

THE REGULATION AND ENFORCEMENT OF NUTRITION AND HEALTH CLAIMS FOR FOOD

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Abstract

The regulation of food is a contested domain (Ansell and Vogel, 2006). Who should bear responsibility for manufacture, distribution, sale and supply and consumption of the food we consume is one of the overriding political questions of our time. The legal, moral and political authority for the regulation of food faces challenges and is subject to intense negotiation. This study sets out to explore one small part of this multifaceted and global debate.

The regulation of nutrition and health claims represents a concentrated area of the broader treatise. Nutrition and health claims are common in commercial communications used in the promotion of food. The use of such claims is strictly controlled by the Nutrition and Health Claims (England) Regulation 2007 and much has been written about the rationale for the Regulation. By contrast, the study of the enforcement of the Regulation is relatively neglected. The original contribution to knowledge made by this work is the finding that the enforcement of the regulation relies on the application of the broad discretion allowed to local authority enforcers and this results in variances in enforcement style. Notwithstanding such differences in style, one clear theme emerged: that enforcers largely deploy an accommodative approach based on advice rather than a deterrent approach reliant on prosecution. The study adopts a qualitative methodology with semi-structured interviews of those responsible for the enforcement of the law, namely trading standards officers and environmental health officers to assess their views and attitudes. It was found that factors affecting the application of the discretion ranged from the local priorities of the authority and the availability of resources to effectively control the use of such claims. While the discretion allowed for authorities to respond to the particular needs of their community, it makes for a 'postcode lottery' in differences in the way in which the same claims that are used across multiple authorities are enforced. It was found that in common with other legislation where enforcement is ceded to local authorities, the system of enforcement would benefit from greater consistency of practice.

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Chapter 1

Introduction

1.1 Prosecutor or advisor? The role of a trading standards or environmental health officer

The function of the Regulation on Nutrition and Health claims (EC, 1924/2006) (the Regulation) is to provide information for consumers to be able to make informed food choices (Caswell and Mojduszka, 1996). Consumers are not well placed to judge the nutritional and health characteristics of a food as such attributes are latent. Therefore the problem arises where more readily assessed attributes such as price and sensory qualities of a food dominate consumer decision-making (Akerlof, 1970) and the outcome may eventually be poorer health and obesity for consumers in the long term.

The rationale of the Regulation (EC, 1924/2006) is to provide information in order to correct the quality signalling problem rather than to impose a restriction or limit or ban on the sale of poor quality foods (Patel et al., 2012). However, this is merely the means by which the Regulation seeks to achieve its more ambitious outcome of improved health and welfare of consumers. The efficacy of the Regulation may depend on how enforcers go about the operational task of enforcement. Therefore, the aim of this study is to investigate how trading standards or environmental health officers enforce the Regulation and understand how this relates to existing literature in economics, political science and socio-legal studies.

The benefit of food law enforcement is an economic good like any other. In extrapolating the economic theory to enforcement, the key problem is that the benefits of enforcement are diffuse and are enjoyed by all. However as with 'public' goods generally, 'no 'market type' solution exists to determine the level of expenditure on public goods' (Tiebout, 1956). In this respect, the benefits of food law enforcement are allocated in a non-optimal way when compared to other goods.

The application of the economic theory to the practice of enforcement provides that economic actors will comply with regulation if, and only if, the costs of compliance with regulation are exceeded by the benefits (Law, 2006). This means that the size of the sanction and the risk of apprehension and sanction must be such that together they amount to a sufficient deterrent

to make a rational business comply with the regulation (Becker, 1974; Stigler, 1974; Polinsky and Shavell, 1999). The socio-legal perspective is captured by Hawkins and Hutter who state that 'the task of a regulatory bureaucracy is, by various means, to induce a potentially unwilling business organisation to bear costs which it would in many circumstances not wish to assume' (Hawkins and Hutter, 1993). However, do either the economic or socio-legal perspectives adequately characterise the behaviour of businesses? Moreover, does it provide a sufficient basis to inform enforcement strategy? To what extent can behaviour be controlled or influenced by legal penalties?

Rather than businesses who behave as economically rational actors, enforcers are faced with a more complex picture of a mixture of small and large businesses who may or may not be aware of the regulations which apply to their activities and differ in the extent to which they are willing to comply with regulations.

Examining how enforcers enforce and the aims that they are seeking to achieve may provide an understanding of how the law, sanctions and enforcement strategies may be used to control business and thus inform regulatory design. This study identifies the common enforcement practices of environmental health and trading standards officers.

One view is that enforcement of the law refers to legal action. This is known as the deterrence model (Reiss, 1984). In this model the methods of enforcement are penal and adversarial and prosecution plays an important role and there is greater reliance on imposing sanctions (Hutter, 1989). By contrast, the accommodative model of enforcement seeks to secure compliance by the remedying of existing problems and the prevention of others. In the accommodative model, compliance is achieved by cooperation and negotiation. The methods used to ensure compliance are persuasion, negotiation and education. The use of legal action, particularly prosecution, is regarded as a last resort to be used only in the event that everything else has failed (Hawkins, 1984). In this model; 'the importance of legal methods lies in the mystique surrounding their threatened or possible use rather than their actual use' (Hawkins, 1984).

Chapter 2.0

Literature review

2.1 Summary

This chapter provides the context of the regulation and enforcement of nutrition and health claims for food. It is divided into two sections: the first deals with regulation and the legal and economic rationales provided for it. The second examines the way in which enforcers work. It focuses on the way in which enforcers apply the significant discretion afforded to them and the impact that can have on the effectiveness of the regulation of nutrition and health claims. While the current literature on enforcement is derived from industries ranging from water pollution, railways and food hygiene, this chapter seeks to place the findings from it into the context of the regulation and enforcement of nutrition and health claims.

2.2 Introduction

The Regulation (EC) 1924/2006 relating to nutrition and health claims made for food (EC, 1924/2006) presents many challenges for enforcers. Particular among these are the number of potentially false claims on commercial communications from advertising to labels that are not compliant and the limited resources available to enforcers. It is difficult to define what the outcome of the Regulation should be and how the effectiveness of enforcement should be measured. It is not inconceivable that many transgressions of the Regulation will be undiscovered and therefore it is impossible to measure with any accuracy the efficacy of enforcement.

Previous studies have attempted to capture and illuminate the negotiation between enforcers and regulated firms (Braithwaite et al., 1987; Hawkins, 2002; Hutter, 1997).

Theories of the 'regulatory pyramid' of a hierarchy of actions from negotiation to prosecution to risk based regulation, a more recent concept, aim to provide strategic level guidance on how enforcers should carry out their duties.

Such theories define non-compliance, but they do not provide a complete picture into how to design enforcement strategies. They do not say how a regulator should deal with 'resource constraints, conflicting institutional pressures, unclear objectives, changes in the regulatory environment, or indeed how particular enforcement strategies might impact on other aspects of regulatory activity, including information gathering, and how regulators can or should assess the effectiveness of their particular strategies' (Black and Baldwin, 2010)

2.3 Aspects of food labelling other than nutrition and health claims

Mandatory food labelling: The Food Labelling Regulations 1996

The law in relation to health and nutrition claims concerns the regulation of claims which are made by suppliers in order to promote the sale of foods. The law is voluntary in so far as where suppliers do not make claims relating to health and nutrition, the regulations will not be invoked. In this respect, the law is different from the information that food suppliers must provide, the mandatory food labelling rules.

In the same way, the Regulation may be distinguished from regulations that involve notifying consumers about the matters that may affect their health and nutrition but which are not within the scope of the Regulation. The application and scope of the Regulation is set out in Article 1; 'This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer' (EC, 1924/2006). The following types of information are not covered by the Regulation and they do not form part of the scope of this thesis: allergy information, genetically modified foods, notifications about hydrogenated fats and the use of cloned animal products.

The mandatory rules relating to food labelling may be divided into two categories depending on their purpose. The first category is that set of rules that are aimed at providing consumers with a description of the food itself, therefore those which purport to answer the question; 'what is it?' This is concerned with identifying the food and communicating its name to consumers, for example, burger or pizza. The main rules relating to ensuring the accuracy of a description are contained in the Food Labelling Regulations (1996).

A further set of rules relates to the content of food; in answer to the question; 'what is in it?' The rules are aimed at providing consumers with information about its composition.

It may be asserted that the purpose of the rules in both cases is to avoid misleading consumers. This allows consumers to exercise choice and to put into practice healthy eating based on the link between diet and health. (Hu, 2003).

The 1996 Regulations, inter alia, impose a positive obligation on the supplier of food to provide specified information. The Regulations concern the mandatory information that must be provided. In contrast, the rules relating to the use of nutrition and health claims are negative in that they impose restrictions on the claims which may be made for the food where such claims are primarily a means of promoting its sale. The regulation governing health and nutrition claims concerns information that is provided at the discretion of the supplier.

2.4 General labelling requirement

There are certain names which are recognised under the 1996 Regulations as legal names, for example; jam, sugar or milk. In addition producers may add further words to make the description more precise, for example; strawberry jam, granulated sugar or skimmed milk. Where a recognised legal name is in existence, it must be used.

In addition to the legal name, there may be a customary name which is widely accepted by UK consumers. This may be best illustrated by reference to an example:



Figure 1 Waitrose Lemon Meringue Pie

Image from *Food Labelling in the UK* compiled by Dr David Jukes, www.reading.ac.uk

2.4.1 Name

The name of this product is given as; '*Lemon Meringue Pie*'. The term 'Meringue Pie' is a customary name and is widely understood among UK consumers. The use of the term 'Lemon' indicates that the flavour of the product comes mainly from lemons. It is not however a literal name so that the product does not need to be made of or mainly from lemons and it is acceptable for other ingredients for example sugar, to constitute a larger ingredient. The supplier here might argue that the description 'Lemon Meringue Pie' is a customary name which is recognised by UK consumers however the Regulations require that a supplier should provide a description that is sufficiently precise to inform a purchaser of the true nature of the food. In this respect, the packet goes on to provide the words;

'A butter rich pastry case with lemon filling topped with meringue'

2.4.2 Ingredients

In addition to the description of the products, the packaging should specify the ingredients which go into its manufacture by listing them in order of quantity starting with the greatest first. In addition, the ingredients that form compound ingredients, for example, mayonnaise may be listed separately after reference to the compound ingredient or subsumed within the general list of ingredients.

2.4.3 Other information

Additional information that is required, is disclosure of ingredients, or a statement concerning certain ingredients, associated with allergies, the size or weight of the product, the country of origin, the name of the manufacturer and the use of additives such as 'E' numbers, storage instructions and date marking showing the 'use by date'. In addition to this information suppliers will often voluntarily provide information about whether the product is suitable for vegetarians and environmental information for example whether the packaging is recyclable. There are many further labelling requirements some of which are specific to particular foods; for example chocolate, sugar, fruit juices. In addition, there are products which are exempt from the general regulations for example alcoholic drinks, fresh fruit and vegetables sold loose.

2.4.4 Voluntary provision of nutrition information

From December 2016 most pre-packed foods will be required to show nutritional information under the Food Information for Consumers Regulations (EU FIC). However, presently, there is no requirement for food suppliers to provide information about the nutrition content. Nevertheless it has become common practice with pre-packaged foods from large suppliers, particularly supermarket own label products, for a detailed list of ingredients to be displayed. This is organised on a voluntary basis and is not done in the context of a health and nutrition claim. For example, there is no health claim made in relation to the protein content in the spinach and ricotta pizza shown below and therefore the Regulation 1924/2006 does not apply.

Spinach & ricotta pizza						
Nutrition information				Guideline daily amounts		
Typical values (cooked as per instructions)	Per 100g	Per ½ pizza	% based on 604 kcal for active	Women	Men	Children (5-10 years)
Energy	1001 kJ 238 kcal	1977 kJ 470 kcal	23.5%	2000 kcal	2500 kcal	1800 kcal
Protein	9.3g	18.4g	40.9%	45g	55g	24g
Carbohydrate	28.7g	56.7g	24.7%	230g	300g	220g
of which sugars	2.7g	5.3g	5.9%	90g	120g	85g
of which starch	25.9g	51.2g	-	-	-	-
Fat	9.6g	19.0g	27.1%	70g	95g	70g
of which saturates	3.7g	7.3g	36.5%	20g	30g	20g
mono-unsaturates	4.0g	7.9g	-	-	-	-
polyunsaturates	1.6g	3.2g	-	-	-	-
Fibre	2.3g	4.5g	18.8%	24g	24g	15g
Salt	1.0g	2.0g	33.3%	6g	6g	4g
of which sodium	0.40g	0.79g	32.9%	2.4g	2.4g	1.4g

You may want to keep an eye on your **salt** intake as too much may increase your blood pressure.

It's important to watch your **calorie** intake, as without regular exercise too many may lead to weight gain.

A diet low in **fat**, particularly **saturated fat**, could help to maintain a healthy weight and a healthy heart.

To maintain a healthy lifestyle, we recommend aiming for at least 30 minutes of moderate exercise each day, such as brisk walking.

Figure 2 nutrition panel Sainsbury's Spinach & ricotta pizza

Since the passing of the Food Labelling Regulations 1996 the primary source of legislation dealing with misleading claims has been the EU. The original Directive 77/94/EEC established an EU wide framework for making nutrition claims for food. This was superseded by Council Directive 89/398/EEC as amended several times. However the most important regulation of health and nutrition claims has been the EC Regulation 1924/2006 on nutrition and health claims (EC 1924, 2006)

2.5 Consumer protection and food – from food safety to fraud to nutrition

The history of consumer protection in general may be traced back to regulation of the sale of food in particular. The statute of the Assize of Bread and Ale 1266, is the earliest recorded piece of legislation dealing with the sale and content of food (Cartwright, 2003). The legislation was aimed at regulating the price, quantity and quality of bread and beer (Davis, 2004). It was 'intended as an instrument to protect consumers, especially the poor...but its aim was also to provide bakers with an adequate living whatever the price of grain.' The legislation represents one of the earliest attempts to protect consumers from being deceived by supplies of adulterated food. Suppliers who were found to have breached the law could be fined, pilloried or flogged (Whetham, 1964).

Religion has played a significant role in influencing behaviour of its adherents in determining the food that such followers may or may not consume. The restrictions may originate from religious edicts or holy texts that act as ancient codifications of good practice in relation to food and health. Restrictions or prohibitions on the consumption of certain, in particular, animal products may be founded in religious tradition and they may also be traced to practical social and health benefits. 'Food taboos have an adaptive value; production of milk or eggs has the potential to feed far more people than the flesh of one individual cow or hen'(Shatenstein and Ghadirian, 1998). Historically, religious restrictions on particular foods were meant to prevent moral, psychological and physical harm (Qureshi, 1981).

'The development of meat hygiene is traced from its historical beginnings in ancient religious tradition to the veterinary-science-based organoleptic inspection systems of today.'(Bell, 1993) There are several examples that come to mind from prohibitions against eating discovered carrion, not eating pork in very warm countries where trichinella infections might be prevalent or avoidance of the eating of a meat which degrades rapidly in heat.

While governments have faced significant challenges in changing consumer behaviour in relation to food, religion has played a more influential and effective role, at least in delivering benefits that accrue from abstinence. A closer examination of the effectiveness of government in changing behaviour as framed by the emerging science of behavioural law and economics is provided later in this thesis.

As for enforcement of the standard, this was difficult and even fraught with a notion of political control by association with feudal lordship. 'At local level such control could cause

considerable resentment, for it could be seen by the lower orders as yet one more instrument of oligarchic or seigniorial oppression'(LeGoff, 1988). 'Control over their [weights and measures] standards emerged as a sovereign attribute and developed in tandem with the establishment of political authority'(Wood, 2002).

The deception of consumers was viewed as an example of one of the worst types of mercantile fraud and merchants and traders were viewed with the same suspicion as tricksters (LeGoff, 1988). The following extract from *Medieval Economic Thought* by Diana Wood (Cambridge University Press 2002) highlights the types of mischief that the early regulation of food was designed to deal with:

'...butchers who painted the eyes of rotten sheep carcasses with blood to make them look fresh (Bromyard, 1484). A similar crime was highlighted in 1475 when the guild of cooks in London petitioned that 'no one of the craft shall bake roast, or boil flesh or fish two times to sell, under penalty [for thereby putrefying flesh might be passed off as fresh' (Myers, 1969)...Bakers too had their own brands of chicanery. They might bake loaves with 'bad dough within and good dough without', as a certain Alan de Lyndeseye did in London in 1316. The same year two bakers were pilloried for baking bread of 'false, putrid and rotten materials through which persons who bought such bread were deceived and might be killed' (Riley, 1868). Sometimes the punishment really fitted the crime, as when a seller of unsound wine in London was made to drink a measure of it before the rest was poured over his head (Myers, 1969). Finally there were livestock traders, especially horse-dealers, who resembled shady second-hand car dealers in hiding the faults of the animal, or selling 'a crokyd hors for a clene'(Bromyard, 1484).'

