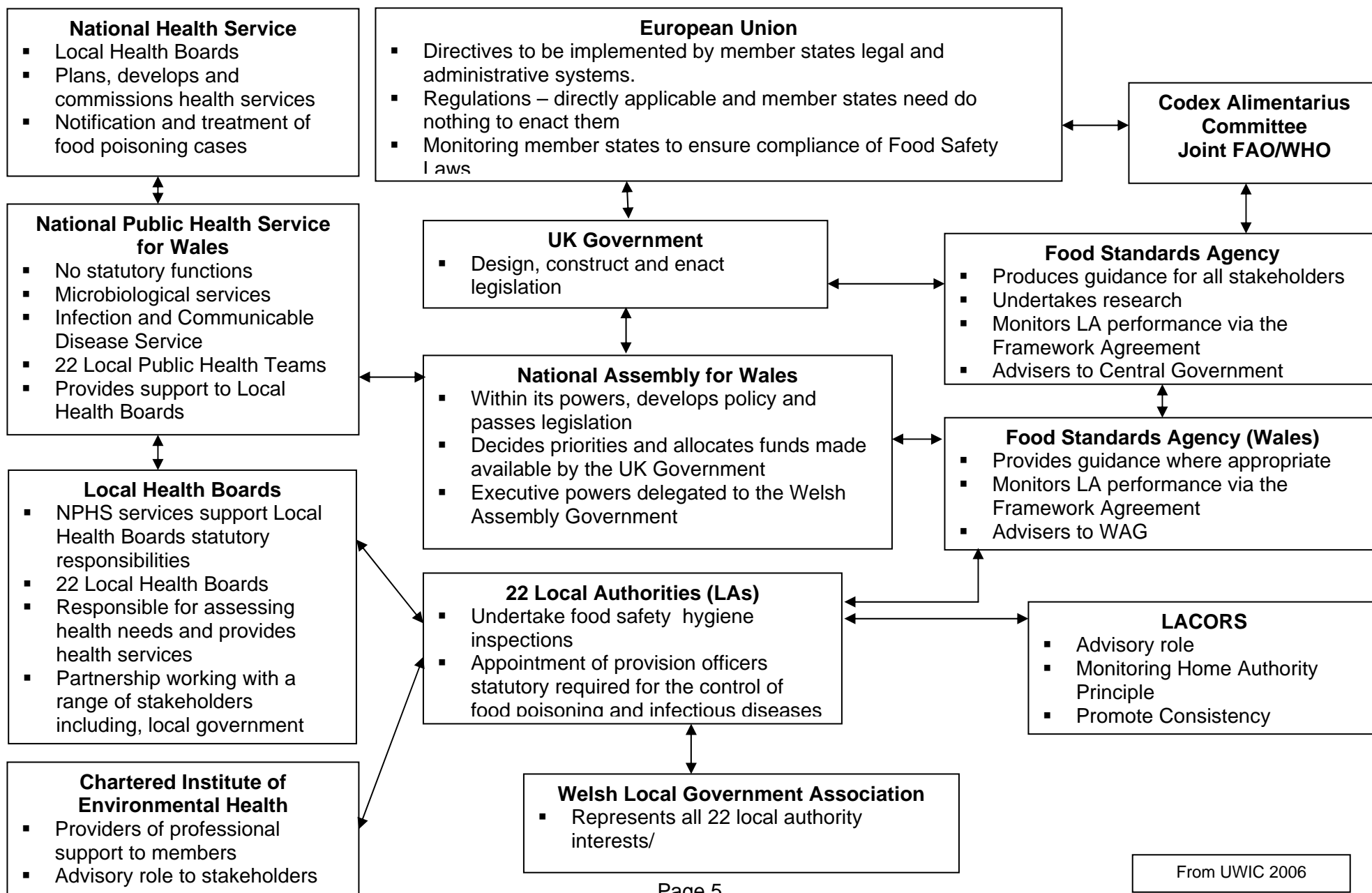
Regulating Food Safety in the UK in 21st Century

2. The UK's regulatory structure for food safety risks was the subject of a number of key reforms in 2002. These prompted major institutional change in central government arrangements for food safety and food hygiene but left the institutional arrangements for local enforcement largely untouched.ⁱ It is not our purpose to explain these changes in any detail, rather to set out some basic background information about the legal and institutional frameworks in existence in 2005 at the time of the E. coli O157 infection in South Wales.ⁱⁱ

3. Food safety laws centre on protecting the consumer by ensuring that food is safe for human consumption. Many of the provisions spotlight prevention rather than cure. Food business operators (FBOs) must show that they have adopted hygienic practices on premisesⁱⁱⁱ suitable for the purpose.^{iv} The risks associated with food processing and preparation have to be assessed by FBOs, industry and the enforcers of food laws. Standards of protection are achieved through the enforcement of specific provisions (with breach resulting in criminal sanction^v) and through a framework that seeks to minimize the risk of unsafe food being present in the market from 'farm to fork', i.e. from the production process through the retail and hospitality sectors to the point of consumption.^{vi} The law and its enforcement are governed by European and domestic law.^{vii} In each case food law protection is based upon principles of risk management (see below). Many of the provisions comprise broad principles which are then carried forward in more detailed terms by secondary legislation in domestic law, or clarified by Codes of Practice.^{viii} The process may change the fundamental principles upon which national legislation is based or amend those provisions relating to enforcement.