Throughout history, there have been shifts in emphasis of the rationale for consumer protection in food. It is clear from the above that early legislation was designed to deal with financial fraud arising from selling food which was inferior to that described. There is also concern for the health and safety of consumers and how they might be protected from the risks of contaminated and food that had gone bad through the passage of time. Often these concerns overlapped and were not distinguished as in the example of the pilloried bakers above.

With the exception of price controls, current food legislation adopts the rationale of the Assize of 1266. Price controls as a means of consumer protection have all but been abandoned as anti-competitive in the UK. However, as a general principle, suppliers should not be permitted to make false or misleading claims about food and consumers are entitled to receive food made from the ingredients or with the characteristics that are claimed for it. There are a number of reasons why this is important (Turner, 1995). First, fairness: consumers are entitled to receive what they pay for. If consumers are deceived into paying for a particular product and they actually receive a cheaper or inferior one, they will suffer a financial loss. False and misleading claims are also associated with market failure and the misallocation of resources and the loss of confidence in the truth of all seller claims (Ramsay, 1985). The second reason relates to competition; the supplier who flouts the law enjoys a price advantage over those who comply, which would allow it to sell for a lower price and therefore gain more sales or alternatively it would enable it to make a larger profit. Finally, misleading information about the composition of food can lead to illness, allergic reaction or even death for example as a result of the failure to disclose the presence of a substance which may harm the consumer because he or she suffers from an allergy.

The primary focus for modern food regulation and enforcement is food safety and hygiene. In this respect the Food Safety Act 1990 (Food Safety Act, 1990) represents the key consumer protection measure in the UK today. It provides the regulatory framework and the key statutory obligations for the UK food industry (Atwood, 2009). Section 14 is concerned with, 'selling to the purchaser's prejudice any food which is not of the nature or substance or quality demanded by the purchaser.' This apparently innocuous statement represents the key protection for consumers and risk for food businesses in UK domestic legislation. Of an altogether broader nature is the General Food Law Regulation (EC 178, 2002). Article 14 is concerned with food safety by providing that 'food shall not be placed on the market if it is unsafe.'

The supporting provisions of the Regulation are concerned with restrictions on import and export, traceability and recall and withdrawal of unsafe food, reflecting the experience of the food scares of previous years, for example, the outbreak of Bovine Spongiform Encephalopathy (BSE) in the 1990s.

In relation to hygiene, the following EC Regulations of 2002 lay down the food hygiene rules for all food businesses in the EC: on the hygiene of foodstuffs (EC 852, 2004); the hygiene for food of animal origin (EC 853, 2004); and on the organisation of official controls on foods of animal origin (EC 854, 2004).

2.6 General rationales for intervention

One rationale for intervention by modern law making in developed economies is that the effect will provide conditions which are closer to that of the perfectly functioning market than the current position. The 153 member countries of the World Trade Organisation (WTO) subscribe to the ideals of free trade and open markets, although food production and agriculture is of course beleaguered by protectionism (Anderson et al., 2013; Tyers and Anderson, 1992).

In the EU this is enshrined in the Treaty of Rome Article 2:

The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing the common policies or activities referred to in Articles 3 and 3a, to promote throughout the Community a harmonious and balanced development of economic activities, sustainable and non-inflationary growth respecting the environment, a high degree of convergence of economic performance, a high level of employment and of social protection, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States. (92/C191/01, 1992)

The aim of market efficiency and competitiveness is made explicit in the Lisbon Strategy; with its aim for the EU 'to become the most competitive and dynamic knowledge based economy in the world.' (EC 2005, 2005).

There are a number of examples of law and policy making where the aim of the legislation is not to deliver market efficiency by the optimum allocation of resources (Arrow, 1969) but to pursue an alternative goal. Other reasons for regulation may be justified in that; (i) it seeks to promote a socially desirable goal, such as protection of vulnerable or disadvantaged groups, (ii) redistribution of wealth, (iii) health promotion or (iv) that it delivers environmental protection. A description and an example of the application of each of these rationales is provided below. In relation to the protection of vulnerable groups, which may include the elderly, mentally or physically disabled or those from a low income household (i), an example of this may be found in the Consumer Protection from Unfair Trading Regulations 2008 (CPRs) (2008). The CPRs create a general standard of what might constitute unfair commercial practice by reference to the impact of the activity on the 'average' consumer. However where the activity is likely to

affect only an identifiable group of vulnerable consumers, then it is assessed by reference to the average member of that group. The CPRs represent a statutory implementation of a variation on the classic economic free market model of the consumer as rational and always acting in their own best interest. It acknowledges the potential for variety in the types of consumers, which again represents a break from the classic economic model.

An example of laws that are aimed at the redistribution of wealth would be the normative approach of the income tax system, which has as its dual purpose the redistribution of resources while maintaining the incentives to ensure the maximisation of wealth. The creation of the system of taxation provides revenues for the collective goods for which there is invariably state provision, such as defence, and which cannot be provided by individuals. It also provides for education and health services which may benefit lower income households who are not resourced to purchase these goods in the private sector.

In relation to health promotion, The Smoke-Free (Premises and Enforcement) Regulations 2006 (Smoke-Free (Premises and Enforcement) Regulations, 2006) were introduced to protect employees and the public from the harmful effects of second hand smoke. They may be deemed to be fiscally and market neutral at best but may have financial consequences as an unintended effect and, at the time of their coming into force, businesses such as licensed premises were particularly concerned about their potential effect on their trade.

The Environmental Protection Act 1990 (Environmental Protection Act, 1990) has as its policy objective the prevention of pollution to the air, land and water in an integrated fashion where such protection was provided previously in a piecemeal way.

2.6.1 Making markets work

Policy makers aspire to create perfect markets to ensure the efficient distribution of resources, provide optimal conditions for business, promote a high level of competition and therefore provide low prices for consumers (Sharpe, 1964). In a perfect market, consumer sovereignty is the natural result of competition between suppliers.

The free market ethos has dominated economic and consumer policy making in the UK since 1979 with the election of Margaret Thatcher as Prime Minister for the Conservative Party and it has remained so since notwithstanding the political, social and economic challenges it has faced and weathered. Evidence of this may be found in key consumer policy papers spanning

the period from 2000 with *'Modern Markets: Confident Consumers'* (DTI, 1999) to 2010 with *'A Better Deal for Consumers: Delivering Real Help Now and Change for the Future'* (Department of Business Innovation and Skills, 2009) in which market theory is applied to deliver benefits for consumers. In the period 2010 to 2015 the Liberal Democrat and Conservative coalition consumer policy aimed to provide clearer information for consumers rather than stronger intervention, as enshrined in the Consumer Rights Act 2015. The characteristics of a true free market are worth revisiting as they provide such an important part of the creed that informs consumer protection, regulation and policy.

The key features of a free market are the following:

1. That there are many buyers and sellers, therefore there is no concentration of market power and that all suppliers are price takers and not price makers.
2. That there are no barriers to entry to the market so that anyone willing to exchange at the market price may participate in the market.
3. That everyone sells the same thing; that there is no product differentiation and that goods and services are commodities.
4. That all the costs are borne by the seller and that all the benefits accrue to the consumer so that there are no externalities.
5. Finally, and perhaps most importantly in relation to food, that buyers and sellers have the same information, that there is perfect information and there are no information asymmetries (Ramsay, 1985).

Where markets bear the characteristics of a functioning free market the price of the goods or services will transmit all the necessary information and it is not necessary for governments to intervene other than to maintain effective optimum market conditions.

In classic market theory, consumers are able to make unfettered choices between price and quality. However, in relation to the nutritional content of food, the market does not work effectively because buyers (and possibly sellers too) do not have the information to be able to assess the quality of food as described in Ramsay's fifth characteristic of a functioning market above.

2.6.2 Making markets work and consumer behaviour – the application of market theory to the market for nutritional properties of food

It is instructive to look at the key reasons put forward for the range of consumer protection measures and, in particular, the chief reasons for regulation in food law. The market for food quality, by which we mean its safety and nutritional value, is not perfect. The principal reasons

for justification of consumer protection are to correct recognised market failure; in relation to food this is to put right information gaps between buyers and sellers (Caswell and Mojduszka, 1996). Sellers are, generally speaking, better informed than buyers and consumers may have misconceptions about the safety and quality of various foods. In choosing between different foods that form their diet consumers are making decisions based on their perceptions of the quality (e.g. risk or nutritional attributes) of the food that they buy. If consumers' perception of these is incorrect then this will distort the marketplace by sending the incorrect signal to suppliers about which products and characteristics consumers value highly and wish to be supplied with. As a result of the distortion, the market may be over or undersupplied with food with characteristics at variance with those which consumers wish to buy. In this case regulatory intervention directed towards the provision of information will aim to correct such distortions and alleviate their effect by allowing accurate market information signals to be transmitted (Caswell and Mojduszka, 1996).

2.6.3 Buyer behaviour - Search, experience and credence attributes

Perhaps the most important insights into the role played by information on consumer behaviour are those evolved from the work of Phillip Nelson writing in the *Journal of Political Economy* in the 1970s, specifically, but not exclusively, '*Information and Consumer Behaviour*' and '*Advertising as Information*' (Nelson, 1970; Nelson, 1974). In applying these insights to food markets, it is helpful to distinguish between search, experience and credence goods (Karni, 1973).

In relation to search attributes, consumers are able to ascertain the characteristics of a product before purchase. Generally, in relation to food, consumers have access to an abundance of information so that they may protect themselves. Consumers may directly examine the product by first hand inspection as in the case of face-to-face retail sales of food and by reference to the product description in the case of online sales. Alternatively, they may carry out a pre purchase enquiry. This is accomplished by investigation of the product by reference to independent research and product testing, critical review by journalists and public relations in media and increasingly, consumer feedback accessed quickly and at minimal marginal cost online. In relation to search attributes generally, advertising and marketing play the most important role and in relation to food, point of sale labelling will play a crucial role (Nelson, 1974). In food markets, consumers make frequent purchases. Search attributes for food may include colour or packaging but not those related to safety or nutrition. The effect of the availability of information, frequent purchasing and the relatively low value of the products is

that the market may be relied upon to effectively provide information to suppliers about the qualities that consumers value.

For experience attributes, 'consumers cannot determine the quality of the product until they buy and use it' (Caswell and Mojduszka, 1996). With respect to food, this would apply to its taste and other qualities which may only be determined by experience. Where products fall short of consumer expectations with reference to the price, information signals will be received by other consumers and will have the effect of deterring subsequent purchases and the market for food with its dependence on repeat purchasing will function effectively.

Where quality cannot be signalled and consumers make purchases based only on price (which is readily signalled) problem of 'lemons' as identified by Akerlof in relation to second hand cars, arises (Akerlof, 1970). Just as it is difficult for the seller of a high quality used car to communicate the qualities of his car which are hidden and therefore obtain a premium price, the same analogy may be applied to food markets. In the absence of intervention that requires disclosure, only lower quality products are offered for sale. (This does not mean that there is no market for premium quality foods at higher prices. There has in fact been significant growth in the market for such produce and the organic food market is one example of this (Yiridoe et al., 2005). However, the concern here is for the market for nutritional properties of food (Caswell and Mojduszka, 1996). The information asymmetry that exists because buyers are unable to assess the nutritional and health quality of the food provides sellers with the incentive to pass off lower quality food as high quality. Akerlof's highly influential paper, *The Market for Lemons*, provided the rationale for the 'Lemon Laws' consumer protection legislation to deal with defective cars which repeatedly exhibited faults. However, the theory has met with the criticism that it fails to take into account the reputation of the seller in relation to repeat purchases. The rationale of the Regulation on Nutrition and Health claims (EC, 1924/2006) is to provide information in order to correct the quality signalling problem rather than to impose a restriction or limit or ban on the sale of poor quality foods. This is done by the application of the Regulation to all commercial communications (Article 1) including advertising and labelling. The impact of the provision of information will depend on the extent to which consumers are responsive to such information and the transaction and search costs associated with finding the information.

With credence attributes, consumers cannot determine the quality of a product even after purchase and consumption. In this respect nutritional value of food is a credence good in that consumers are unable to assess the worth of food from a single experience and even in the

case of long-term consumption, it would be impossible for a single consumer to be able to isolate the effect of a particular food. For example, following consumption of a cholesterol lowering spread, an individual consumer will not be able to test the reduction in their risk of coronary heart disease claimed for it. The inability to isolate a cause and effect relationship between foods and their health or nutritional qualities and the latent effect of the consumption of foods makes *ex post* evaluation of quality so difficult that; 'informed consumer and reputational models of markets for quality do not apply here' (Caswell and Mojduszka, 1996). This analysis presents a challenge for regulators. In relation to nutritional content and health effects, the deficiency of information on the part of consumers and its effect on the market is apparent and therefore the argument for regulatory intervention is stronger. The nature of the informational failure will influence the regulation design.

One regulatory response might be to stipulate the nutritional levels required for specific foods. It is possible to ban or restrict the availability of foods with particular nutritional characteristics. However economic analysis drives us towards regulation where sellers must provide information about the nature and characteristics of their products (Viscusi et al., 1987). A striking example of this may be seen in the regulation of financial services where sellers are obliged to provide specific information in a specified format at particular points in the transaction. The benefit of providing such information is to maintain incentives for sellers to continue to compete to provide their products and to innovate for new ones and for consumers to use information to exercise the choice to protect themselves against poorer quality or unsafe products. Information is provided in a twofold manner: first, by the requirement for disclosure of specified information, for example, nutritional values of food and second, by the control of promotional claims, for example health effect claims. Both of these forms of control are evident in the Regulation.

Information requirements have the effect of transforming credence and experience attributes into search attributes. For example, mandatory nutrition labelling rules that require the fat content of the food to be displayed makes such a characteristic a search attribute and as such it may be verified by the consumer reading the label. The effect of this on the market is that it improves the quality signalling so that the market for quality attributes functions effectively and deals with the problem identified in Akerlof's Lemons theory.

The impact of labelling on the quality of food is difficult to quantify. Information and labelling is only one factor in the mix of influences on consumers in their choices between products and factors such as price, context and choice architecture may play significant parts (Jolls et al.,

1998). Notwithstanding this, Ippolito and Mathios' study of consumer behaviour in response to the information about the health benefits of cereal consumption found advertising to be of major importance (Ippolito and Mathios, 1990).

Caswell and Mojduszka find evidence in their work that information can play a positive part in consumer decision making. In turn, this provides a confident outlook on informational labelling and a reason for optimism in relation to the Regulation's ability to achieve its goals:

'Informational labelling requirements are likely to have a significant impact on demand patterns and the dynamics of markets for food quality. As information about quality and use characteristics improves, manufacturers will compete for market shares from sales to attribute conscious, label-using consumers. Products and industries with less desirable quality profiles may reformulate or redesign processes to avoid unfavourable comparisons with other products.' (Caswell and Mojduszka, 1996).

2.6.4 Regulation defined

There is no universally agreed definition of the term 'regulation' and therefore this makes it difficult to arrive at a precise meaning for it. Indeed, as Ogus observes, regulation has a 'bewildering variety of meanings' (Ogus, 1994). Regulation denotes different things depending on the context. Even in this narrowed down legal and quasi-legal context, the term has several meanings. The traditional view of regulation is that it is an authoritative and mandatory rule or a set of rules or laws created by an administrative body. The Oxford English Dictionary defines regulation as 'a rule or principle governing behaviour or practice' (OED, 2015). The Cambridge dictionary defines regulation as 'an official rule' or the 'act of controlling' (Cambridge, 2005). The Better Regulation Task Force has a much broader definition; 'any measure or intervention that seeks to change the behaviour of individuals or groups' (BRDO, 2015b).

The idea of regulation as a rule may not provide the whole story and may therefore be misleading. It is more helpful to contemplate regulation as an ongoing process rather than in terms of a set of rules or even as a single desirable particular outcome (Feintuck, 2004). Notwithstanding the fact that the idea of a process is captured in this definition by Feintuck, it omits an essential element: that of the public nature of regulation. A potentially more valuable model for regulation for this research is Selznick's definition of 'a sustained and focused control exercised by a public agency over activities that are valued by a community' (Selznick, 1985). Of course, truthful commercial communications for food are valued by society. Perhaps they rank behind risks such as food safety but their potential impact on the health and

economic welfare of consumers is significant. The public element in relation to nutrition and health claims is provided by local and central government agencies.