4. The diagram below (from UWIC, 2006) illustrates the organisations involved in food regulation in Wales in 2005.^{ix} Here, as in the rest of the UK, food hygiene law and its enforcement are carried out by a number of actors operating at local, national and European levels. Some such as Ministers and central governmental officials formulate policy and tend not to be specialists in food safety protection. Others such as the Food Standards Agency (FSA) and the Food Standards Agency Wales are independent Government Departments with specialist knowledge of the domain. These Agencies formulate policy and good practice whilst overseeing and directing (often remotely) the enforcement activity of local actors more directly responsible for legal enforcement on the ground.^x The devolved governments are competent to make food hygiene laws and issue Codes of Practice having regard to the advice of the FSA.^{xi} The Meat Hygiene Service, an executive agency of the FSA, is the independent enforcement agency responsible for carrying out statutory inspections of licensed premises (including slaughterhouses, cutting plants and cold stores) in the UK producing meat for sale for human consumption and for auditing hygiene standards. Its purpose is to protect public health and animal welfare at slaughter through its inspection activities.^{xii}

Figure 2.1 Overview of organisations involved in food law enforcement and/or outbreak control in Wales, September 2005



5. Local authorities perform a key role in enforcing food safety laws through the functions carried out by Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs). Typically food safety is the responsibility of EHOs and food standards the responsibility of TSOs.^{xiii} EHOs monitor compliance with the minimum standards required by EU and UK government legislation; promote guidance and best practice on higher standards; and they may take enforcement action against businesses which are non-compliant with the legal requirements. Unlike the Meat Hygiene Service, local authorities undertake generic enforcement activities and TSOs and EHOs often carry out a range of functions not limited specifically to food safety enforcement.

Principles and Philosophies of Risk Regulation

6. There have been a number of broad regulatory trends and debates in the past decade which have influenced the regulation of food safety. We will consider two areas, first the move to emphasize the responsibilities held by businesses and second the rise of risk-based approaches to regulation, particularly as embraced by the Hampton Report (2005).

7. The degree to which risk management is recognized as the responsibility of business varies. Systems of pure self-regulation rely on businesses and/or industry associations to regulate risks themselves. In traditional command and control regulatory systems, standards and targets are set by the state and the responsibilities of business were often overlooked as it was assumed that it was the job of the regulator to ensure risk management standards. In recent years there has been a move to emphasize the responsibility of business and simultaneously give it more leeway to determine how to manage risks itself. We will focus on the example of risk regulation that has grown in popularity, including the food sector in the UK, namely enforced self-regulation.

8. Enforced self-regulation is a mix of state and business regulatory efforts. The government lays down broad standards which companies must then satisfy. Businesses are expected to develop risk management systems and rules to secure, monitor and review compliance. Where this is not being achieved, companies are expected to have procedures in place to deal with non-compliance. Regulators play a meta regulatory role as they oversee businesses' efforts to self-regulate and can impose public sanctions for non-compliance.^{xiv}

9. These ideas were first prominent in the Robens Report (1972 Cmnd. 5034) and the subsequent Health and Safety at Work etc Act, 1974 which places primary responsibility for regulation with business; regards regulation as the everyday concern of everyone at work; attempts to constitute structures, routines and procedures for regulation which will be incorporated into organizational routines and become part of everyday individual activity; and where this fails the law can intervene through more overt forms of control, notably external regulation and sanctions. Businesses are effectively required to make risk management a constitutive part of their everyday operations and life. But it is an effort which is undertaken in the shadow of the law.

10. The advantages of enforced self-regulation are that it is seen to maximise the advantages, and avoid the major pitfalls, of pure state regulation and of pure self-regulation. So, regulation is not left entirely to the willingness of companies to regulate nor is it heavily dependent upon state systems of control. It builds on business

regulatory capacity and affords companies the flexibility to devise systems and rules which meet the broad standards but which are adapted to their particular circumstances and the risks associated with their particular workplace. Meanwhile, the efforts of state regulators are directed to those companies which are either unable or unwilling to effectively self-regulate. Another advantage of this system is said to be that businesses will be more committed to rules and systems which they have devised themselves, indeed this could lead to innovation in techniques and systems of risk management and regulation. Moreover, enforced self-regulation is seen to have major financial benefits, notably for the state by reducing the costs associated with drafting highly specific regulations and enabling the targeting of enforcement efforts. This model subcontracts regulatory functions to private actors.

11. There are also disadvantages. For example, enforced self-regulation is very dependent upon the regulatory capacity of the business. Generally it is most suited to large, well-informed and well-resourced companies and crucially it is also reliant on the readiness of companies to self-regulate. It depends also upon a balance being established and maintained between too much and too little state oversight of corporate self-regulation. If state agencies exercise too much oversight then the ambition of companies taking regulatory responsibility may be lost. Too little oversight may result in poor levels of compliance and lower standards of risk management than are either required or desirable. From a business perspective another possible limitation of this approach is that it moves the costs of regulation more firmly onto business. The success of the enforced self-regulation model very much pivots around the commitment and capacity of companies to self-regulate and the ability of the state agency to find and maintain an optimal monitoring and oversight role.

Responses to state regulation: issues of compliance

12. Socio-legal scholars have identified a number of reasons why businesses may not comply with the law. Motivations for compliance with regulation on the part of business may be many and complex (Gunningham et al., 2003). Only some forms of non-compliance can be seen as the product of a rational calculation that it is more profitable not to comply than to do so, on the part of the business concerned (Kagan and Scholz, 1984). However, where business is more able to pass on the costs of regulation, the greater the likelihood of compliance (Kagan and Scholz, 1984).

13. There is considerable research showing how the moral stance of organizations can lead to an institutionalization of certain practices and ways of seeing laws and regulations. Organizational myths, rules and models can impact heavily on the way enterprises and industry behave (Meyer and Rowan, 1977; Powell and DiMaggio, 1983 and 1991). This may lead to compliant behaviour because it is seen as the 'right thing to do' or because the regulations fit with their own reading of the law. Those being regulated may not see necessarily that there is anything wrong (morally or otherwise) in the way that they operate despite the fact that they are not complying with the law (Baldwin, 1995). They may misunderstand or be misguided in their understanding of their legal duties (Hutter, 2001). Businesses may resort to opportunistic conduct and react negatively to control where the regulations are perceived as illogical or wrong (Kagan, 1994). The more loosely worded the regulations, the more scope those being regulated may have to interpret the law according to their own advantage. In the case of the enforcement of food hygiene, systems may be effective only when a full commitment

from management and workforce exists (Jones et al., 2008). Academic studies show smaller businesses can experience particular difficulties complying with their legal obligations. They may not have sufficient resources (financial or technical) to understand what the law requires of them (Grabosky and Braithwaite; 1986; Hutter and Jones, 2006). The food hygiene domain is no different (Fairman and Yapp, 2005; see also Fielding, Ellis et al., 2005).