2.6.5 Rationale for regulation

Having established a working definition for regulation the next question is when is regulation necessary or desirable? According to Tombs, regulation is necessary to protect us from the most dangerous behaviour and its consequences because without regulation there would be 'death, injury and illness...not to mention systemic cheating, lying and stealing' (Tombs, 2002). One of the more commonly cited and prosaic reasons for regulatory intervention is that it is designed to protect consumers (Ogus, 1994). The protection of consumers is the justification for the regulation of health and nutrition claims. By restricting the claims which may be made for foods (the term 'food' includes drink throughout this thesis) the government is seeking to change the behaviour of food suppliers to only make claims for foods where they can be justified and for consumers to be better informed about the health and nutrition properties of the food that they consume. This may then in turn lead to the benefit of consumers being able to choose and consume healthier foods as a result.

While the law provides for minimum standards for food safety with statutes such as the Food Safety Act 1990 (Food Safety Act, 1990) prohibiting the sale of unsafe food, classical economists view food safety as a commodity like any other with the interaction between supply and demand to decide a market 'price' for that safety. Government intervention in making food safe can be justified on the basis that consumers are not aware of and do not have the expertise to assess the risks associated with food that might be unsafe. The problem arises as a result of the latent nature of the risks and from the failure of the price mechanisms to reflect the full costs or benefits of changes in food safety (Henson and Caswell, 1999).

The rationale behind the regulation of health and nutrition claims is to allow consumers to make informed choices in relation to their diet and health. As the risks involved are not as acute as those which arise in food safety, this may be argued to be a more paternalistic intercession by the state. It is one that is based on protecting consumers not from the risks of imminent illness or death from harmful food but to enable them to obtain the benefits of food which may have properties that have been demonstrated to profit their health (Brennan, 2008). Regulation as an intervention in markets for the purposes of consumer protection is a long established and widely used rationale for law making (Breyer, 2009). However, it is defining consumer protection and determining the form it should take which is arguably more problematic. As Ramsay (1985) states, 'there are three fundamental questions in consumer

protection: 'Why do consumers need protection? When ought governments to intervene to protect consumers? And finally – how ought governments to intervene?'. In terms of the objectives of consumer protection, there are, according to Ramsay, two central objectives for regulation of the consumer marketplace: '(a) the improvement of economic efficiency by remedying market failures; and (b) equity (Ramsay, 1985). In the context of the regulation of health and nutrition claims, it is clear that only the former objective provides the basis of the law. In fact, experience suggests that better off consumers may benefit more from the regulation than poorer ones (Law, 2003).

There exists, at least in theory, a difference between economic and social regulation with justifications for a regulation predominately based on economic grounds. In such cases, economic regulation is aimed at promoting competition and ensuring consumers enjoy the benefits of competition. Much of our understanding of the relationship between regulation and economics is based on the highly influential work of Stigler *inter alia* (Stigler, 1971). Social regulation is concerned primarily with consumer protection albeit often using economic tools in order to achieve its goals. In this respect, is impossible to isolate the two types of regulation as any attempt at social regulation will have an economic effect. An example in nutrition and health is the use of taxes or subsidies to discourage or promote the consumption of particular foods. In addition, the effect of mandating minimum standards of food safety or labelling requirements will affect the costs of production for the supplier and the final cost to the consumer.

Commentators such as Cranston argue that the distinction between economic and social regulation is artificial because they both have in common the application of coercion at their core (Cranston, 1982). Similarly, Feintuck argues that economic and social regulation may be consolidated into the single concept of 'the public interest'; a commonly used phrase in legal reasoning but one that faces similar problems of definition as regulation. However for those economists with a general presumption against state intervention, such as Posner, regulation is deemed a well-intentioned but futile attempt to promote the public interest (Posner, 1974).

2.7 Why regulate health and nutrition claims?

The regulation of nutrition and health claims is a qualitative measure aimed at protecting the public interest by ensuring that the information provided to sell foods is not misleading. It represents a further step along the line of intervention beyond mere safety. This progression is predicted by Richardson et al who claim that once the minimum safety standards for

regulation are met, it seeks to extend to matters which go beyond the original intentions and which seem removed from what is required in the public interest and safety (Richardson et al., 1982). For example, requirements which depict the size of font to be used on labels.

Regulation is frequently advanced as a solution to societal problems. What then is the problem which regulation on health and nutrition claims are trying to solve? The problem is the impact of poor diet on health and more particularly the potential for misleading consumers about the health and nutrition properties of particular foods. The problem, as is often the case with regulation, is that it has unintended consequences and sometimes it may even be argued to have the opposite of the effect that was originally intended for it. For example, where regulation is proposed to raise standards and protect consumers, such measures may be supported by incumbent suppliers as a way to control market entry under the guise of maintaining standards (Stigler, 1971). The effect for consumers is therefore to maintain higher prices by curtailing competition and allowing inefficient suppliers to maintain profits. In relation to nutrition and health claims, the requirements of the Regulation may be represent a costly hurdle for smaller businesses and a barrier for potential new entrants.

There is no doubt about the marketing potential for nutrition and health claims. The shelves of every supermarket are heavy with the weight of products that claim to defend against infection with friendly bacteria in a yoghurt drink, tea and coffee that is rich in antioxidants that will ward off cancer and the effects of aging and spreads that will reduce cholesterol. Consumers are not in a position to test these claims and the regulation is therefore aimed at ensuring that the claims are supported by scientific evidence (Economist, 2009a).

The promotion of health is a vital and constant issue. As an illustration of this point, two brief but salutary examples of reports of health problems that may be linked to the consumption of food maybe found below:

1. 'Over the past 30 years, circulatory diseases including ischemic heart disease and stroke, have been the most common cause of death in the UK for both males and females.' (Office for National Statistics 2008).
2. Obesity alone costs the UK £6.6 to 7.4 billion per year (House of Commons Health Committee, 2004).

While the picture of the growth of obesity has been variable in different areas, the prevalence of childhood obesity has risen worldwide in less than one generation (Lobstein et al., 2015).

The Global Burden of Disease 2010 study found that the major causes of death worldwide are non-communicable diseases: primarily heart disease and diabetes associated with obesity. In 2013 some 32 million adults aged between 20-79 had diabetes. It is estimated at around 20% of the EU population or 150 million people are obese. The cost of treating diabetes is estimated at around 100 billion euros. Diet is considered to play a significant role in the risk factors for both heart disease and diabetes (Lim et al., 2013)

Consumers are provided with more information about what they eat and they are interested in the relationship between diet and health. This interest is reflected in the volume of health journalism and 'lifestyle' advertising and by the proliferation of health and nutritional material in broadcast television. In relation to health and nutrition claims specifically, there is an increased tendency to promote food through advertising as a type of medicine with curative properties. A content analysis of magazine food advertising for the period 2000 – 2008 found there was an increase in health and nutrition claims among other health related food promotion (Zwier, 2009).

Reliable nutrition and health claims will enable consumers, particularly those from vulnerable groups with particular nutritional requirements or with different genotypes to implement dietary advice. It could even allow for the application of 'personalised nutrition' plans linking genotyping with specific nutritional advice to reduce the risk of chronic diseases associated with diet (Joost et al., 2007).

Evidence based nutrition and health claims may promote 'sustainable nutrition'. By successfully communicating reliable nutrition and health data relating to foods, consumers will be able to implement efficient nutrition plans and avoid environmental impacts of the wasted cost consumption based on false or unsubstantiated claims (Lettenmeier et al., 2012)

2.8 The link between diet and health

There is overwhelming evidence supporting a link between nutrition, diet and better health and the prevention of disease (Hu, 2003). Therefore, it would appear that there are real benefits to consumers from improved diet. The advent of functional foods, 'foods that claim to improve well-being or health' (Katan and de Roos, 2003) and the use of claims to promote such foods may lead to improved health as consumers may make better choices. Alternatively, the promotion of such foods may, in itself, be potentially misleading and dangerous to consumers

by giving consumers the impression that certain foods may provide a 'silver bullet' for good health and disease prevention (Dwyer, 2001). A third option is that food suppliers make fraudulent claims for health benefits for foods that in fact do not have such properties.

In truth a 'fundamental public health nutrition principle is that it is the total diet, not individual food products that determine health' and that 'there is no such thing as good or bad food, only good or bad diets' (Lawrence and Rayner, 1998). In the words of Sue Davies, Chief Policy Adviser at *Which?*; 'people embrace food products offering health benefits because there's a natural tendency to go for the quick fix rather than cut down on saturated fat, sugar or salt, or eat more fruit and vegetables.'(WHO, 2009).

What are the main functional foods for which health and nutritional claims are made? The current market is made up principally of breakfast cereals fortified with vitamins, probiotic yoghurts containing 'friendly' bacteria and cholesterol lowering margarines containing plant stanols, but there are also breads, ready meals, fruit juices and bottled waters for which similar claims are made. What are the health benefits that are claimed for such foods? They are mainly problems associated with aging or with the development of children; including heart and digestive health and bone structure and growth.

2.9 The link between health claims and increased consumption of functional foods

The sale and promotion of such food by the food industry assumes that there is a link between the making of nutrition and health claims in advertising and marketing and the increased consumption of such foods. However, the success of this sales and promotion activity depends on consumers being aware of and having understood the health claims made for a particular food and their expectation that they will enjoy the benefits of consumption as promised by the supplier. On the other hand, proponents of restrictions on the promotion of food containing high fat, sugar and salt base their case on the presumption that there is a link between advertising of high fat, sugar and salt foods and their consumption. Many of these assumptions are untested and the evidence for them is patchy at best.

There are difficulties with defining 'healthy' foods. A product such as milk or cheese may be high in a specific desirable nutrient, for example, calcium and at the same time contain high levels of an undesirable type of nutrient, in this case, fat. Some consumer groups, for example *Which?*, have argued that nutrition and health claims should not be permitted in the promotion

of such products as it may lead to their increased consumption especially among children. The US Food and Drug Administration approach is that if a food has high levels of fat or salt than this will automatically undermine any health claim.

2.10 Changing behaviour - aims and effectiveness of the Regulation compared with advertising and self-regulation

Types of regulation range from the economic, which includes the regulation of prices or sets conditions that are required to be met for entry to a market, to social regulation covering health.

The normative theory of economic regulation places emphasis on the role of markets. The rationale underlying normative measures include the correction of market failure and encouraging of competition (Peltzman, 1977). Commentators in the area of economic regulation have been highly influential in setting the policy agenda. The same commentators often criticised the efforts of governments in attempting to achieve social purposes; for example improved health or environmental benefits where price controls and entry conditions were seen as inadequate (Stigler, 1961).

Consumer protection law has largely adopted the market approach towards regulation. In line with economic theory, this involves the assumption that consumers act rationally and in their self-interest. Underpinning this is an economist's respect for consumer sovereignty. That is, consumers are best placed to make choices for themselves and that where government has tried to influence those choices in order to deliver a policy goal, this has resulted in failure coupled with inefficient allocation of resources and protection of incumbent interests (Ramsay, 1985).

The presumption has been challenged by behavioural economists seeking to apply insights from psychology to understand consumer behaviour and the implications that has for policymaking and regulatory design. The manifesto for nudge theorists is the book by Richard Thaler and Carl Sunstein, *Nudge* (Thaler, 2008). The influence of behavioural economics in policy has been marked. In 2010 the UK coalition government set up a 'nudge unit' within Cabinet Office with the aim of improving consumer economic choices. The key area in which the policy will play a part is health (Wintour, 2010). Since 2014 the unit has been independent of government and is known as the Behavioural Insights Team. However nudge will also play a direct part in influencing consumer policy and there is an explicit reference to 'nudge' in the Department for Business Innovation and Skills consultation *Empowering and Protecting*

Consumers of June 2011, referred to as 'light touch consumer empowerment – how we can 'nudge' people to make better choices.' (BIS, 2011a)

According to nudge theory, our choices are inconsistent and depend on the context. The theorists construct the idea of 'choice architecture' to describe the way in which what we choose depends on the way that choice is framed and that the results can be arbitrary and unstable (Thaler, 2008). Its advocates argue that nudge represents a benign and innocuous way of helping consumers make the right choices which will make them healthier, wealthier and happier. The opponents of nudge argue that it represents paternalism under a different guise and undermines the respect for an individual's right to make his own choices without unnecessary state intervention. They find that its apparent innocuousness is disingenuous and therefore dangerous (Bernheim and Rangel, 2009).

In considering Nudge theory and the broader issues in behavioural economics the debate has a clear political dimension and the fundamental fault line of liberalism and paternalism is raised.

In order to deal with the question of how, if at all, to restrict the promotion of foods, we need to ask what is the regulation seeking to achieve? Is it to improve the health of the population or is it merely to provide transparency and to provide better information to consumers so that they can make informed choices? Subject to the answer to that question, a further question arises; is regulation the best way to go about achieving the purpose?

Free marketers would argue that intervention by government or regulators in markets is generally ineffective; 'The history of government regulation vividly demonstrates the inability of the political process to cure a failure of the market process.' (Seldon and Robinson, 2004). As Boddewyn observes 'It is too readily assumed that if the market fails, only government regulation can correct its shortcomings.' And that, 'there are readily observable limits to what regulation, as a form of societal control, can achieve.' (Boddewyn, 1986)

This criticism of law making may be considered as one based on pragmatism rather than principle; that whatever the case for intervention by reference to economic and behavioural models, it does not follow that such intervention will be successful in achieving the outcomes that it sets out to deliver. The real world turns out to be more complicated and confounds the theory.

The opposing view is that there is a market failure in the sale and promotion of food as a result of an information asymmetry and direct intervention is required beyond simply creating the right conditions for a competitive marketplace (Spence, 1975). Furthermore, the risks to consumers are such that market forces cannot be relied upon to achieve policy aims of improved health and the risks of the harm that may follow can justify intervention. What is the most effective way to promote health? Is banning or restricting the promotion of health claims the way to promote better health or should consumers be provided with the information to be able to make informed choices?

The question of justification of intervention by the state is not just a political one. There is a practical dimension: the experiences of the curbs on smoking seem to indicate that marginalising harmful behaviour is as important as imposing restrictions. 'Nudge Theory' (Jolls et al., 1998) has its roots in libertarian free market ideals but the arguments for it are based in pragmatism, i.e. that it may work, rather than in ideology.

2.11 Self-regulation

Prior to the regulation from the EU, health claims were dealt with by industry self-regulation, in particular under the Joint Health Claims Initiative (2007, 2007). This is in keeping with the UK's proclivity for self-regulation over legislation. As early as 1989 it was observed that 'Britain appears to be something of a haven for self-regulation' (Baggott, 1989). This observation continues to be true and in fact, Britain has influenced the EU in its regulatory design towards greater use of self-regulatory models. The role of self-regulation and the case for and against it is well established (Senden, 2005). For advocates, self-regulation, when compared to legislation, is flexible, quicker and cheaper. For its critics, self-regulation is ineffective because it is not taken seriously by industry and regulators are toothless because they lack real powers and an effective sanction (Ogus, 1995).

2.12 Advertising

In one view of advertising, it 'can contribute to consumer dietary knowledge and subsequent behaviour' (Brennan, 2008). There is evidence to suggest that commercial communications provide information in a form that is more readily accessible to consumers and especially to disadvantaged groups (Ippolito and Mathios, 1990). (The proposal is subject to scrutiny later by close examination of the models used by Ippolito and Mathios in relation to the cereal market.) The question of how such communications are regulated needs to be carefully

considered in the light of the possible unintended consequences of the restriction of information to consumers. This is not however an argument for misleading and spurious claims to be permitted. The removal of restrictions on the promotion of foods would result in the undermining of claims that can be justified and this may damage consumer confidence and contribute to consumer scepticism in nutrition and health claims made for industry as a whole. Whatever the evidence of the efficacy of the use of nutrition and health claims in the promotion of foods, such claims have been seized upon and put to use with gusto. Today you 'can't walk down the aisle of a supermarket in any developed country without seeing ads touting the benefits of additives, such as omega-3's/DHA, lycopene or antioxidants. Even sugar-packed fizzy drinks proclaim their 'electrolyte value' and call themselves 'sports drinks' (Patel, 2012). But does adding vitamins to sugar water make it any healthier? And what about adding extra bacteria to yoghurt?' (WHO, 2009). Therein lies the problem; consumers are baffled by the sheer volume and questionable reliability of information and find it difficult to distinguish from those claims grounded in established research that are meaningful, claims that are controversial and yet unproven and the mere puff of sales gimmickry. 'If the only real function behind such labels is to bolster profits, consumers and regulators will eventually see through the hype' (Economist, 2009b) . This is notwithstanding the attempts at consumer education by government sponsored advertising campaigns to promote health such as 'Change4life' aimed at equipping consumers to be able to navigate and discriminate between the various types of claims.

2.13 The regulatory response: The European Commission's regulation on nutrition and health claims (EC No 1924/2006)

The European Union has passed legislation on the control of nutrition and health claims to 'better inform consumers and to harmonise the market'(EC, 2003). These aims appear to be modest claims for the benefits of the regulation and it is noteworthy that they stop well short of the more magnanimous aim to improve public health. In fact, there is no assumption that regulation of the claims made by advertisers and suppliers will lead to the goal of better health for consumers. Indeed to make any such claim would be unwise in the light of the unproven assumptions that need to be made to demonstrate a causal relationship between regulation of information and improvements in health. When placed in the context of the bold ambition of the potential improvement of consumer health and welfare, the aim to provide better information appears diffident.

In relation to harmonisation, the EU aims to remove the barriers to trade raised by the differences between country's regulatory regimes: 'differences between national provisions relating to such [health and nutrition] claims may impede the free movement of foods and create unequal conditions of competition. Thus they have a direct impact on the functioning of the internal market.' (EC 1924, 2006). Of course, harmonisation of the market relates to the general EU aim of the free flow of goods and services, the internal market, and this is examined within this thesis. It should be noted however that this aim relates primarily to the functioning of the internal market and not to consumer protection.

A recent study investigating the likely impact of the EU regulation on broadcast advertising, examined the potential impact on one entire week of free to air broadcast commercial television. In respect of the Regulation and its impact on advertising, the study found that, 'little is likely to change in terms of claims currently being made...because most advertisers rely on nutrition content claims or comparative claims...which are fairly easy to substantiate; in the case of nutrition content claims, they generally do not make any direct health claim.' (Brennan, 2008).

That there is a reluctance by promoters to compete on the basis of health claims may be a reason for disappointment. The promise seems to have been whittled down from the potential for the improvement of general health to one of minimal impact on the content of food advertising. Therefore this thesis is concerned as much with the role of regulation and its limitations as with the intended outcomes of a proposal.

The Regulation takes a two pronged approach: firstly in relation to nutrition, and, secondly in dealing with health claims. Nutrition claims are concerned with the content of the food and may refer to what is or is not in it. For example, 'low fat' or 'high fibre'. The Regulation is aimed at harmonising the use of such claims so that products claiming to be 'high fibre' have a defined minimum amount of fibre per a defined unit. It does this by the creation of nutrition profiles that set out the standards which foods must meet in order that defined nutrition claims may be made for them.

Health claims refer to what a food or an element in a food does to the consumer. 'Health claim means any representation that states, suggests or implies that a relationship exists between a food or a nutrient or other substances contained in a food and a disease or health-related condition' Codex Alimentarius Third Edition 2006 (WHO, 1963). The rationale behind the legislation is that health claims must be backed up by scientific evidence. Some health claims are well established: such as the proposition that calcium is important in promoting healthy

teeth and bones. Other health claims are more controversial such as the alleged relationship between whole grain and the prevention of coronary heart disease. The Regulation prohibits health claims unless they can be substantiated. The Commission has produced a list of established health claims which may be used by producers to enable them to be able to make a meaningful claim. As a result, consumers should be able to rely on clear and verifiable claims.

The response of the food industry to the Regulation has been cautious. The Confederation of Food and Drink Industries of the European Union (CIAA) fears that the higher standards in the Regulation may lead to reduced innovation in the production of food and less consumer choice and that it will not necessarily succeed in promoting better understanding of nutrition and health by consumers (WHO, 2009). Also the requirement for approval from the EU being contingent upon the submission of a full scientific dossier places small to medium sized enterprises at a competitive disadvantage when compared to better resourced multinationals. Only the largest concerns will have the reserves and access to expertise and resources to be able to compile the supporting evidence required for a claim to obtain approval.

In the case of Probiotics, the industry claims that the evidential burden on producers is too high and that the effect of the regulation will be catastrophic; 'the regulation is killing this industry and the job losses are already being felt' Ioannis Misopoulos, director general of the International Probiotics Association (IPA). Notwithstanding such criticism, a review of the systematic review process applied by the European Food Safety Authority (EFSA) in assessing claims made for probiotics found that it was 'reasonable' to use this well-established method of assessment of the totality of the evidence (Glanville et al., 2015).

By July 2009 the EFSA had received and assessed 70 claims of which 54 had been rejected. By 2012, there were 222 approved claims (EU Business, 2012). In 2015 EFSA had published 256 authorised claims out of the 44,000 that it had received (EFSA, 2015). The result of such apparent stringent application of standards may be that producers are deterred from applying for approval at all. Therefore an unintended consequence of the Regulation may be that the decision not to apply for approval and rejection of unsuccessful claims will lead to consumers receiving less information about nutrition content and health properties of food.

Even where claims are approved, the requirements imposed on suppliers by EFSA relating to their use are so 'dull' and unattractive to consumers that they were too difficult to use such wording deterred consumers from gaining the benefits from functional foods (Chen, 2015). This is a view held by some nutritionists including Dr Carrie Ruxton who claims that 'EFSA-

approved health claims make it hard for firms to create exciting wording on functional food products'. As a result, consumers did not notice healthy foods because the claims mean nothing to them. An example in support of this theory is how a product which benefits the immune system is required to be labelled as potentially able to; 'play a role in the normal function of the immune system'. This was found to be uninspiring. The loss to the food industry attributed to restrictive health claims was estimated at £27 billion (Foodmanufacture.co.uk, 2015).

Health claims that are made for foods may begin to resemble the claims made in the promotion of drugs in their certitude. The analogy between the marketing of foods and drugs is instructive. The sale and promotion of drugs is strictly controlled. The licensing of drugs is subject to approval by the Medicines and Healthcare Products Regulatory Agency (MHRA) which is concerned with their safety and efficacy. The claims relating to the efficacy of drugs must be substantiated by evidence obtained as a result of clinical trials and drugs will not be licensed for distribution unless their benefits outweigh their risks. The approvals system set up under the EC Regulation 1924/2006 for health and nutrition claims for food and the requirement for substantiation of claims brings food closer in line with medicines. However, there are important differences between food and medicine and the requirement for evidence should not remove that distinction by 'medicalising' the supply of foods. It would be undesirable for the supply of food to be subject to a licence the terms of which required a prescription from a medical practitioner in response to a specified condition. (Lawrence and Rayner, 1998). On the other hand, consumer trust and confidence in the food industry relies upon evidence that the products can in fact provide the benefits claimed for them. 'If food companies wish to make the sorts of claims about their products that pharmaceutical companies do, they must be prepared to submit to similar scrutiny. 'Extraordinary claims, require extraordinary evidence.'(Economist, 2009b). In so far as it is possible, the rules should be 'industry neutral ' in that they do not create one regime for drugs in which say, a particular claim requires evidence and a separate one for food where a similar claim may be made but which is not subject to the same scrutiny. To provide different levels of scrutiny depending on whether a product is classed as a medicine or a food but for which similar claims are made would create a regulatory loophole through which products may be passed resulting in distortion of markets and confusion among consumers. This could be said to exist under the current regime, where for example, the cholesterol lowering effects of oats or butter substitutes are treated differently to cholesterol lowering effects of drugs such as statins. The differences may lie in the degree rather than in the substance of the claim.

2.14 The chain of causation

In creating a regulatory framework and enforcement policy for nutrition and health claims there are many assumptions which may not be proven. Health claims are required to be substantiated by evidence which is likely to be obtained by clinical trials. Such trials demonstrate the effect of the food or nutrient in individuals rather than populations therefore the findings of clinical research may be of limited relevance to public health policy and regulation. A further assumption is that the consumer has read and understood the health claim. This means that the claim is made in plain and intelligible language and that their level of nutritional education is sufficient for them to appreciate its content. It may follow from that the consumer was influenced by the health claim and acted upon it and purchased the food and consumed it in the context of a diet which would yield such a benefit. If the benefits are in fact realised, it will then follow that this will lead to improved health for the consumer and an increase in sales for the supplier. The flaws and possible breaks in the chain of causation are evident.

2.15 The application and enforcement of nutrition and health claims

The importance of the Regulation cannot be overstated. The control of the marketing of foods affects all of us in the claims to which we are exposed and consequently our everyday choices about what foods we consume. An illustration of the extent of the part played by health and nutrition claims is provided by a survey of the Irish food market in 2007. The survey found that some 47% of packaged foods contained a nutrition claim and some 18% a health claim (Lalor et al., 2010). Similarly a study in Australia presented a widespread use of health claims (Ni Mhurchu et al., 2015).

A nutrition or health claim has little effect unless consumers in fact read it. In this regard, several studies conducted in Australia or New Zealand have shown that up to 85% of people, particularly those most vulnerable groups with special health needs claim that they read nutrition and other health related information found on food labels (Worsley, 1996; Cowburn and Stockley, 2005; Mhurchu and Gorton, 2007; Harris et al., 2011). However an observational study actually shows this to be a much smaller percentage (Grunert et al., 2010). Prior to the Regulation, there was no harmonised legislation governing the use of health and nutrition claims. Member states of the EU were left to control such claims at national level and as described above there was no specific regulation in the UK but general legislative control of misleading advertising under the Control of Misleading Advertisements Regulations 1988 (Control of Misleading Advertisements Regulations, 1988) and the self-regulatory codes of the ASA.

Apart from the issue of legislation, there is the equally important question of how the law is to be enforced. Whereas the Regulation provides a universal approach to the regulation of health and nutrition claims, the same cannot be said for enforcement, which remains a matter for member states. Notwithstanding the comprehensive approach of the Regulation, the lack of effective enforcement or the differences in the approaches of the member states may yet jeopardise the aims of competition and consumer protection of the Regulation.

2.16 A brief history of the enforcement of claims relating to food generally

Historically, enforcement has been linked to oppression by the land owning wealthy of the working poor (LeGoff, 1988). Such a view of enforcement has all but disappeared to give way to a modern view of enforcement which is often justified as a way to protect the most

vulnerable consumers. An example may be found in the Consumer Protection from Unfair Trading Regulations 2008 (The Consumer Protection from Unfair Trading Regulations, 2008). The regulations set a benchmark of the average consumer for assessing whether a practice is unfair and in addition it creates the standard of the vulnerable consumer in order to provide additional protection to consumers that might fall into this category.

The history of consumer protection is in some ways the history of the enforcement of claims relating to food in that the earliest records of formal consumer protection concern the sale of short measures or adulterated food. The Assize of Bread and Ale of 1266 regulated the weight of the Farthing Loaf, and the quantity of a Penny of Ale according to the price of the ingredients (Patricia, 2006). The principle adopted by the assize of bread was straightforward; 'a unit of loaf would be sold at a constant price (usually a farthing or halfpenny) while its weight would vary according to changes in the market price of grain. 'As the price of corn increased, the size of the loaf would decrease and vice versa.'(Davis, 2004). This would ensure that the poor would be able to buy a loaf of bread costing a farthing (the smallest unit of currency in use at the time) even though they would receive less bread for the same money.

The significance (as distinct from the efficacy) of the assize cannot be underestimated. The legislation remained on the statute books until the 19th Century and it was 'one of the most widely enforced statutes in medieval England' (Davis, 2004). The penalties that were imposed for the breach of the assize were severe: bakers or brewers who gave short measure could be fined, put in the pillory (denounced, humiliated) or flogged.

The enforcement of the legislation was the remit of the Clerk of the King's Market. This arrangement of laws or standards with a designated organisation for enforcement has provided the blueprint for today's Trading Standards departments. The Assize represents not only the earliest attempts at UK food law but it also provides one of the first attempts at regulation of trading and commerce. However it is the Food and Drink Act 1860 and the Public Health Act 1875 that have provided the framework of the existing law (Bradgate, 1991). These are general in their application to all foods but a study of the milk trade in London provides an illustration of the risks that it was designed to deal with, ranging from ill health and disease to adulteration. According to Whetham (1964) 'to discourage adulteration was the object of the first legislation dealing with milk; as 'the germ theory' of disease became generally accepted, public health authorities sought, with varying degrees of enthusiasm, to enforce minimum standards of cleanliness and hygiene in cowsheds, dairies and milk-shops.'

Unscrupulous producers and traders would add sawdust to bread dough, grease to coffee and even sulphuric acid to vinegar. Where adulteration resulted in widespread serious illness or even death, the tradesmen could be executed (Whetham, 1964).

Modern food legislation is characterised by one of three aims: concern with adulteration, public health and quantity. Evidently, the Assize adopted a more holistic approach by dealing with all three in a single pronouncement. However the primary aim was to ensure that there was a reliable supply of bread, a vital foodstuff to the population, according to Davis (2004) 'the assize of bread was not merely intended as an instrument to protect consumers, especially the poor, but that its aim was also to provide bakers with an adequate living whatever the price of grain'. This was a measure of price and income control, a financial distribution measure with a clear social aim, ensuring that suppliers of food were not able to exploit consumers by raising prices to a level which might risk upsetting the social order.

Not surprisingly, the aims of the assize reflected the concerns of medieval. In the same way, modern food law can hold a mirror up to the concerns of modern consumers. And, in this respect, the law relating to health claims attempts to deal with the legislative aspect which is of most concern to consumers: the relationship between nutrition and health. Evidence of this may be found in a survey conducted by the International Food Information Council in 2009, where in response to the question, '*How interested are you in learning more about foods that have health benefits beyond basic nutrition?*' 85% of American consumers said that they were somewhat or very interested.

2.17 Enforcement: the economic and socio legal perspectives compared

Along with similar market driven consumer protection, the aim of the Regulation on Nutrition and Health claims (EC, 1924/2006) is to provide adequate and reliable information for consumers to be able to make informed food choices (Caswell and Mojdzuszka, 1996). An information asymmetry exists between suppliers and consumers of food which cannot be resolved in the absence of regulatory intervention. This is because consumers are not well placed to judge the nutritional and health characteristics of a food as such attributes are latent and difficult to discover. Therefore the problem arises where more readily assessed attributes such as price and sensory qualities of a food dominate consumer decision-making (Akerlof, 1970) and the outcome may be poorer health and obesity for consumers. The consequence

of this is that the general ambition of health policy of improved welfare for the population may be undermined by the ill-informed decisions of consumers.

The economic analysis of enforcement is expressed in terms of the cost benefit equation: 'According to the economic approach to law enforcement, economic actors will comply with regulation if and only if the benefits of compliance with regulation exceeds the costs' (Law, 2006). Therefore, the focus of the literature in the economics of law enforcement is directed towards the question of how regulated businesses are affected by the penalty for breach of the regulations. This means that the size of the sanction and the risk of being caught combined must be such that together they amount to a sufficient deterrent to make a rational business comply with the regulation (Becker, 1974; Stigler, 1974; Polinsky and Shavell, 1999).

Similarly, policy of 'optimal deterrence' where the enforcer 'tries to establish how a trader is likely to behave in different circumstances, and takes the decision whether or not to prosecute accordingly' is founded on the rationale that enforcers should minimise harm at the lowest cost.

According to the economic theory, effective regulation is achieved by setting appropriate financial penalties and conducting the optimal level of monitoring. However, does this analysis actually explain the enforcement of food law in practice? Litigation, whether civil or criminal, plays an important role in this theory as providing the sanction; but the threat of legal action with the aim of deterring non-compliance is diminished when considering the financial costs and risks of using courts 'ex post' or after the event. This raises a question about the efficacy of such an approach, and whether it actually provides a sufficiently compelling account that describes the relationship between the enforcer and the regulated business. Moreover, does the economic theory adequately explain the behaviour of businesses? Furthermore, does it provide a sufficient basis to inform enforcement strategy? Finally, to what extent can behaviour be controlled or influenced by legal penalties based on a 'command and control' policy?

An alternative analysis of enforcement maybe found in political science and socio-legal studies. In this analysis changing constituent or political feedback or changing costs of regulatory action, specifically resource constraints, are key determinants (Olson, 1996). Specifically, budget constraints and a deregulatory political agenda augment less resource intensive enforcement action away from multiple routine inspections and investigation with eventual litigation and towards fewer targeted inspections with education and cooperation playing a significant role.

The most influential depiction of the socio-legal perspective is provided in the work of Keith Hawkins and Bridget Hutter. Hawkins and Hutter capture the central difficulty thus; 'the task of a regulatory bureaucracy is, by various means, to induce a potentially unwilling business organisation to bear costs which it would in many circumstances not wish to assume' (Hawkins and Hutter, 1993).

Examining how enforcers enforce and the aims that they seek to achieve may provide an understanding of how the law, sanctions and enforcement strategies may be used to control business and thus inform regulatory design. It is with this in mind that this study identifies the common enforcement practices of environmental health and trading standards officers.

One view is that enforcement of the law refers to legal action. This is known as the deterrence model (Reiss, 1984). In this model the methods of enforcement are penal and adversarial and prosecution plays an important role and there is greater reliance on imposing sanctions (Hutter, 1989). By contrast, the accommodative model of enforcement seeks to secure compliance by the remedying of existing problems and the prevention of others. In the accommodative model, compliance is achieved by cooperation and negotiation. The methods used to ensure compliance are persuasion, negotiation and education. The use of legal action, particularly prosecution, is regarded as a last resort to be used only in the event that everything else has failed (Hawkins, 1984). In this model, according to Hawkins (1984) 'the importance of legal methods lies in the mystique surrounding their threatened or possible use rather than their actual use'.