14. Business attitudes towards regulation matter when assessing compliance responses. For example, the culture of the workplace has been identified as important. Non-compliance may be associated with a negative culture where compliance is not encouraged and where there may be peer pressure not to comply (Sigler and Murphy, 1988; Hutter, 2001). A positive workplace culture can encourage compliance and lead to intra-organizational pressures to comply (Bardach and Kagan, 1982). There may be a variety of pressures upon employees and it may be that non-compliance results where other more highly prized business objectives take first place, for example, 'getting the job finished as quickly as possible' (Dawson et al., 1988; Hutter, 2001).

15. Where the regulations are vague or uncertain, business may find it difficult to comply (Genn, 1993). This is particularly true for small business. Fairman and Yapp (2004, 2005) noted that for small firms themselves, compliance equated to "doing all they were told to at an inspection, or advisory visit or other intervention"; adherence to the law itself had little relevance. In the food hygiene, context the clarity of regulation has been found to be important with businesses often being ignorant of the risks associated with their activities (Worsfold, 2001) as well as the effects of non-compliance in enforcement terms. In the construction context small operators have been found to prefer directive 'command and control' regulation (Loosemore and Adonakis, 2007). The existence of competitive markets and tight profit margins can influence business compliance rates. This may make business less willing to self-regulate, relying instead upon more formal enforcement strategies. Compliance can be shaped by the contractual (or other) obligations imposed throughout the supply chain (Mohtadi et al., 2005; Balsevich et al., 2003). Large companies are particularly well placed in the food industry to exert pressure on smaller enterprise so as to enhance compliance rates (Fulponi, 2006). The importance of being able to exert pressure throughout the food chain should not be underestimated. This is consistent with the 'farm to fork' approach promoted by the FSA.^{xv} Large food distributors (and in some cases end users) are well-placed to develop and secure quality assurance programmes which will apply to smaller producers and intermediaries within the food chain who may be less aware of the inherent risks of their current business practices (Garcia Martinez, et al., 2007; Havinga, 2006).

16. It is known that reputational issues and consumer preferences can shape compliance by business. For larger firms reputation issues can have both positive and negative effects (Gunningham et al., 2005). Concerns about the loss of reputation for firms already in compliance may be a strong driver for future compliant behaviour. Whilst the size of the sanction or penalty for non-compliance is known to have limited impact upon compliance rates (Scholz and Gray, 1990), formal sanctioning can play a role as a general reminder to particular firms and prevent declining industry standards overall. Where business reputations are at stake, the use of informal sanctioning (including embarrassment, fear and shame (Parker, 2002) can be strong motivators for compliance. Similarly consumer and media influence can shape compliance behaviour (Hutter and Jones, 2007). In the context of meat hygiene, studies appear to show that

both economic drivers and long established perceptions of acceptable practices shape compliance rates (Clayton, 2002; Jones et al., 2008).

17. There is therefore a complex of explanations for business compliance and non-compliance and crucial to understanding the issue of compliance is the fact that it is a dynamic, ever present issue. In the case of food safety this may demand constant vigilance by all levels of staff, some of whom may not fully understand the risks involved and all of whom may, on occasions, be subject to production pressures which lead them to cut corners and take risks.

Risk based approaches to regulation

18. Food safety regulation is one domain that has witnessed the increasing alignment of risk and regulation, one manifestation of which is risk-based regulation (RBR) (Black, 2005; Hutter, 2004). The term RBR embraces a very broad range of approaches but it is possible to delineate some basic characteristics. For example, in risk-based regimes risks are typically conceived as manageable and controllable (Bernstein, 1996) and this leads to an anticipatory approach which looks forward to consider the prevention of risks not yet fully realized. This approach is premised on a holistic, co-ordinated approach to risk management which conceptualises risks as interrelated to each other and as having potential consequences for broader economic, natural, social and political environments. The complexities involved may well lead to an emphasis upon output based as opposed to prescriptive regulation. This is translated into practice through a greater emphasis upon technical risk-based tools, emerging out of economics (cost-benefit approaches), and science (risk assessment techniques).

19. Risk-based approaches are attractive to policy makers for a number of reasons. Risk-based tools have come to be seen as efficient instruments for making policy choices and aiding in decision-making (National Audit Office, 2000: 40), and they are regarded as particularly helpful in resolving conflict between competing interests and groups over appropriate levels of risk management. Moreover, their apparent objectivity and transparency may justify the allocation of resources in a way which is well tested and trusted by the business community.

20. There are however some problems with the approach. Risk-assessment tends to involve a simplification of problems, often through quantification, which typically disguises the full complexity of risks (Cohen, 1996; Toft, 1996). Bias in quantification and in the use of information may be concealed by an appearance of objectivity. Determining acceptable costs has long been a subject of contention: indirect costs and benefits are rarely considered and the figures often look different from different perspectives (Ackerman and Heinzerling, 2004; Sunstein, 2004). Even if the causes and costs of risk are clear, *acceptable* risk must still be defined, and that is essentially a political decision (Douglas, 1992). There are also resource issues. Not all regulators have the resources to adopt RBR, the evidential demands of which can be considerable. Information is crucial and the approach depends on what sort of information is available to regulators, the quality of this information, the regulatory burdens of collecting it, and who uses the information and how (Lloyd-Bostock and Hutter, 2008).