In the accommodative model of enforcement officials 'educate, persuade, coax and cajole' (Hawkins, 2002). The strategy is underpinned by patience and understanding (Braithwaite et al., 1987). A further refinement of the accommodative approach is the insistent strategy where there is not an unlimited supply of patience and there are clear limits to the tolerance of enforcers. As Braithwaite, Walker and Grabosky note, there is an important and empirically significant middle ground between the sanctioning and compliance models identified in the binary model of enforcement (Braithwaite et al., 1987). This insistent strategy forms part of that middle ground where enforcers are flexible both in their interpretation of the rules and in their readiness to use legal coercion (Bardach and Kagan, 1982). An example of the insistent model in practice is the use of improvement notices in food hygiene cases where a business is given a limited time to remedy a specified breach failing which legal proceedings will be issued. Such notices are not generally issued in food standards cases and therefore there is

no equivalent step available prior to the issue of proceedings in cases of the breach of the Regulation.

Both the deterrence and the accommodative models of enforcement involve regulators or enforcers responding to cases of suspected non-compliance rather than initiating investigations based on intelligence gathering. Such a responsive approach to regulation is commonplace and involves regulators who enforce 'in the first instance by compliance strategies, such as persuasion and education [but] apply more punitive deterrent responses (escalating up a pyramid of such responses) when the regulated firm fails to behave as desired' (Black and Baldwin, 2010). The most influential and cohesive theory on responsive regulation is that promulgated by Ayres and Braithwaite in *Responsive Regulation* (Ayres and Braithwaite, 1992).

In the pyramid of responses, as one regulatory intervention fails, the regulator moves upward to the next more serious level and as the risk subsides, the regulator should move back down to a lower level. In this way, the pyramid provides a proportionate and reasonable exercise of power the justification of which is based on the failure of the less serious previous action. However, the model does not deal adequately with cases of where the risks are immediate and potentially catastrophic so that the most appropriate action would be to apply a higher-level intervention urgently. In addition, it may prove difficult to move down the pyramid once stronger measures have been applied and consequently undermined the trust between enforcers and firms required for lower level actions. The mere threat of stronger sanctions such as prosecution may prejudice resolution by negotiation or other lower level action. Moreover, a responsive approach assumes that firms do change their behaviour as a result of regulatory action whereas in fact other forces, such as competition, may play a greater part in influencing business behaviour (Baldwin, 1990).

A practical limitation to the pyramid approach is that it depends on an ongoing relationship between the regulator and enforcer. Enforcers may be influenced by matters beyond the case in hand so that factors such as resources or performance targets and practices within the workplace play a role as much as the evidence and legal merits of a case.

There is also a matter of principle at stake in the application of responsive regulation based on consistency and rationality: responsive strategies may be justified on grounds of 'substantive rationality' (Black and Baldwin, 2010) but, 'they inevitably come up against

criticisms of lack of formalism and as undermining both the rule of law and broader constitutional values' (Yeung, 2004).

2.17.1 The empirical evidence

Prosecution provides a very limited insight into the way in which enforcement is conducted. To provide an indication of the propensity to legal action we need to know the number actions as a proportion of the total cases of unauthorised claims. Such a quantitative exercise is beyond the scope of this thesis. Such work has been carried out with reference to the work of environmental health departments to discover marked differences between departments in their propensity to initiate legal action (Hutter, 1989).

In her interviews Hutter found differences between the enforcement officers' attitudes where those who adopted a persuasive strategy would refer to sanctioning officers as 'little Hitlers' and who would themselves in turn be criticised for being 'softies'. Similarly in their work on the factory inspectorate, Bartrip and Fenn found 'within the inspectorate there were those who favoured an enforcement policy weighted towards conflict and prosecution, and those who were sympathetic towards an approach emphasizing co-operation and persuasion' (Bartrip and Fenn, 1983). This is echoed in the report of the Health and Safety Executive which highlights, '[a]dvice, encouragement and enforcement as essential elements of the Inspectorate's work' (Executive, 1986).

While prosecution is talked about often it forms only a small part of the work of enforcers and provides a 'helpful but not normal tool of enforcement' (Bartrip and Fenn, 1980). Several enforcers said they would prosecute if all else failed but that in having to consider prosecution they would consider they themselves had failed (Hutter, 1989).

In her work, Hutter found that organisational controls where there are accepted procedures based on peer and hierarchical review will favour a persuasive approach by default as such review provides a further opportunity to explore alternatives to prosecution. Officers are discouraged from being overzealous in their enforcement of the law on the basis that their workload is unlikely to be able to accommodate any more than the occasional legal action. Hutter discovered that in the majority of cases facing legal action approval was required from the council's elected committee thereby introducing an independent and political dimension to the process.

2.17.2 Organisational factors

As well as variations in enforcement policy, which translates into variations in style, enforcement may also be affected by the department's budget, numbers of staff available and the complexity of the cases under the Regulation. Where resources are tight this might lead enforcers to be more likely to take legal action as they lack the time necessary to devote to educating the businesses within their jurisdiction. In their study of the Office of Surface Mining in America, Shover et al. found this argument which was used to account for greater use of prosecution at the time (Shover et al., 1983).

There is some evidence of the opposite view, where constrained resources will deter the issue of court proceedings as legal action is also resource intensive and legal costs rules mean that it presents a very high level of risk and this may mean that enforcers do not have the appetite for the considerable uncertainty involved in the process (Bartrip and Fenn, 1980). The cost of prosecution will rule it out in a large proportion of cases but it may not be the prime or even the most significant consideration. Prosecution action, even if it appears to be an expensive option in a particular case, may be justified by providing a deterrent effect and acting as a warning signal to others. Those studies showed that 'it is not resources alone that determine policy', but the 'way in which they are used is determined by the interplay between their availability and other influences' (Hutter, 1989).

2.17.3 Political factors

Enforcement practice will be sensitive to non-bureaucratic influences such as the level of public concern in relation to a specific issue. This may be expressed by elected councillors who represent the local population and who will take up matters raised by their constituents. In the UK, decisions to proceed with legal proceedings will be subject to the approval of the council's environmental health committee composed of elected councillors as well as council employees. It would be rare for a case to proceed without such approval. In this way, the risks presented by food hygiene are likely to attract interest over false claims relating to nutrition and health. In her study of environmental health officers Hutter found that 'each of the councils which controlled the departments [in my sample] played its part in determining policies and guiding strategy decisions' (Hutter, 2008). To illustrate the point; a major outbreak of food poisoning from a food outlet is likely to be widely reported in the media and the response from local authority regulatory services will be carefully scrutinised.

One might hypothesise that councils under Conservative party control might present a different attitude to breaches of food law than Labour or Lib Dem councils. However, food law enforcement is not an obvious political issue. Research has failed to show that party political influence might account for differences in enforcement style with councils of a particular political complexion favouring a certain approach and being disinclined towards another (Hutter, 1988).

2.18 Trading standards or environmental health?

The boundary between environmental health and trading standards is central to the operation of food law enforcement. Broadly environmental health officers are concerned with risks to consumers' health and they do this primarily by upholding standards of hygiene or food safety. Trading standards officers, meanwhile, focus on the protecting consumers' financial interest by controlling unfair trading practices such as misleading food labels in relation to composition; also known as food standards. Therefore, strictly speaking, the enforcement of the Regulation is a food standards matter and ought to fall within the jurisdiction of trading standards (Harrison et al., 1997). However, the boundary between the two is fluid and it is not unusual to find environmental health officers concerned with food standards. There may also be an element of internal politics at play, particularly in an environment of severe cutbacks. Since around 2000, councils have merged trading standards with environmental health into a single regulatory services department. This has provided a way to organise the regulation of food along thematic lines which might be more transparent for consumers and for businesses who are unlikely to appreciate the technical distinction between the regulation of food standards and food hygiene. The trend towards merging of departments was accelerated from 2008 when council spending cutbacks encouraged the making of cost savings from such mergers. In such an environment, officers may worry that their particular department, for example, trading standards, may lose out by having its staff cut back and its duties being passed to the other regulatory team, in this case, environmental health.

The trend has been towards takeover by environmental standards rather than a merger of equals. In such councils food standards has been transferred from trading standards to environmental health to provide a single point of regulation for food matters. In such an environment, officers may wish to undertake more prosecution work to demonstrate their worth. However it is extremely difficult to measure the effectiveness of any department by

reference to its impact on the local environment and the quality of life of the population when so many other factors play a part.

Research into the work of environmental health officers has suggested that there was a greater tendency to use legal action in councils based in urban environments where there is less likely to be a close relationship between the regulated businesses and environmental health and trading standards departments (Hutter, 2008).

That food law enforcement is not an issue ever likely to find itself into the manifesto of a political party does not mean that food law is without political repercussions. The food scares of the 1980s and 1990s from listeria, salmonella, BSE and then horsemeat in 2013 demonstrate the potential for food regulation and enforcement as an attention-grabbing issue (Smith, 1991; Yamoah and Yawson, 2014). In each instance, regulatory matters moved overnight from being matters of public indifference to sources of outrage and in each case exacting a more stringent response from regulators (Hutter, 1988). The consequences of food being at the top of the political agenda were tangible and long term. In the case of the food safety scandals of the 1980s, the government passed the Food Safety Act 1990. In the case of the BSE crisis, the government created the Food Standards Authority.

2.19 Risk based regulation

Having descended in a 'striking wave of regulatory homogenisation' (Black and Baldwin, 2012) risk based regulation has become the prevailing mantra among policy makers across many sectors ranging from finance to food, safety and the environment. In his report, *Reducing administrative burdens: effective inspections and enforcement* Hampton advocates targeting resources based on an assessment of risks that a firm presents to the objectives of the regulator. In order to do this, the risk needs to be evaluated based on the evidence. It provides a systematic approach that allows regulators to relate their enforcement activities to their objectives and the basis for evaluating new risks. Unlike responsive regulation where the regulator uses the pyramid to escalate actions, a risk-based strategy emphasises analysis of the risk to determine the action. Risk based regulation has the most impact on inspections which move from routine visits to risk rating firms according to the possibility of non-compliance and the potential impact of such breach. As with responsive regulation, a technical approach based on an administrative and technical procedures may lead to policy making becoming less accountable and open (Black, 2005).

The policy requires that regulators should prioritise higher risks by allocating greater resources to them. Inevitably, this means withdrawing resources from elsewhere. Risk based regulation will tend to ignore lower levels of risk even where the cumulative effect may be considerable (Black and Baldwin, 2012). In fact, it may lead to persistent non-enforcement in relation to certain activities, which once characterised as low risk, will cease to attract regulatory scrutiny. In considering the enforcement of the Regulation, given the relatively low risks associated with nutrition and health claims one might expect that the attention of enforcers might be drawn towards other higher risk areas such as food safety.

However low risks cannot simply be ignored. The harm they are designed to prevent is latent and long term and, in the case of nutrition and health claims, political concerns about public health may require that they are attended to in some way or other. Ignoring low risks may potentially substitute the supervision of many widely spread low risk activities with fewer larger risks which may or may not reduce risk overall. When subjected to economic cost benefit analysis, risk based regulation may not lead to the most efficient use of resources. Large risks can lead to fewer very resource intensive actions which also may not lead to the greatest overall reduction in risk in return for the expenditure.

There are particular challenges of dealing with low risks, including their identification and classification and ultimately the level of failure an enforcer is prepared to accept. There are many ways in which to quantify risk, usually by reference to probability and impact (Weber et al., 2002) but there is no single accepted method. Therefore, in practice 'low risk' is often defined by the relevant regulator itself as meaning low priority. Having identified health and nutrition claims as lower risk, the challenge for enforcers is to pick up the 'accumulations of such risks when they become an issue without expending significant amounts of resources' (Black and Baldwin, 2012).

However, the level of risk associated with an activity is not fixed; it may change over time. For example, if there are more diet related diseases among the population or that particular foods are identified as causes for public health concern then this will raise the risk profile of nutrition and health claims. Risk has a context so that when considering nutrition and health claims a manufacturer who makes nutrition and health claims but who operates high standards of food safety would be considered high risk when compared with an unhygienic takeaway. Concerns raised by consumers, politicians and NGOs will affect the prioritisation of a risk so that it may be difficult to justify the categorisation of a risk as low priority if it has in fact materialised and

there is a public demand for something to be done. The opposite may also be true where it may prove difficult to tackle a common problem if it does not command the interest of media or the public.

Whatever the level of risk, the regulatory activity is often the same: so that in all cases, there is inspection and monitoring. In practice, the difference between a low risk and high risk is in the frequency of inspections or the intensity of the monitoring. In deciding what action regulators should take and how often they should take it, enforcers may directly inspect premises or use proxy indicators such as compliance history or evidence of deviation by a business from their own systems.

In the event of a low risk, where there appears to have been little harm, enforcers are faced with the dilemma as to what action to take. For example, if an unauthorised claim is made on the label of a product with low sales, should enforcers adopt a more conciliatory approach than if it had sold larger quantities? Or should they take a more principled approach where they treat contraventions of the law equally regardless of the harm or potential harm that ensues.

2.20 How regulated firms respond to regulation

Research into the effect of the regulator's actions on the behaviour of firms can provide insight into the effectiveness of regulatory interventions. This is not unrelated to the costs imposed on business and the benefits offered to consumers. Lipsky (Lipsky, 2010) coined the term 'street level bureaucrats' when referring to officers in the public sector with a high degree of independence in their work who also interact within the community. These workers rely on their professional judgement and discretion to enforce rules that are open to interpretation and which often have a high level policy goal that is ill defined in operational terms.

According to Lipsky street level bureaucrats have responsibility for a range of matters and the demand for their services is difficult to predict or to control. They also face competing pressures from the limited resources available to them and the competing demands on their time and effort. Lipsky argued that street level bureaucrats develop strategies to cope with such demands including choosing to deliver sub-optimal policy delivery and selective non-enforcement.

In England and Wales, regulators generally enjoy a high degree of autonomy and they exercise a significant discretion at field level. Environmental health officers are no exception where enforcement is marked, 'on the one hand by an emphasis upon discretion rather than rule, and on the other by a corresponding emphasis upon conciliation and compromise, rather than coercion and compulsion' (Hawkins and Hutter, 1993). The enforcement style is marked as 'adaptable and variable in the demands it places on business' (Hawkins and Hutter, 1993) and individual officers are 'encouraged to make their own decisions about interpreting situations and how best to tackle them' (Hutter, 1989). In this way it may be argued that environmental health officers are an example of street level bureaucrats. This may result in significant differences in enforcement policy, style and outcomes for business and consumers depending on the particular local authority (Hutter, 1989).

In highlighting the importance of environmental health officers in a similar piece of research into Australian environmental health officers, their role is described by one interviewee as 'huge, definitely huge. They are the first contact between community and public health and they've got a very, very, difficult job...'. (Condon-Paoloni et al., 2015)

The variables in enforcement may range from the behaviour of the individual enforcer, the authority and the resources available to it and the regulatory climate in which it operates. In addition, the size and wealth of the business may provide some indication of the regulatory attention which they may attract. For example a supermarket or leading brand has a strong incentive to ensure that nutrition and health claims for which they are responsible are compliant because to be found to be otherwise would undermine the high level of trust demanded by consumers in food purchasing (Kumar, 1996). By comparison, small businesses such as independent takeaways or home based suppliers dependent on unskilled workers without the training of a larger organisation may be seen as more immediately risky. This may influence the way in which their activities are monitored by regulators.

The nature of the activity may also influence the regulatory response so that hygiene breaches which pertain to food safety will be more likely to lead to legal action than false health claims. There may be variations between local authorities' ratios of enforcement officers and the number of food businesses for which they are responsible which will affect the frequency and duration of inspections. A closer knowledge of a business and its personnel will permit enforcers to use persuasion and education to a much greater extent than in circumstances where those working in food businesses are largely unknown to them (Hawkins and Hutter, 1993).

Galanter contrasts 'repeat players', the few firms who have a recurring relationship with regulators, with 'one shotters', the majority of firms which are rarely inspected (Galanter, 1974). The repeat players become familiar with regulatory expectations as a result of more frequent contact with inspectors and this provides greater scope for education. In contrast, smaller firms, who might expect to be inspected once every few years, may be uninformed about the law and ignorant about the expectations of the regulator.

Enforcers come into contact with business as a result of routine inspection work or complaints (Hutter, 2011). Therefore, the frequency and the nature of the inspections are essential factors in determining the number and types of violations that come to light. Reactive responses involving third parties such as complainants are likely to be met with a stronger response than violations discovered from a routine inspection (Lloyd-Bostock and Hutter, 2008).

Environmental health and trading standards officers will have perceptions about why businesses comply or fail to comply with the law, regardless of whether these are actually correct and enforcement strategies are built on them. From their studies of inspectors, Hutter et al show that enforcers believe compliance is the result of a variety of factors. Firstly, that compliance with the law is a matter of moral principle so that a firm believes that it should not deceive consumers whether or not this is required by law. In this way, businesses comply with the law out of deference to the authority of the law, whether or not they agree with it. Secondly, regulated firms believe that it is economically prudent to do so because the penalty which will be suffered if you are caught is such that the risks outweigh the benefits. Of course these theories of why businesses comply with the law are not necessarily mutually exclusive (Hawkins and Hutter, 1993).

Businesses may fail to comply for financial or technical reasons or because they are negligent; whereas others act deliberately in choosing not to comply by calculating the risk and deciding they wish to avoid the cost of compliance. An example might be a factory that does not wish to re-label stock that has become non-compliant as a result of the coming into effect of the legislation. Alternatively, it may be due to a belligerent and irrational belief that their product does have the nutritional and health properties they claim, notwithstanding the lack of scientific evidence, and that the regulator has no right to tell them what to do. Many beliefs about the nutrition and health effects of foods are based in folklore even at an official level. As an illustration of this, it was found that claims submitted to EFSA and rejected by it were supported by evidence based on religious texts or similar non-scientific grounds (Gilsenan, 2011) and that these were supplied by senior ministry officials with approval from domestic regulators.

The applied theories of enforcers on firm compliance will present a picture of the moral character of that type of firm. Takeaways and back street supplement providers are examples of businesses who can have a vaguely disreputable quality and which may attract the suspicions of enforcers (Cranston, 1979). Where a claim originates from such a 'bad' firm this creates an expectation in the environmental health or trading standards officer's mind that the claim is deliberate or negligent and that it should be met with a stronger response than if it had been made by a large reputable supermarket. That is not to suggest that supermarkets do not make false claims. The case files of the Advertising Standards Authority show that they do but such false claims are almost certainly viewed by enforcers as accidental and will be met with an investigation with an invitation to provide the evidence for the claim rather than criminal legal action. Instead 'bargaining becomes central in such a relationship' (Hawkins, 1984).

In summary, 'regulatory enforcement in England and Wales is highly discretionary, and varies according to regulatory arena, legislation, bureaucracy, and agency policy. At field level the high degree of effective discretion may lead to enforcement that seems individualized, fragmented and ad hoc' (Hawkins and Hutter, 1993). In Hawkins's research, the arena was environmental and health and safety regulation. In this study, the field is local authority regulatory services' enforcement of the regulation on nutrition and health claims.

2.21 The impact of health claims on consumer behaviour and innovation by producers

From the consumer perspective, the effectiveness of health claims depends upon the ability to access the information contained in the health claim and to act upon it. This raises questions about whether consumers understand health claims and whether they are prepared to act on them. In the article *Information, advertising and health choices: a study of the cereal market* (Ippolito and Mathios, 1990), the authors examine the effect of information on consumer and producer behaviour, in particular; how to disseminate known health information to consumers who might be able to act on it and benefit from it.

Consumers are not generally well placed to assess the health claims made for foods, they rely on producers for information and if such information is not regulated effectively, there is little incentive for producers to be truthful in their claims. In addition, the risk of consumers being deceived by exaggerated claims for foods would lead to more harm. This was the justification for the ban on the making of health claims by food suppliers in the US.

The ban was lifted during the period of study and this enabled the Ippolito & Mathios to examine the impact of advertising on consumers' consumption of fibre and on producers' innovation of products. The authors found that 'the evidence clearly demonstrates that fiber [sic] cereal consumption increased once the ban on health claims advertising was removed.' This would seem to indicate that advertising represents a valuable source of health and dietary information for consumers and that where such information can be acted upon that consumers will do so. The authors of the study controlled for the potential increase in consumption as a result of advertising generally which was not related to health claims. The study was restricted to the impact of lifting the ban on cereals only and therefore the conclusions from it may not necessarily be applied to other products. The cereal market is dominated by a group of a few large suppliers who would find it relatively easy to provide consumers with the information through labelling and advertising while complying with the regulation. Markets where there are many smaller producers may respond differently to the removal of the restriction.

The idea that advertising is a valuable source of information for consumers and that it plays a key role in the market and in competition between suppliers has been explored before (Stigler, 1961). Studies which examined markets where advertising is prohibited or at least restricted so that suppliers are stopped from making claims in relation to their products or services have shown that in such markets, of which optical and legal services are two such examples, prices tend to be higher. (Benham, 1975).

Individuals' responses to information vary according to their level of education, how they value their health and their ability to absorb information and change behaviour. For example graduates were more likely to stop smoking following the Surgeon General's Report on Smoking in 1964 (Ippolito and Ippolito, 1984). In addition, the costs of acquiring new information and transactional costs affect the different ways in which different consumers react differently to health information.

In 1984 the cereal manufacturer Kellogg began to promote its products by reference to the link between the consumption of fibre and the reduction in the incidence of colon cancer. The study attempts to isolate the effect of the use of health claims from other possible factors, for example, increased awareness of colon cancer as a result of the publicity surrounding the then President Ronald Reagan's diagnosis of colon cancer.

In restricting health claims, the government through its regulators places itself in a position of responsibility for the dissemination of health information. In that position, it may be viewed as

a trusted source of information. However there is an alternative view of the role of government regulation, that it has a bureaucratic risk aversion and it is beholden to the influence of the lobbying of the food industry (Stigler, 1971). A further question posed by the research is who is the more effective provider of information to consumers? This is a question that should be seen in the context of the fact that advertisers have a strong incentive to reach a wider audience. Finally, would competitive forces lead to greater use of health claims related to the fibre content of cereals?

In critically assessing this position, one might argue that governments also have incentives to seek improvements to the health of their populations by enhanced nutrition, as healthier people are more productive and require less healthcare. However, the nature of the incentive is different in that a food business has the more specific goal of selling more of its particular product. In addition, although improved nutrition may not be the primary purpose of a food business that competition based on health claims for food is more effective in providing better health outcomes.

Professor Michael Porter of Harvard Business School develops this idea further in his work *The Competitive Advantage of Social Philanthropy* (Porter and Kramer, 2002). Porter posits that there is little advantage in corporations seeking to harm their consumers. In fact, there is every incentive for companies to seek to actively promote the welfare of their consumers. He goes further in his criticism of Corporate Social Responsibility (CSR). For many organisations, CSR is used as a form of public relations to promote the business in a positive light. However, according to Porter:

there is a more truly strategic way to think about philanthropy. Corporations can use their charitable efforts to improve their competitive context--the quality of the business environment in the locations where they operate. Using philanthropy to enhance competitive context aligns social and economic goals and improves a company's long-term business prospects.
(Porter and Kramer, 2002)

Porter's ideas are concerned with broad corporate strategy but they may enlighten the underlying argument in food claims between government regulatory intervention on the one hand and allowing business to exploit the competitive advantage that might be obtained from a liberal approach to health claims.

In this regard, a further study by Levy and others, contemporaneous with that of Ippolito and Mathios, examined consumers' knowledge of the cancer prevention potential of fibre bran or whole grains. It showed an increase in consumer awareness about the benefits of fibre. In that survey consumers were asked, 'what things that people eat and drink might make them less likely to get cancer?' In 1984 only 9% mentioned fibre, bran or whole grains but in 1986 that figure increased to 32% (Levy, 1989).

The studies appear to provide support for a permissive approach to health claims. In isolating the effect of the lifting of the preceding ban on health claims on consumer behaviour the authors found 'fiber [sic] cereal consumption increased significantly once advertising of the health benefits was allowed.'

Lifting the ban on health claims allowed food businesses to compete on the basis of the increased fibre content of their cereals. Food suppliers were able to make claims for the higher fibre content of their products. As a consequence, the lifting of the ban seemed also to promote the innovation of cereal with higher fibre content with the average fibre increasing from 1.56 grams per ounce in 1984 to 2.59 grams per ounce in 1987. The study did not however take into account the popularity of a product. In relation to one of the justifications for the ban on health claims, that it would cause consumers to ignore some of the harmful nutrients in a food and that consumption of these would therefore increase, the study seemed to show the opposite, that newer high fibre cereals also contained less sodium and that average sodium levels decreased. There may have been an accompanying increase in sugar content but this is not recorded.

One of the arguments against the use of health and nutrition claims promulgated by consumer groups such as *Which?* is that consumers would respond by over reliance on the health benefits while ignoring the possible negative effects in other areas of their diets. Concerning this, Ippolito and Mathios measured the consumption of salt and fat in cereals before and after the lifting of the ban and found no evidence to support this theory. Of course the study does not measure the effect of the health claims on other aspects of consumers' diets, for example, an increase in salt and fat from sources other than cereal consumption. There may still be an overall negative impact on the diet of the consumer as a result of the misuse of health claims as a 'magic bullet'.

Ippolito and Mathios examined the question of whether producers would voluntarily disclose health information, that is, fibre content, which might be valued by consumers. The existence

of a credible and low cost means of disclosure of a feature that is valued by consumers combined with the effect of competition should lead to the voluntary labelling of health information from all but the lowest quality producers (Grossman, 1981). The result of this finding seems to point to the benefits of liberal regulation. The EC Regulation on nutrition and health claims (EC, 1924/2006) may be reconciled with such a permissive approach. It provides for the food business to be able to make health claims but this is restrained by the requirement of evidence. In this way, a food supplier may make a choice about whether to provide nutrition and health information as opposed to a regulation based on mandatory disclosure.

Ippolito and Mathios considered the question of what, if any, differences there are in the responses of different groups of consumers to the information on health benefits of fibre consumption from cereal. The study found that consumers who placed a greater value on health are more likely to eat high fibre cereals. Such consumers were identified as non-smokers and/or those who took vitamin supplements. The study also examined factors like race, income and education and found that they were relevant in determining consumer response to the use of health claims in advertising. Non-white, lower income and less educated consumers are less responsive to health messages from sources such as government health education campaigns. By contrast the study appears to show that advertising may have a greater impact on groups that are not well reached by other available information sources.

Ippolito and Mathios conclude that the improved understanding of the relationship between diet and health will only lead to benefits for consumers if they can access the necessary information and act on it. In relation to the cereal market, the lifting of the ban on health claims advertising appears to have increased the consumption of fibre without any corresponding negative effects. The study seems to provide some evidence that the prohibition on health claims across the board may have come at a cost to consumers' ability to exercise choice based on health information. However, it does not then follow that producers should enjoy the right to make claims without any restrictions. There is a clear information asymmetry between consumers and producers and potential for deception by producers. The challenge for the regulation of claims is to allow producers to find a low cost and credible way of disseminating the information (Grossman, 1981). One way to do this would be the implementation of an evidence-based system of claims approval. It should be emphasised that this study is restricted to the manufactured breakfast cereal market and that the results are therefore subject to the features of this market, for example, that there are a few large producers that

dominate the market, cereals are purchased in large boxes with labelling from supermarkets, cereals are eaten in the same way for breakfast – such uniformity of consumption patterns are not necessarily found with other foods and this may restrict the ability to extrapolate the conclusions of the study by Ippolito and Mathios to other food products and markets.

2.22 The Joint Health Claims Initiative 1997-2007

Prior to the passing of the Regulation the UK adopted a voluntary approach to nutrition and health claims in which suppliers were encouraged to comply with a set of agreed standards known as the Joint Health Claims Initiative (JHCI). The JHCI was composed of industry, consumer and enforcement representatives who administered its code and whose main activity was to provide approval to specified claims. The system was aimed at ensuring that claims were; 'scientifically true, legal,... and meaningful and not misleading to consumers'(2007, 2007). During its time the JHCI approved five claims related to saturated fats, whole grains, soya protein, oats, and omega 3 all of which are associated with blood cholesterol and/or heart health for the period from 2001-2005.

The Code of Practice applied to all traders, suppliers, manufacturers, caterers, agencies, retailers and importers involved in the supply, advertising, promotion and/or labelling of food when making claims that state or imply that consumption of a particular product carries a specific health benefit (JHCI Code of Practice on Health Claims on Foods, the 'Code'). The Code has the objectives of protecting and promoting health, providing accurate information relating to food and promoting fair trade in the food industry ss.1.2.

The JHCI code Administration Body adopted a practical and proactive approach to health and nutrition claims in contrast to the aims traditionally associated with legal controls. The practical guidance it would provide would be to provide pre-market advice to companies including copy clearance in a similar way to the Advertising Standards Association does with advertising generally. Of course only a court can provide a final interpretation of the law and the voluntary code of the JHCI cannot decide on a health claim in the final instance. However adherence to the code would potentially provide a defendant with a defence of due diligence if prosecuted for making a false or unsubstantiated health claim. Therefore the advantage of the JHCI approach for a supplier was its pro-active approach geared towards providing a solution rather

than finding an instance of a breach to form the basis of a potential legal action. The disadvantage was its voluntary nature and the limited legal security that it would provide.

Under the Code a health claim (as opposed to a nutrition claim) is a 'direct, indirect or implied claim in food labelling, advertising and promotion that consumption of a food carries a specific health benefit or avoids a specific health detriment.' (s3.1 of the Code). Under the Code a health claim is distinguished from a 'generic health claim' which is 'based on well established, generally accepted knowledge from evidence in the scientific literature' (s.3.2 of the Code). The Code goes on to draw a distinction between food and medicines and makes clear that it only applies to food and food supplements;

'This Code applies to the use of health claims in labelling, advertising and promotion of all foods as marketed to the general public whether foods, drinks or food supplements. It does not apply to products which are medicinal products subject to medicines laws.' (s.4.1 of the Code)

In seeking to regulate health claims the JHCI adopts a clearly defined position and this is demonstrated by the fact that the Code examines the health claim from the consumer's point of view. Therefore, under the Code; 'the overriding principle is that the consumer perception of the health claim is paramount. In other words what the consumer thinks the health claims means.'

Unlike legislation which is generally subject to narrow interpretation, the Code should be applied 'in the spirit as well as in the letter' s.6.1.1 of the Code). This allows for greater flexibility in its application. As is characteristic with self-regulatory measures, the Code seeks to take advantage of the flexibility afforded by its relatively informal nature. In adopting the consumer point of view, an important specified factor is whether there is a direct or indirect or implied claim. A direct claim is for the food rather than its ingredients and an implied claim may be assessed from the overall impression given, for example, a picture of a heart may give the impression that the food will reduce the risk factors associated with coronary heart disease.

In accordance with the Legal and Nutritional Principles of the Code; 'health claims must be truthful and must not deceive directly or by implication.' (s.6 of the Code). They should be consistent with the evidence, and, if the benefits have been shown to apply following tests on only a specific section of the population, then the claim should only refer to a benefit for this group and not for the population as a whole. The Code allows claims that might refer to the

maintenance of good health in general or of a specific part, for example, heart. A health claim must not encourage excessive consumption of a food. The benefit must be attained within the context of a healthy diet and lifestyle. A claim should not denigrate other foods or imply that normal foods cannot provide a healthy diet.

The core of the Code relates to the substantiation of claims which is dealt with in section 8 of the Code. In the case of generic health claims no specific substantiation is required and such claims are already approved by the Code Administration Body in the light of international scientific consensus. Health claims must be based on a review of all the scientific evidence relating to its validity and this review must include the totality of the evidence and not just data which support the claim. The studies should be based on experimental studies in humans and should establish an improvement in well-being or the lessening of disease. The code acknowledges that gathering full clinical evidence on foods can be difficult and expensive and therefore allows for evidence of the effects of foods on markers where there is a strong correlation between markers and well-being. For example, research showing that a food reduces levels of serum cholesterol would be acceptable to support a claim for maintaining a healthy heart.

In cases where an innovative health claim is made this claim must be supported by scientific evidence following a systematic evaluation of all the data. Although it is possible to market a food without it, companies are advised by the JHCI to seek pre-market advice from the Code Administration Body.

The following are examples of acceptable words and phrases that may be used in health claims:

- *Is beneficial to the health of the stomach and digestive system*
- *Helps maintain normal blood flow to the brain which is particularly important in old age*
- *Folic acid contributes to the normal growth of the foetus in the womb*
- *Helps maintain normal cholesterol levels. Healthy cholesterol levels are known to play a part in maintaining a healthy heart.*

2.22.1 Critique of the JHCI

The JHCI provided a flexible and practical approach which served the needs of the food industry while attracting the support of consumer and enforcement groups. Much has been

said to promote co-regulation as a potential way forward for greater involvement in delivering the aims of regulation by business (Senden, 2005). The concept of co-regulation has been promoted by governments at a national and EU level (BIS, 2011b; EC 139, 2006).