21. In food hygiene contexts risk rating systems are an important tool for enforcers to apply when deciding upon their inspection regimes. They may however rely upon

intuition or 'feel' in circumstances which instead require objective standards to be applied. Studies suggest that risk assessment methods adopted by EHOs may be ineffective when deciding which business to inspect for this reason (Jones et al., 2008) and that inspections alone may not be sufficiently protective against food poisoning outbreaks (Mullen et al., 2002; Tebbutt, 2007).

22. A key example of enforced self-regulation and risk based approaches coming together in food regulation is the growing popularity of the food safety Hazard Analysis and Critical Control Point (HACCP) (Coglianese and Lazer, 2003). HACCP is a preventative risk based approach to food safety which seeks to minimize risks but cannot eliminate them.^{xvi} The HACCP approach requires that FBOs plan what needs to be done to maintain food safety, to write this down, to follow the plan and to monitor and verify that the plan has been followed. HACCP systems are only protective to the extent that the workforce and management are fully committed to their implementation (Elson, et al., 2004; Fielding et al., 2005; Jones et al., 2008). Adequate training is of fundamental importance for effective HACCP programmes (Little, Lock, et al., 2003; Clayton et al., 2002). The rigors of the regime can present particular difficulties for meat premises (Worsfold, 2001) and for small businesses (Fielding, et al., 2005; Worsfold, 2005). Studies have shown that historically the practices adopted by meat businesses have increased the possibility of food contamination (Worsfold, 2001). Further, training may in some circumstances improve hygiene practices but the limited resources (economic and otherwise) available to smaller enterprises can be a real constraint on providing this (Worsfold, 2005).

23. Risk based approaches to food safety regulation seek to ensure that greater emphasis is placed upon FBOs managing their own risks, and in so doing reserve enforcement agency attention for the worst offenders.^{xvii} This approach makes assumptions about the capacity of business to appreciate and manage attendant risks, which can be lacking in the case of smaller businesses. Using HACCP systems can lead to gaps in the detection of non-compliance with potentially adverse consequences. Food hygiene enforcers may need to rely upon highly technical microbiological assistance to detect and remedy instances of breach.^{xviii} HACCP strategies can give a role to many actors (including producers, suppliers etc.) who may or may not be a party to legal proceedings and have conflicting reasons for acting in the way they do.

24. The whole RBR approach resonates with moves to minimize the so-called regulatory burden on business through cost justifications, and with the UK Government's 'better regulation' agenda, exemplified in the Better Regulation Task Force's *Principles of Good Regulation* (2000), namely transparency, accountability, targeting, consistency and proportionality: all regulators in the UK are subject to these so-called deregulatory moves. The importance of RBR was underlined in the UK by the Hampton Inquiry (2005) whose objective was to reduce the administrative burden of regulation on business and to promote more efficient approaches to regulatory inspection and enforcement. The review recommended that there should be fewer inspections; and more advice to improve compliance. The Review was especially concerned to reduce the burdens on small businesses. It claimed that there was 'over-inspection' at local level and advocated that all regulatory activity should be on the basis of a clear, comprehensive risk assessment. The Inquiry placed central emphasis upon risk-based approaches to inspection and enforcement. As a result of this recommendation RBR has become a cornerstone of Treasury recommendations for regulation in Great Britain (see HMT, 2006).^{xix} One difficulty with the Review is that often local authority officers such as

EHOs, can only establish compliance levels through inspection and typically such inspections are the main means of advising and educating small businesses (Hutter, 1986; Fairman and Yapp, 2004). Risk based approaches typically rate small businesses as a low risk compared to larger businesses,. This may gloss over some very real difficulties with individual small businesses which can, as the Scottish and Welsh outbreaks testify, pose a serious risk. Moreover, it fails to recognize the risks posed by the general micro, small and medium-sized enterprises (SME) sector.

25. These bigger picture changes have implications at ground level and highlight a number of tensions and debates which characterise many regulatory issues. The focus of responsibility is clearly on business organizations to manage the risks generated and the onus is on regulators to intervene where businesses clearly fail to do this. But are all businesses able to manage their own risks and are regulators always able to identify this and act when necessary?

The regulatory practices of 'state' regulators

26. EHOs are key players in food safety regulation. They are the people who translate the law in books and policy decisions into action on the front line. Typically they are in possession of high levels of discretion about how to implement the law in individual premises. The evidence is that, like many other UK regulators, they deploy this discretion flexibly.^{xx} Their overall approach does not take enforcement of the law to simply refer to legal action; rather it refers to a wide array of informal enforcement techniques such as education, advice, persuasion and negotiation. Securing compliance is its main objective, both through the remedy of existing problems and, above all, the prevention of others. The preferred methods to achieve these ends are co-operative and conciliatory. So where compliance is less than complete, and there is good reason for it being incomplete, persuasion, negotiation and education are the primary enforcement methods. Accordingly, compliance is not necessarily regarded as being immediately achievable; rather it may be seen as a long-term aim. The use of formal legal methods, especially prosecution, is regarded as a last resort, something to be avoided unless all else fails to secure compliance. Indeed, the importance of legal methods lies in the mystique surrounding their threatened or possible use rather than their actual use.

27. There are number of reasons that EHOs adopt this approach. Enforcers of regulations may experience problems when taking legal action because of the way in which the laws or regulations have been drafted (Kagan and Scholz, 1984; Baldwin, 1995) Often national and European laws are drafted differently, with the latter being more general and taking the form of broad principles. This does not make them easy to apply. In domestic law the Food Safety Act creates general offences whereas regulations made under it can be very detailed. This can complicate enforcement practices by causing confusion. National regulations adopt multiple and sometimes conflicting regulatory styles. Whereas the Food Safety Act focuses upon command-based prosecution, HACCP principles are found in food hygiene regulation. Although both are inspection focused, they may require the enforcement agency to operate in different ways. HACCP may require the agency and its inspectors to adopt a role as educator rather than enforcer but where training fails the fallback remains formal enforcement with its attendant risks. Further EHOs may rely heavily on guidance (which may or may not have legal force) to simplify their actions. The guidance itself may be seen by enforcers as highly prescriptive and limiting even where this is not the case

(Brandsen et al., 2006). Enforcers may also believe that informal strategies such as the provision of advice and guidance are more effective than bringing formal proceedings (including prosecutions) (Hawkins, 2002; Hutter, 1988 and 1997).