The JHCI represented an example of co-regulation in practice. It did not offer a long-term solution and it was not comprehensive in its application and of course it was weakened by its voluntary nature. Since the passing of the Regulation, the JHCI has become redundant. This thesis will go on to consider the difference between the approaches of the JHCI and the Regulation and their difference in impact and in particular their outcome, that is, the type and nature of the claims that are permitted.

2.23 Architecture of enforcement of general food law in the UK

While the responsibility for the making of policy and law remains with central government the responsibility for enforcement is largely ceded to local authorities and specific central agencies. There are over 400 local authorities in the UK and primary responsibility for enforcement of food law lies with their trading standards and environmental health departments, sometimes combined into a single Regulatory Services department.

In considering food law, the single most important piece of legislation is the Food Safety Act 1990. The content of the Act has been extensively and authoritatively analysed by Howells et al. (Howells et al., 1990). The impact of this legislation upon the enforcement activities of environmental health officers was examined by Harrison et al (1997). That research examined the nature of local authority food regulation to understand how enforcement officers implement national legislation and reviewed the implementation of the regulatory doctrines of the home authority principle and the application of codes of practice on enforcement (Harrison et al., 1997). This research, on the other hand, overlays the Regulation on nutrition and health claims onto that same enforcement infrastructure as it has evolved by reform and practice, some 20 years later.

Although general responsibility for food law rests with local authorities, there are cases of reserved duties held by central agencies. The most important one of these is the Food Standards Agency (FSA) which acts as the enforcement authority in relation to 1700 licensed premises in the UK producing meat for human consumption including slaughterhouses, cutting plants and cold stores (Authority, 2010). The FSA is charged with investigation, prosecution in order to maintain public confidence in the meat industry. The food scandals of the 1990s including BSE which led to the creation of the FSA may have influenced this decision. The FSA also has responsibility for the enforcement of EC regulations relating to wine.

Other agencies of central government which have responsibilities for enforcement for specific areas of food law include the Pesticides Safety Directorate (PSD), the Veterinary Medicines Directorate (VMD) and the Egg Marketing Inspectorate (EMI); all within the Department for Environment, Food and Rural Affairs (Defra) with responsibilities that are in accordance with their titles.

2.23.1 Enforcement and penalties under the Nutrition and Health Claims Regulations 2007

Section 4 of the Nutrition and Health Claims Regulations (Regulations, 2007) makes the following provision for enforcement; 'each port health authority within its district and each food authority within its area shall execute and enforce the provisions of these Regulations and of the Regulation'. The competent authorities are identified in the Regulations as the Food Standards Agency, the port authority and the food authority in section 3 (Regulations, 2007). A breach of the provisions of the Regulation is a criminal offence triable either way, either in the magistrates' or crown court. The penalty on summary conviction is a fine up to the statutory maximum and or three months' imprisonment. The penalty on indictment is up to two years imprisonment and/or a fine of up to the statutory maximum.

2.24 The relationship between local and central government food law enforcement

The FSA retains an overarching monitoring and supervisory role over the local authorities in relation to enforcement:

'Under the Food Standards Act 1999 the Agency has a package of statutory powers to strengthen enforcement of food standards, and to ensure national objectives are delivered.

The Act gives the Agency powers to:

- Set standards of performance in relation to enforcement of food law
- Monitor the performance of enforcement authorities
- Require information from local authorities relating to food law enforcement and inspect any records
- Enter local authority premises, to inspect records and take samples
- Publish information on the performance of enforcement authorities
- Make reports to individual authorities, including guidance on improving performance
- Require enforcement authorities to publish these reports and state what action they propose in response' (Authority, 2010)

There is an important footnote with regard to the enforcement and regulatory structure that relates to food. Since the Comprehensive Spending Review of 2010 the government has announced its intention to dismantle the FSA and to divide its responsibilities between the

Department of Health (DoH) and the Department for Environment, Food and Rural Affairs (Defra). Presently the FSA is still functioning but with some of its duties passed to DoH and Defra. A further important reform is the creation of Local Government Regulation (LGA), previously Local Authorities Coordinators of Regulatory Services (LACORS). LGA is the coordinating body in relation to various consumer protection functions including food safety. It gives advice and guidance to local authorities and the FSA on enforcement issues.

2.24.1 Duties of local authorities

The orthodox model for law making and regulation is concerned with the relationship between government and citizens at a national level. This model fails to take into account the level above: the European Union and below: local authorities. This theory is articulated by Harrison et al: 'Regulationist analysis is at its strongest in dealing with the nation-state but less confident in its conceptualisation of local modes of regulation and of central-local state relations. We argue that, at least in the case of food policy, the interconnectedness of different tiers of the state must be addressed' (Harrison et al., 1997).

The ongoing harmonisation of European Union legislation with the aim of promoting competition in the internal market and specifically in promoting food standards relies on local enforcement. It raises a crucial question: 'how can the diversity of local regulatory practices be integrated at the national level and beyond?' (Harrison et al., 1997). Such integration is essential to the consistency of enforcement and therefore success of the legislation. The key actors, here, environmental health officers and trading standards officers are not passive recipients of regulatory practices; rather, they enjoy a significant discretion which they use to shape enforcement.

Enforcement of food law in the UK has been traditionally focussed on safety. This is not surprising in the light of the immediate and serious risks that the issue of safety presents. As such, enforcement of food safety law has rested with Environmental Health whereas enforcement of the Regulation will fall to Trading Standards as the nature of the risk is primarily economic.

Inspection of food premises forms an important part of the strategy of food law enforcement by local authorities. In this respect, the Food Standards Act 1999 provides local authorities with wide powers to inspect any stage of the production or sale of food and to take samples.

Although local authority responsibility for enforcement of food law is often expressed as a duty; for example, a local authority must investigate every consumer complaint about food, enforcement action may include a range of measures from warnings, improvement notices, prosecutions and closure of a business. Also local authorities' food safety officers will take a risk based approach to inspection and enforcement taking a more frequent and interventionist approach in proportion to the risk presented by the food producer/supplier.

Generally the failure to enforce the law leads to the potential for abuse and consequent loss of confidence in legal rules (Landes and Posner, 1974). Specific rules that are not enforced may do harm by leading subjects to lose respect for legal rules in general. Although passing of legislation with the lack of enforcement may have a symbolic value and deterrent effect, the lack of rigorous enforcement will have a wearying effect on the regulation (Polinsky and Shavell, 1999).

From the initial proposal on nutrition and health claims in 2003, the European Commission acknowledged that such claims 'are often not properly enforced.' As a result, 'consumers can therefore be misled by claims that have not been properly substantiated. The proposed Regulation will give legal security and address these issues by specifying the conditions for the use of nutrition and health claims.' (EC, 2003). There is an implicit acknowledgement that the failure to enforce nutrition claims may be the result of the lack of clarity in the law. The subsequent legislation, that is Regulation 1924/2006, aims to provide sufficient clarity in order to promote enforcement. Whether this has happened or whether the lack of enforcement may be attributed to other causes, for example, by having different priorities, is one of the questions for this thesis. The thesis will examine the policy framework, to the extent that it exists and is applied, that underlies the enforcement of health claims.

2.25 Enforcement options and the factors affecting enforcement choices

Various studies have examined the relationship between the economic, political and social forces in understanding the regulation of businesses (Gunningham et al., 2005). In determining the enforcement actions of a local authority, these studies provide some general insights into the enforcement of food law by trading standards officers. But this thesis seeks to develop this work by examining the factors and applying the general insights into regulation to food in particular.

One of the notable trends in regulation across a range of sectors from financial services to food safety has been towards a risk-based approach. The approach has touched food law enforcement as well. A risk based approach may be defined as, 'systemised decision making frameworks and procedures to prioritise regulatory activities and deploy resources principally relating to inspection and enforcement based on an assessment of the risks that regulated firms pose to the regulator's objectives' (Black, 2002). The risk based approach is promoted as a transparent and coherent approach to regulation and by focussing on the areas which present the greatest risks it may provide an efficient allocation of resources. The risk based approach was put into practice following Sir Phillip Hampton's 2005 review *Reducing administrative burdens: effective inspections and enforcement*. In the final report the review adopts the principle that; 'regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most' (Hampton, 2005). The attraction of a risk based approach where responses are determined by the logic of risk analysis is obvious but there are potential shortcomings of the approach, in particular that of, 'the challenges of regulation to which regulators have to respond vary across the different regulatory tasks of detection, response development, enforcement, assessment, and modification'(Black and Baldwin, 2010).

In relation to food claims, one of the factors which may have led to a significant level of unsubstantiated food claims prior to the passing of the Regulation may be uncertainty about the legal position. The greater the latitude in relation to the precise legal position the more scope there is for interpretation by providers to their own full advantage. On a more generous and less misanthropic interpretation, they may genuinely be unaware of their legal duties or be mistaken as to the existence and application to their own enterprise (Hutter, 2001).

The food industry comprises a large variety of different types of businesses ranging from the multinational conglomerate encompassing complex distribution and licensing arrangements to the small direct producer (sometimes farmer)/seller. Smaller businesses can find compliance with their regulatory obligations more difficult; through a lack of resources or the failure to understand what is required from them (Yapp and Fairman, 2006). Whereas large businesses such as supermarkets are expected to be aware of legislative requirements, independent traders are thought to need more education regarding their regulatory responsibilities and place greater reliance on advice and assistance from enforcers, particularly during inspections (Harrison et al., 1997).

Trading Standards Officers represent the first line of response to the enforcement of the Regulation. They are the people who interpret the law in statutes, cases and procedure and translate it into action on the frontline(Hutter, 2008). Trading Standards Officers enjoy a high level of discretion about how to implement the law in relation to individual businesses. The evidence shows that regulators generally deploy this discretion flexibly (Hawkins, 2002). Regulators including Trading Standards Officers make use of a range or 'menu' of enforcement options available to them. These may range from education and advice, agreement on a course of action or undertakings as well as court action. The main objective of enforcement action is for securing compliance 'both through the remedy of existing problems and, above all, the prevention of others' (Hutter, 2008). The possibility of the use of a range of options raises questions about the nature of enforcement, its purpose and at what point that purpose is achieved:

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.

(Hutter, 2008)

There are a number of reasons why action on enforcement does not necessarily mean taking legal action. The general way in which regulations and law, particularly European regulations, are drafted can make taking legal action difficult for enforcers (Baldwin and Sunkin, 1995; Kagan and Scholz, 1984). Enforcers may consider that informal action such as advice and guidance may be more effective and a provide a more efficient way to utilise their resources than prosecution or other legal action (Hawkins, 2002).

The local level at which trading standards operate and the discretion that is afforded to trading standards officers within a local authority will lead to differences in the way in which the same law is enforced by different departments. A key factor in this variation will be the availability of resources, particularly the department's budget and staff numbers (Hampton, 2005). The

question of what resources are available for enforcement of health and nutrition claims may be affected not only by the resources available to the department as a whole but also to the allocation of those resources to various aspects of the many responsibilities of trading standards officers. That is a question of allocation of resources within the priorities of the department.

Notwithstanding risk analysis and a scientific approach, in deciding what action to take, a trading standards officer will also be affected by their own personal and intuitive assessment about the nature of the breach and its potential impact (Tebbutt et al., 2007). Formal action may only follow where an incident is viewed as so serious as to warrant legal action or that the trading standards officer feels that informal action will not lead to a positive response from the business involved.

While the local aspect of Trading Standards enforcement is seen by many as one of its great strengths in providing regional accountability, the structural organisation of local authorities with the incorporation of elected councillors opens up the system to political interference. In this respect, the concept of representational democracy and ideologically driven support for a particular policy represent contrasting facets of the same issue.

The range of matters that fall within the duties of trading standards officers to enforce is extremely wide. The broad areas covered are; 'economic recovery, environmental protection, improved health, community safety' (Trading Standards Institute, 2011). The day-to-day work may include policing of; age restricted sales, counterfeit goods, overloaded vehicles, weights and measures and food related inspections. The expertise required to effectively monitor such a broad variety of activity is increasingly technical and more demanding. This leads to a trading standards officer, like their environmental health officer cousins, having to become a 'Jack of all trades' and inevitably 'a master of none' (Hutter, 2008). Condon-Paoloni also use this phrase with reference to the fact that officers are required to adapt and find ways to get things done with a wide range of duties. In addition they describe the 'difficulties environmental health officers faced in trying to maintain a working knowledge of a large amount of legislation and applying it to different situations.' (Condon-Paoloni et al., 2015). The extent of this feature as a problem will vary between authorities. Large metropolitan authorities will be able to employ and develop specialist teams but in smaller authorities where there are fewer employees, they will need to adopt several functions and provide a more generalised approach to their role.

The Food Standards Authority has a role in establishing the policy for enforcement of food law and setting the statutory duties for enforcers. In this way, trading standards policy on

enforcement priorities for food has been influenced by guidance from the FSA. However since the FSA has been partially dispersed and its functions devolved between DEFRA and the Department of Health this factor will have become less important; although its influence may still remain.

Businesses play an increasing role in influencing the regulation of enforcement of law in general and this also applies to the activities of trading standards. There has been a shift in focus from the traditional role of the state regulator as a strict legal enforcer and prosecutor to that of educator and advisor. In making this shift, trading standards officers have needed to become more attuned to the needs of the businesses that they oversee. This is evidenced in the consultation process sanctioned and even required by central government, sometimes as part and parcel of a broader deregulation agenda. Such an agenda is frequently the focus of lobbying activities by industry groups and public relations firms. In relation to the influence of one business on another, large businesses, particularly supermarkets, can exert considerable influence on those smaller food businesses for whom the supermarket represents their distribution channel (Balsevich et al., 2003).

Smaller businesses generally speaking have lower levels of awareness of the law and the way in which it is enforced (Fairman and Yapp, 2004; Henson and Heasman, 1998). Having fewer resources smaller businesses are less likely to have access to lawyers, consultants and other professional advisers and correspondingly rely more on trading standards for advice and guidance on compliance (Genn, 1993). Large businesses are also more likely to have insurance against liabilities arising from negligence or contractual breaches that may also be regulatory infringements. In addition, such businesses, through their strict compliance procedures, may require higher standards than that imposed by law and in doing so they act like quasi regulators in relation to their own operations and to those with whom they deal.

2.26 Enforcement policy and enforcement action by UK trading standards

The way in which trading standards officers seek to carry out their enforcement duties is a matter of public record for the purposes of openness, consistency, accountability and transparency for decision making that affects those who are being regulated; specifically food businesses and the public. Some local authorities publish the details of the enforcement policy on their web sites and such policies are collated on the web site of the Trading Standards Institute, which oversees standards for the profession. The policy provides guidance about the

way in which trading standards officers approach the enforcement of health and nutrition claims. An analysis of a representative policy from Gloucestershire Trading Standards (GTS) is provided below as an illustration of practice. Local authorities are required to conform to mandatory reforms aimed at removing unjustified differences in enforcement approaches between regions. Therefore the enforcement policy of one authority will be representative of the strategy across others.

The legal underpinning for enforcement policy is provided by the Legislative and Regulatory Reform Act 2006 and further guidance is bestowed by the principles in the Enforcement Concordat and the Regulator's Compliance Code. Enforcement is defined as 'any action taken by officers aimed at ensuring that businesses comply with the law and this may include offering advice, issuing warnings, issuing cautions and initiating legal proceedings including prosecution' Gloucestershire Trading Standards Enforcement Policy (Gloucestershire Trading Standards, 2015).

The purpose of the policy is to provide an equitable and consistent framework for trading standards and to ensure that enforcement is practical. At the outset the policy makes it clear that it will be applied objectively and in compliance with discrimination laws and therefore without regard to the 'ethnicity, gender, religious beliefs, political views or the sexual orientation of the suspect or the victim, or witness or offender'(Gloucestershire Trading Standards, 2015). The breadth of the scope of the work is set out in the statement, 'We enforce a wide range of business and consumer protection legislation relating to quality, quantity, safety, description and price of goods and services.'(Gloucestershire Trading Standards, 2015).

The policy makes clear the preference for alternatives to prosecution aimed at prevention of breaches of law and that prosecution will only be brought if there is a realistic prospect of conviction and it is in the public interest to do so (thereby adopting key elements of the Crown Prosecution Service test for instigating prosecution proceedings).

Part 2 of the policy sets out the principles of inspection and enforcement with an explanation of what they mean by the terms. Briefly, the principles are; targeting, proportionality, accountability, fairness and consistency, openness and transparency. Interestingly '[s]upporting the local economy' is cited as a further 'principle' but one might contend that it is in fact an aim of the policy. The policy also states that where there is an overlap with another

agency, for example, the police, there will be a coordinated approach to reduce the enforcement burden on the businesses affected and maximise the effectiveness of the action. The Home Authority Principle means that a business based in a single authority that has outlets and carries out business outside that authority is subject to the jurisdiction of its home authority rather than that of another authority where the branch resides or where the business is transacted:

The Home/Lead Authority Partnerships help councils work together effectively and avoid duplication of effort when regulating businesses who trade across local council boundaries, and support them by providing contact points for advice and guidance in order to maintain high standards of public protection and develop a consistent approach to enforcement.