28. There are variations in the ways in which EHOs implement regulation and these differences may be accounted for by a variety of factors. Some variation, for example, is inherent in the legal framework. Differences in the size and location of the local authority may also lead to variations in enforcement approach. For example, enforcement practices are sensitive to the organizational resources available, particularly the department's budget and staff numbers, viewed in relation to the number and complexity of environmental problems encountered (see also Hampton, 2005). Differences in the severity of the regulatory problems encountered are reflected in enforcement approach. Hutter (1988) found that the more urbanized the local authority, the more stringent the enforcement strategy seems to be. In these local authorities environmental health problems are likely to be immediately visible, for example a high concentration of rented accommodation and a close proximity of industry and housing. As a consequence, the political salience of environmental health is heightened and there may be greater public and local council pressure upon the environmental health department to be seen doing something substantive. There is, however, a potential downside for food safety which could be accorded less importance than more visible environmental health problems.

29. Another crucial factor to enforcement style is the nature of the relationship between EHOs and the regulated. The degree to which officers are integrated into the locality they serve affects not only their personal inclination to adopt either informal or formal techniques but also influences officers' assumptions about the population they control. Those who operate in a small and fairly close-knit community generally know the people they are dealing with, and they fear that the positive outcomes of legal action may be outweighed by its negative effects in terms of their working relationships and their social interactions with the regulated and their families. Officers working in these smaller environments typically assume that they are dealing with good, respectable people who are in need of education and advice. Conversely, those working in large conurbations adopt a more suspicious attitude. They are less likely to be acquainted with those they regulate, do not fear to the same extent the negative consequences of legal action, and are likely to adopt a cynical and less charitable view of the regulated. Not knowing the regulated well, the location and incidence of rule-breaking may be less predictable. These factors combine to suggest more frequent recourse to formal enforcement methods (Black, 1971; Hutter, 1988, 1997). Enforcement may be particularly difficult for meat inspectors given their presence on the premises, and this is important given that the financial pressures to which meat operators are subject renders more likely a greater dependence upon external regulation and enforcement to secure compliance in the meat sector (Scholfield et al., 2000).

30. The local authority system has raised a number of criticisms. The merging of responsibilities under unitary systems does not necessarily overcome the potential for conflict between professional actors. For example, there may be great variation in the resources of not just environmental health departments but the financing of the different elements of their many responsibilities. Pressures deriving from Best Value regimes and performance audit may result in shifts in the allocation of resources sometimes to the detriment of enforcement, advisory and educational activities. Housing has sometimes dominated the environmental health agenda to the detriment of other aspects of the remit. The creation of the FSA is credited with placing food safety and hygiene issues at

the centre of environmental health agendas but with the criticism that this has effected a shift in resourcing within environmental health departments which favours this aspect rather than others, not that it has drawn more resources to environmental health overall.

31. The character of the enforcement activity rests upon officers' intuitive assessments of regarding the nature of the breach and its potential impacts, and perceptions of the FBO's response (including any past dealings), in addition to 'hard science' (Tebbutt et al., 2007). It is determined often after consultation with more senior management within the local authority. Formal action including the service of a statutory notice may ensue only where the incident is seen as a "significant contravention of the legislation" or a lack of trust or confidence in the operator's willingness to respond to informal action, or where there is the potential for a serious threat to public health or standards are poor with little demonstrable awareness of the statutory requirements.^{xxi} The continuous monitoring and evaluation of business performance has to be balanced with the limited resources and competing demands placed upon local authority enforcers.

32. The role of local council committees and councillors in enforcement is another point of concern for some, yet the closeness of the enforcement apparatus to the regulated population and the possibility of sensitivity to local issues is said to be the great strength of this very locally based enforcement system. Inevitably, however, this has the potential for great variation as different local populations do not have the same local sensitivities and councillors from different political parties have varying levels of ideological support for each component of regulatory enforcement. This is often carried through in cases of formal enforcement with different local authorities showing marked differences in their approach to non-compliance (this being one of the reasons for the Compliance Code).^{xxii} Standardization by enforcement protocol does not necessarily overcome enforcers' intuitive assessments.

33. EHOs themselves have been criticised for being a source of inconsistency, particularly regarding their levels of expertise – as aspects of their remit have become increasingly technical the adage that they are 'Jack of all trades and master of none' has become ever apparent. EHOs not only inspect food production, catering and retail premises on matters of food safety but they also perform additional duties such as housing standards, pollution control, health safety and welfare and noise control (Hampton 2005).^{xxiii} In larger authorities this can be mitigated organizationally by employing specialist teams but in some areas the pressures for a more generic cross-cutting inspector remain dominant. In the context of food hygiene enforcement, weaknesses have been identified in risk rating systems and the scoring system for management confidence currently operated in England and Wales, each of which require a level of subjective assessment on the part of the EHO (Gilling et al., 2001; Jones et al., 2008).

34. These issues are especially relevant in the context of enforced self regulation, risk-based regulation and better regulation. There may be a temptation for local authorities to use these initiatives to cut resources. Moreover, any increased used of generalist inspectors and a generalist team, especially alongside fewer resources, has profound implications for the collection and assessment of data required for risk-based regulation which demands expert, well qualified staff to collect and assess data and to know how to use it to prioritize work.

35. Local authority policy is directed by FSA statutory and informal guidance and the observations of industry associations. It is devised usually after local consultation and modelled upon local authority enforcement groups' templates. Part of the FSA's remit is to inspect and audit local authority environmental health departments. Under the devolved arrangements the methodology for undertaking audit schemes may differ, with each FSA board co-ordinating their own audit programme.^{xxiv} The FSA has authority to set performance standards, monitor performance, demand information from local authorities and inspect their food enforcement resources. In the interests of transparency any reports compiled as a result of their audit can be made public.^{xxv} The FSA also collects data on all food law enforcement activities and in turn reports them to the European Commission.^{xxvi} These data include, for example, numbers of inspections, numbers of infringements leading to formal action and details of sampling activities. This is presented in summary form and according to local authority. While the FSA has the authority to access local government information and publish reports, these are the limits of its powers over local authorities. Indeed, the limitations of these powers are in many respects illustrated by the content of some of its local authority audit reports which can report repeated deficiencies across time, suggesting that not all local authorities are concerned by the FSA's powers of publication. This is especially relevant as there are no other powers of compulsion available to the FSA.

36. The institutional division of responsibilities for policy, standards and enforcement of food safety and standards between central and local government is unusual as, with the exception of the Meat Hygiene Service, the FSA has no powers to pursue individual cases of enforcement. This arm's length arrangement presents the FSA with many challenges when directing the activities of individuals they neither employ nor fund. The relationship between local authorities and the FSA is not thought to be an easy one with many local authority officers viewing it as overly bureaucratic, impractical and difficult (BRE & NAO, 2008).

Risk regulation and food: regulation beyond the state

37. One significant trend in regulation is the move to involve a variety of non-state players in regulation, sometimes as part of a move to outsource public management functions (Hancher and Moran 1989; Osborne and Gaebler 1992; Scott 2001). This is also a means of empowering different participants in the regulatory process in order to maximize the promotion and achievement of risk management. The move to enforced self-regulation is a perfect example of this as the state harnesses and emphasises the regulatory resources of business. A series of studies have highlighted the importance of focusing on the interplay of economic, political and social forces in understanding corporate regulatory factors. Also relevant is their interaction with the internal organization of a business and the views and behaviours of its management and employees.^{xxvii}

38. Research on the food industry has shown that state regulation remains a key influence on business risk management practices but that those in the industry readily understand that there are other non-state external influences on their risk management practices (Hutter and Jones, 2007). The role of consumers all but equalled that of the state. So consumers and EHOs were deemed to exercise a direct influence over food safety and food hygiene risk management practices. An important finding is that EHOs remain a key influence on food businesses. Indeed their proximity to food retailers can

be crucial in educating SMEs (Fairman and Yapp, 2004). Of course, in procurement situations consumers have no role, moreover it may well be that FBOs overestimate how discerning consumers are with respect to food safety issues (IGD, 1998). Other non-state influences include private consultancy firms and trade associations which *sometimes* have a direct influence, depending on the size of the business. The media and pressure groups were more indirect background influences. Lawyers and insurance companies played a negligible role, with the latter even being described as a negative influence. Large businesses, in particular supermarkets, can exert considerable influence in the supply chain (Balsevich, et al., 2003; Mohtadi et al., 2005).

39. There are some interesting variations in understandings of state and non-state influences on food retailers and caterers' risk management (Hutter and Jones, 2007). Managers' knowledge of EHOs was most widespread and most sophisticated. This is not entirely surprising as they are in most contact with the industry at floor level and their remit directly relates to the food safety and food hygiene risks. Knowledge of the nationally-based FSA is high at senior management and policy levels of large businesses but less so at junior management levels. But the main axis of variability in understandings focused on the size of a food business.

40. Several studies have found that SMEs generally have lower levels of knowledge of regulatory laws and state regulatory systems (BRTF 1999; Fairman & Yapp, 2004; FSA 2001; Gunningham, 2002; Henson and Heasman 1998; Hutter and Jones, 2007; Vickers et al., 2005). They also appeared to rely on state regulatory systems for education and advice. One reason for SME reliance on state systems is that many small businesses have less contact with non-state sources which provide information and advice. They might not be members of trade or business associations which may provide updates or even training on food safety and food hygiene matters, nor do they tend to use consultancies (Fairman and Yapp 2004; Genn, 1993; Hutter and Jones, 2007). This of course contrasts with large businesses which have greater regulatory resources and capacity of their own and are more likely to belong to associations, employ consultancies and take out insurance cover. Indeed in the case of large retailers and caterers they may even become a source of regulation for other parts of the food chain as they impose standards which are sometimes in excess of state regulatory requirements. These findings are important in the context of our discussion of risk regulation trends in the food safety area as they demonstrate the difficulties in relying on non-state sources of risk management in the SME sector.

Discussion

41. Food safety regulation, like all other risk regulation, is subject to a variety of tensions and contradictions which are not unique to this domain but which may be exacerbated by the nature of the retail and hospitality sectors and by some features of the legal and institutional arrangements for food safety.

42. The food retail and hospitality sectors include a high proportion of small and medium sized enterprises, many of whom have relatively low regulatory capacity. This may lead to ignorance of the regulations of the risks attaching to non compliance; and knowledge of how to remedy problems. They may have few resources to comply, including financial resources and also knowledge based resources. This limits their ability to self-regulate

and most especially to understand the intricacies of HACCP. The principles based enforced self-regulatory system may be difficult for small businesses to comprehend; typically they prefer detailed rules. Their lack of resources also means that they are much less likely than larger businesses to employ external sources of help such as consultants. They are also less likely to be connected to other sources of help and education such as trade associations and insurance companies. This leads to a reliance on state mechanisms and here EHOs are especially important as a source of advice, education and enforcement.

43. There are some features of the regulatory system which make it difficult for the demands of small businesses to be met. Better regulation calls for less inspection and for increased advice, these calls may well be in tension especially for small businesses where inspection is the main source of advice and education. Moreover, better regulation demands may lead to a cut in resources at central and local government levels, making it difficult to deploy those capacities formerly used for enforcement, for advisory purposes. Enforcement may also be especially difficult in a system where there is a division between centralised policy making, a highly fragmented and dispersed system of local enforcement and the presence of conflicting organizational cultures in local government that may demand the adoption of market-based principles to service delivery. Indeed, there is some evidence that local authorities (and the Meat Hygiene Service) are ill equipped to deal with risk-based regulation and the demands of HACCP. Historically meat regulation has presented a number of challenges. These relate to the potentially higher impacts of failures to manage risk and also to culturally engrained ways of proceeding that may be difficult to eradicate in a regulatory context that emphasizes risk-based regulation.

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Notes

ⁱ The preamble to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 lays down the general safety principles and requirements to be applied, OJEC No L 31/1 1.2.2002 p.1

ⁱⁱ See generally UWIC (2006); FSA site <http://www.food.gov.uk/>

ⁱⁱⁱ Some regulations relate to specific sectors of the food industry as with the Food Safety (General Food Hygiene) Butchers' Shops) (Amendment) Regulations 2000 (S.I. 2000/930) and the Food Safety (General Food Hygiene) Butchers' Shops) (Amendment) (Wales) Regulations 2000 S.I. 2000/3341 (W.219). Others are of general application e.g. The General Food Regulations 2004 (S.I. 2004/3279) applying Regulation (EC) No 178/2002

^{iv} See the duties imposed upon food businesses to satisfy food law requirements under Article 17 Regulation (EC) No 178/2002. The current provisions are contained in Regulation (EC) 852/2004 on the hygiene of foodstuffs (applying HACCP principles to all food businesses at Art. 5 and imposing registration requirements (Art. 6) and Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin including structural and operational requirements for meat production from slaughter and cutting of meat, through to meat preparation and processing. Regulation (EC) No 854/2004 covers the official controls (enforcement) of products of animal origin, including the inspection and auditing duties of official veterinarians, meat inspectors and the role of the Meat Hygiene Service in enforcement. These are applied by Food Hygiene (Wales) Regulations 2006 (S.I. 2006/31 (W.5)) (as amended) which came into force on 11 January 2006. Food operators can be required to carry out structural improvements and adaptations to premises for this purpose (see section 10 the Food Safety Act 1990 and its amendments).

^v As with the Food Safety Act 1990 (S.I. 1990/16) section 6 and the Food Safety (General Food Hygiene) Regulations 1995 (S.I. 1995/1763) regulation 6 (more recently amended by the Food Hygiene (Wales) (Amendment) Regulations 2007 (Welsh SI 2007/373 (W.33)) which came into force 14 February 2007 amending the Food Hygiene (Wales) Regulations 2006 (S.I. 2006/31 (W.5) and S.I. 2005/363 (W.30) of 2005)

^{vi} This covers product withdrawals and recalls, imports and exports, the labelling and marketing of food and its traceability (its source). Regulation (EC) No 178/2002 relating to food safety (Article 14), traceability (Article 18) and product recall and withdrawal (Article 19) came into force on 1 January 2005.

^{vii} European laws have established a structure applying food safety provisions throughout the European Union, which impose duties upon Member states to enforce food law by monitoring and ensuring that requirements are met through a system of monitoring and verification. Many are regulations making them directly applicable and binding without further enactment by EU member states. The Food and Veterinary Office of the European Commission (FVO) carries out checks on Member state compliance with EU food safety requirements. The Food Safety Act 1990 (Amendment) Regulations 2004 (S.I. 2004/ 2990) and the General Food Regulations 2004 (S.I. 2004/ 3279) amend the Food Safety Act 1990 to ensure the alignment of national law with EU regulations.

^{viii} Section 40 of the Food Safety Act 1990 provides for codes of practice to which food authorities must have regard. The Food Safety Act 1990 Code of Practice and associated Practice Guidance for Wales were issued in October 2004. The Food Law Code of Practice (Wales) 2006 (National Assembly for Wales 2006 No. 57) came into force 1 August 2006 concerning the execution and enforcement of the Food Safety Act by Food Authorities. The Food Standards Agency has drafted numerous codes and is currently undertaking a consultation exercise into the Food Safety Act 1990 – A Guide for Food Businesses (consultation in England and Wales) Consultation paper 2008 edition draft

<http://www.food.gov.uk/multimedia/pdfs/consultation/fsaguide08incip.pdf> <24 July 2008> See also UWIC Report 2006

^{ix} Aside from devolution little has changed in terms of institutional complexity since the Food Standards Agency Report - An Interim Proposal by Professor Philip James 30 April 1997

published by MAFF, Department of Health and the Scottish Executive well before 1 April 2000 when the Food Standards Agency was established. Whilst local government reorganization in Wales created 22 Unitary Authorities bringing together environmental health and trading standards services, professional representation remains distinct (referred to in UWIC, 2006, Ch. 2).

^x Under the Food Standards Act 1999 the Food Standards Agency has responsibility for developing food policy and advising Ministers and other public authorities, for advising consumers and other interested parties and for keeping abreast of developments relevant to its remit (sections 6-8); functions relating to surveillance (ss 10-11); and for monitoring the performance of food law enforcement authorities (including powers of setting performance standards relating to enforcement at section 12) (sections 12-16). For a general explanation of the FSA's enforcement powers see <http://www.food.gov.uk/enforcement/foodlaw/about/> <30 July 2008>

^{xi} FSA Wales was created as the link between the Welsh Assembly Government and Parliament to ensure Welsh representation whilst securing a consistent UK wide approach to food safety (http://www.food.gov.uk/wales/aboutus_wales/ <13 August 2008>). It was launched in April 2000 and powers devolved for food safety and standards to the National Assembly for Wales the source of its principal funding. By virtue of section 108 Government of Wales Act 2006 (S.I. 2006/32) the Welsh Assembly Government has legislative competence for food (Sch. 7 Part 1 Field 8). Welsh Ministers can issue Codes of Practice having regard to the advice of the FSA but there is no direct line of accountability from FSA Wales to Welsh Ministers instead (as with Scotland) the UK Board is responsible as a whole to Ministers of the devolved authorities. However each devolved executive coordinates its own audit programme and the methodology adopted may differ <http://www.food.gov.uk/enforcement/auditscheme/> <11 August 2008>

^{xii} The Meat Hygiene Service (MHS) team is responsible for ensuring that the slaughter and dressing process is conducted by the Food Business Operator (FBO) in accordance with the legislative requirements, and that meat is produced with the greatest regard for hygiene. Previously much of this work was undertaken by local authorities and from April 1995 by MHS as an Executive Agency of MAFF. A detailed history is contained within Volume 6 of the Report of The BSE Inquiry Human Health 1989-96 (6.23 et. Seq.) <http://www.bseinqury.gov.uk/report/volume6/chapte62.htm#749936> <11 August 2008> Current approval procedures are set out in Article 31 of the Official Controls Regulation (EC) No 882/2004, which require establishments handling products of animal origin to obtain approval unless they benefit from permitted exemptions. FBOs must pay attention to temperature controls, working practices, and the general upkeep (cleaning and maintenance) of the premises. A more detailed exposition of the functions of the MHS is contained in <http://www.food.gov.uk/foodindustry/meat/mhservice/aboutmhs/mhsapprovedpremises> <11 August 2008> and the FSA's "Guidance on the requirements of Food Hygiene Legislation, pp. 8-9" <http://www.food.gov.uk/multimedia/pdfs/fsaGUIDEFOODHYGLE.pdf> <11 August 2008>. Its structure is currently under review see Review of the Delivery of Official controls in approved meat premises. Final Report FSA 07/07/06 (Agenda item 3.3, 19 JULY 2007) <http://www.food.gov.uk/news/newsarchive/2007/jul/mhr> and <http://www.food.gov.uk/multimedia/pdfs/fsa070706.pdf> <5 June 2008>. Concerns continue to be raised regarding the function of the Service and the exercise of its enforcement powers, see HL Debs WA 39 (19 May 1999) and HC Debs 1801 W 21 April 2008.

^{xiii} The exception to this arrangement is in London and Scotland where both food safety and food standards are the remit of EHOs and they may have the title of Food Safety Officer.

^{xiv} Ayres and Braithwaite, 1992; Gunningham and Grabosky, 1998; Hutter, 2001. Coglianese and Nash (2001; 2006) use the term 'management based strategies' to refer to regimes of enforced self-regulation, thus emphasizing the fact that they are '...used by those who are *outside* an organization to change the management practices and behaviours of those on the *inside*' (2006: 15).

^{xv} See the FSA's Food Chain Strategy Research Programme (H01) has strategy concentrating on "aspects of food safety in relation to farming practice, establishing critical control points throughout the food chain, and improving the technical knowledge of small food businesses."

<http://www.food.gov.uk/science/research/researchinfo/choiceandstandardsresearch/foodchainresearch/h01programme/> <10 June 2008>]

^{xvi} See Demortain, 2007, for a discussion of the development of HACCP as an international standard. In England and Wales HACCP now applies to all FBOs except farmers and growers. Its application in meat plants is detailed in

<http://www.food.gov.uk/foodindustry/meat/haccpmeatplants/> <18 August 2008>

^{xvii} This trend has continued with the EU Regulations of 2004

^{xviii} Visual inspection by local authority agents without undertaking microbiological swabbing may limit the effectiveness of preventing food poisoning outbreaks (Tebbutt et. al. "Verification of cleaning efficiency and its possible role in programmed hygiene inspections of food businesses undertaken by local authority officers" (2007) *Journal of Applied Microbiology* 102:4 1010-7). Some point to a need to incorporate epidemiological data into HACCP systems (Panisello et al. 2000 *International Journal of Food Microbiology* Sept. 10 59(3) 221-34). Others (Beckers (1988) *Cater Health* 1(1) 3-5) suggest that the microbiological role should be limited to assessing the effectiveness of control measures.

^{xix} Part 2 of the Legislative and Regulatory Reform Act, 2006 (c. 51), enshrines the Hampton principles. A joint BRE and NAO review of the FSA's adoption of the Hampton Principles, conducted in 2008, found that the MHS was not adopting risk-based approaches. It also found some problems in the FSA's relationship with local authorities.

^{xx} See for example Hawkins (2002) and Kagan (1994) for a general discussion and Fairman and Yapp (2005) and Hutter (1988) for more specific research on EHOs.

^{xxi} Taken from a sample of local authority policies, and FSA guidance

^{xxii} BERR *A Code of Practice for Regulators – A Consultation on the Regulators' Compliance Code and the scope of the Code and the Principles of Good Regulation*. May 2007, and the Legislative and Regulatory Reform Act 2006.

^{xxiii} Chart 1.3 of the Hampton Review (p.18) provides a breakdown of the allocation of EHO time between the performance of their functions in England and Wales. Food safety enforcement ranks closely with the enforcement of housing standards.

^{xxiv} <http://www.food.gov.uk/enforcement/auditscheme/> <13 august 2008>

^{xxv} In pursuance of its duties in this respect the FSA has a Framework Agreement on Local Authority Food Law Enforcement which covers issues of agreeing standards, transparency and monitoring performance and securing improvements. The FSA website gives details of their audit scheme and also links to audit reports and follow-up audits, some of which reveal that, despite quite critical public audit reports, local authorities can be slow to respond to the reports (<http://www.food.gov.uk/enforcement/auditscheme/> accessed 2/11/07).

^{xxvi} The Commission also has its own team of auditors from FVO who, in effect, audit the FSA's auditing of auditors by visiting individual business premises in the presence of an FSA official and a local authority official.

^{xxvii} Gunningham, Thornton and Kagan (2005) use the concepts of governmental, social and economic 'licenses to operate' as ways of understanding variations in environmental performance amongst businesses. See also Braithwaite and Drahos 2000; Hutter 2001; Parker 2002.