Local councils help businesses operating in the UK to comply with legislation by providing advice, guidance and information. Businesses will generally build up a relationship with, and receive advice and information from, one particular council. This is usually the local council where the business is based, but not exclusively.

Local Government Regulation (formerly LACORS) (Regulation, 2011)

The creation of the home authority principle was a response to complaints from businesses with multiple branches, about varying treatment by food officials. While each individual store can be inspected by enforcement officials from its local authority, any complaints are required to be channelled to the home authority (Harrison et al., 1997). Clearly, the aim of the Home or Lead Authority Principle is to facilitate the relationship between it and the most pertinent authority rather than to simply determine the question of jurisdiction. This was felt to be a way to diffuse tensions between the authority and business and between different authorities.

The Lead Authority principle is a variation of the Home authority principle which aims to remove some of the anomalies of the latter where, for example, a business has a registered office in one area but in fact carries out most of its business outside of that area. A report by the National Audit Office found that 73% of consumer detriment from unfair or rogue practices arises as a result of threats that span more than one local authority area notwithstanding that Trading Standards are overwhelmingly funded by one local authority (National Audit Office, 2011). This is in fact the case with many large food businesses and all of the large supermarket chains. In such cases the business may

nominate the Lead or Primary Authority which may be more relevant and overcome what may be a mere technical connection with the home authority. In 2011 the government put forward proposals seeking to expand the Primary Authority scheme to include more businesses and to include more policy areas which currently fall outside the scope of the service, see *The future of the Local Better Regulation Office and extending the benefits of the Primary Authority scheme* (BIS, 2011c). The benefits claimed for the Primary Authority scheme are that it, 'reduces risk, reduces the cost of compliance and reduces the cost of failure'(BIS, 2011c). However, the government's reforms form part of its plans to tackle regulatory burdens which include such measures as the Red Tape Challenge and the One in One out process aimed at identifying those regulations which may be removed. The agenda of the consultation the *Transforming Regulatory Enforcement: Freeing up business growth* (BIS, 2011b) is explicit but the prospects for the enforcement of the regulation of health and nutrition claims are unclear.

In its consultation *Empowering and Protection Consumers Consultation on institutional changes for provision of consumer information, advice, education, advocacy and enforcement* (BIS, 2011a) the government sought views on the proposal aimed at 'clarifying its responsibility to tackle cross-boundary threats'. The consultation recognises the limitations of the Home Authority Principle and the problems of the risks of taking legal action for enforcement and the lack of expertise. The consultation acknowledges the need to reduce the disincentive for individual authorities to take on more complex or risky cases, (of which enforcement of nutrition and health claims regulations might be an example), say by creating an indemnity fund. It goes on to discuss how an individual trading standards department might become a designated lead authority with expertise in a particular sector, for example the enforcement of nutrition and health claims regulations. In attempting to understand the decision-making process underpinning the choices of trading standards officers it is helpful to examine the aims of the actions. The aims are described as:

- To change behaviour of the offender;
- To eliminate any financial gain or benefit from non-compliance;
- To be responsive and to consider what is the most appropriate sanction for the particular offender and the regulatory issue concerned;
- For the action to be proportionate to the harm/potential harm caused by regulatory non-compliance;
- To restore the harm caused by regulatory non-compliance, where appropriate;

- To deter future non-compliance; (Gloucestershire Trading Standards, 2015)

In the transposition of these aims to health and nutrition claims for food, it is suggested that reducing the amount of potential harm and proportionality would be the most important criteria. The application of the criteria will inform the action that would be most suitable to take. For example, taking no action may be justified where the impact on consumers may be judged to be small. In relation to health and nutrition claims the impact of financial loss may be significant and measurable, that is, the additional premium paid for a product by consumers as a result of the health claim made for it. However, the health effect is latent and more difficult to attribute and measure.

The authority may take indirect action by referring the issue to another authority that may be the home or lead authority. A further option for a trading standards officer is to issue a verbal or a written warning where an offence has been committed but it is not appropriate to take further action (Gloucestershire Trading Standards, 2015). Other enforcement options that may be relevant to health and nutrition claims might be fixed penalty notices recognised as a low-level enforcement tool or penalty charge notices if provided for in the legislation. In addition, statutory notices are similar to injunctions in that they are used where offenders are required to act in a specific way or to cease to do so. The seizure and forfeiture of goods may be appropriate in health and nutrition claims. Finally, the trading standards officer may seek undertakings and injunctive action under the Enterprise Act 2002 (Enterprise Act, 2002). The range of actions under the Enterprise Act include; informal undertakings, formal undertakings, interim orders, court orders and contempt proceedings.

The most important action that may be taken by a trading standards officer in response to a health and nutrition claim would be a prosecution. The decision to take such action would need to pass the dual test of evidence and public interest (Gloucestershire Trading Standards, 2015).

Other options which are available to trading standards but which are unlikely to be suitable for health and nutrition claims include; anti-social behaviour orders, taking animals into protection or a caution in accordance with the Home Office guidelines.

Prosecution is the ultimate enforcement tool available for trading standards officers. In deciding whether to prosecute a case, Trading Standards adopts the dual test used by the

Crown Prosecution Service. The first limb of the test is the evidential test; is there a 'realistic prospect of conviction?' If the answer to this question is positive, the second part of the test is applied; the question of whether it is in the public interest to prosecute; including a consideration as to whether there is another more appropriate measure available (Gloucestershire Trading Standards, 2015; Service, 2011). At the investigation stage trading standards officers are required to take account of the relevant legislation including the Police and Criminal Evidence Act 1984, Criminal Procedure and Investigations Act 1996, Regulation of Investigatory Powers Act 2000 and the Human Rights Act 1998. Investigating officers are also required to follow codes of practice dealing with interviewing witnesses and disclosing evidence. The nature of Trading Standards prosecution work would suggest that it is concerned with the criminal process and while the Nutrition and Health Claims Regulations 2007 (Regulations, 2007) create offences for breaches, one might enquire as to the suitability of dealing with breaches by invoking criminal proceedings.

2.27 Actual enforcement – cases and regulatory decisions

The Regulation allows member states to implement their own enforcement regimes. It is instructive to examine the decisions made under the Regulation where these are available. Where cases have been determined by courts, these will provide a guide to the way in which the Regulation is enforced. In the absence of common law precedents, the decisions of self-regulatory bodies such as the Advertising Standards Authority provide useful guidance on enforcement (Gilsenan, 2011).

2.27.1 Enforcing health claims on food labels – the Australian experience

In a recent study of the role of environmental health officers in the enforcement of health claims in Australia the authors supported Lipsky's theory of street level bureaucrats accountable to their employers, industry and the public (Condon-Paoloni et al., 2015). The tensions which arise from competing accountabilities may influence their prioritization of their duties and their approach to enforcing regulations. When applied to nutrition and health claims the result may be incomplete enforcement and 'variable veracity and promulgation of claims on food labels.' (Condon-Paoloni et al., 2015). The dominance of such information on a food label may influence consumers' decision-making and undermine health policy initiatives based on consumer education.

2.27.2 Cases prior to the Regulation

Prior to the Regulation coming into force, the legislation relevant to the regulation of health claims was the Food Safety Act 1990 and the Trade Descriptions Act 1968 (since repealed by the Consumer Protection Regulations 2008 (The Consumer Protection from Unfair Trading Regulations, 2008). The control of health and nutrition claims was of a broad nature and not specific to food. It required simply that consumers were not misled (Ruffell, 2003). This was therefore a negative obligation rather than a positive one allowing the use of only authorised claims.

There are only two English cases where courts have considered health claims. Both cases are unreported in official court reports and the records of them are secondary reports from press articles. Both cases involve cereal manufacturers.

The first case *Cheshire County Council v Mornflake Oats Limited 1993* involves Mornflakes Oats' claims made for heart health on the packaging for porridge oats. The claim made was that eating porridge oats as part of a low calorie diet could reduce blood cholesterol and therefore reduce the risks from heart disease. In that case, the High Court held the information on the box had to be taken as a whole and that the claim was in effect a medicinal claim for Mornflake Oats. The claim that porridge oats could 'treat, help prevent or cure a disease' was a precise claim which may only be used for medicines and not foods unless they have been proven to deliver such benefits. As such, the claim was made in contravention of the then regulation. The legal position and therefore the outcome may be different under the permitted claims passed by EFSA under the Regulation (Guardian, 1999). However, the basis of the decision requiring scientific substantiation for the claim is consistent with the Regulation.

In the second case, *Shropshire Trading Standards v Nestle UK Limited 2000*, Nestle was prosecuted for claims made for its Shredded Wheat breakfast cereal. The wording on the packaging of Shredded Wheat stated:

Coronary heart disease...it's the UK's single biggest killer...the British Heart Foundation suggests the following to reduce the risks of CHD; cut down on fat and salt; eat more fibre...take part in a healthy heart campaign and start along the way to a healthier heart...cut down on fat...Shredded Wheat is

98% fat free with no added sugar...cut down on salt...Shredded Wheat has no added salt...eat more fibre...Shredded Wheat is a great source of bran fibre.

The magistrate commented that it was 'clear beyond doubt that the statements about Shredded Wheat attached to each of the campaign steps invite an irresistible inference that eating Shredded Wheat will reduce the risk of coronary heart disease' (Benjamin, 2000).

Nestle was found guilty and fined £2,500 and ordered to pay costs of £13,601 for contravening the Food Safety Act 1990 and the Food Labelling Regulations. It pleaded not guilty by claiming that the food could in fact prevent, treat or cure a human disease but it was unable to adduce evidence to satisfy the court (Food Law Monthly, 2000).

The case was brought by Shropshire Trading Standards which is noteworthy. It would seem that there was a particular interest in food law enforcement in that Authority and although he has since retired, that interest was associated with a particular individual. The case was decided at magistrates' court level; therefore, in spite of the potential implications for the regulation of food, it does not provide a binding precedent for future courts.

2.27.3 Adjudications by the Advertising Standards Authority

Notwithstanding the significance of the above court cases the reports of the decisions provide little in the way of guidance about the courts' approach to health and nutrition claims as there are no published judgements. Perhaps more enlightening are the decisions of the Advertising Standards Authority, in particular the ASA decision on Danone Actimel. The ASA has upheld four complaints about health claims by Danone in the period 2006-2009. The decision on which the ASA provided the most comprehensive account of its investigation and on its rationale was in 2009.

In 2009 the ASA received a complaint about a television advertisement for Danone 'Actimel' which made the claim; 'Actimel. Scientifically proven to help support your kids' defences'. The claim was challenged by a complaint that questioned whether such a claim could be substantiated under the British Code of Advertising Practice section 8.3.1:

8.3.1 Accuracy in food advertising

Nutrition claims (e.g. 'high in vitamin C') or health claims (e.g. 'aids a healthy digestion') must be supported by sound scientific evidence. Advertising must not give a misleading impression of the nutritional or health benefits of the product as a whole and factual nutrition statements should not imply a nutritional or health claim that cannot be supported. Ambiguous wording that could be understood as a health claim must be avoided. For example, 'goodness' should not be used as a synonym for 'wholesomeness' and, if a claim relates to taste, that should be made clear, e.g. 'It tastes good', not 'It is good'. The scientific meaning of the word 'energy', i.e. calorific value, should not be confused with its colloquial meaning of physical vigour

- 8.3.1(b)

Nutritional claims and health claims should relate to benefits that are significant. Claims should be presented clearly and without exaggeration

- 8.3.1(c)

No nutritional or health claim may be used in HFSS product advertisements targeted directly at pre-school or primary school children

- 8.3.1(d)

The fact that a food product is a good source of certain nutrients does not justify generalised claims of a wider nutritional benefit

Danone claimed Actimel would support the human body's natural defence system against common infections. Danone provided the ASA with the body of scientific evidence on which it relied. The studies, it claimed, showed a positive effect for Actimel overall.

The ASA, in consultation with a nutrition expert, considered the scientific studies. The first, by Guerin-Danan et al, did not consider health effects and therefore it was discounted (Guerin-Danan et al., 1998). Two further studies were deemed unsuitable as evidence for the benefits of Actimel for the general population as they were carried out on hospitalised children in India. Two studies by Pedone et al, were examined. The 1999 study, used a sample size that was too small to show the effect on the incidence of diarrhoea in the subjects.(Carosella et al., 1999). In both of the studies the mean ages of the children was 6 and 15.5 months and this was considered by the ASA to be 'lower than the target group of school age children suggested by the ad.' The portion sizes of the children in the study were larger than the recommended serving of one 100g pot of Actimel per day. Further observations by the ASA on the evidence included the inconsistency between the findings of the studies and where research was carried out on children who suffered from allergic conditions, this meant that the results of the study

could not necessarily be extrapolated to apply to normal, healthy children'(Giovanani et al., 2007). Where there were apparent benefits among those who consumed Actimel these were not statistically significant when compared to the control groups.

In conclusion, the ASA found that 'the evidence did not support the claim made in the ad that a serving of Actimel was scientifically proven to support the defences of normal, healthy school aged children against common, everyday childhood infections.' And finally '[w]e therefore concluded that the ad was misleading.'

In a further more recent case of alleged false health claims by 'Protein World' a food supplement supplier, the trading standards department of Northamptonshire County Council referred the matter to the ASA. There are a range of enforcement options across the diverse areas of responsibility available to trading standards. However it is perhaps only in relation to nutrition and health claims with the legal and technical interpretation required that it is conceivable that the response might be for a public body with a statutory duty to enforce to refer the matter to a lay body (Advertising Standards Authority, 2015).

2.28 The role of the European Food Safety Authority (EFSA) and its impact on decisions by courts and the Advertising Standards Authority

Under the Regulation, a claim which is permitted under Article 13.1 and which therefore appears on the list of approved claims may be used in the promotion of food. For a claim to be permitted under Article 13.1 it must be underpinned by generally accepted scientific evidence. The approval is provided by the European Commission but based on the recommendations of EFSA as to whether the claim is substantiated.

Since the Regulation came into force in 2007, some of the responsibility which previously rested with the ASA has been made simpler by the creation of the approved claims list. Therefore the question of whether to uphold a complaint may be determined by reference to the list of approved claims rather than by a fresh inquiry into the evidence.

The Dietetic Products, Nutrition and Allergies (NDA) panel of EFSA has assessed some 1000 health claims (at March 2011) and the vast majority of these have been rejected (Gilsenan, 2011). By 2015, EFSA had received some 44,000 applications and approved 256. In carrying out this assessment EFSA has adopted a quasi-judicial function. EFSA bears responsibility

for deciding whether a health claim is permitted across the entire sector. The outcome is similar to that of a decision of a court or the ASA by determining whether a prospective promotional communication will be used by a food business. In this way, it provides guidance and influences future behaviour. A decision by EFSA carries with it the authority of a scientific assessment that is unassailable and which removes the responsibility of the administrators and courts for difficult decisions. However, governments and the EU need to define the responsibilities of EFSA and it cannot be left to it to determine its own responsibilities. (Meisterernst, 2010)

The individual member states of the EU were invited to submit their claims for EFSA approval for development of the list. Some 44,000 claims were submitted and this unwieldy list was whittled down to 4637 by removing inevitable duplications. It was originally planned to have a final list of claims by January 2010 but the volume of claims has meant that they have been tackled in batches. A fifth batch was published on 30 June 2011 (EU FoodLawWeekly, 2011). By 2015, 256 claims had been approved.

When considering the evidence, EFSA decides if a cause and effect relationship is established, according to Gilsenan (2011) this is 'a scientific assessment to the highest standard'(Gilsenan, 2011). But before this can be determined there are three key preliminary questions that need to be addressed:

- i) Is the food on which the claim is made sufficiently defined and characterised?
- ii) Is the claimed effect sufficiently defined and is it a beneficial physiological effect?
- iii) have pertinent human studies been used to substantiate the claim?

In each case there must be a positive answer to all three questions. In line with the ASA approach shown in the Actimel ruling 'well conducted human studies are central to the claim substantiation. Human studies must be well designed, be of high quality and must be representative of the target population to which the claim is intended. They must be sufficiently powered, address confounding factors and use valid biomarkers for the claimed effect'(Gilsenan, 2011).

Some 80% of article 13.1 proposed claims have been rejected by the Panel. The quality of the evidence provided in support of claims has been variable, ranging from the Bible and Wikipedia to peer reviewed scientific journals. Of those claims which have been rejected they include those relating to probiotic, antioxidant and glycaemic response. All joint health claims have been rejected as the evidence has involved studies carried out using patients with osteoarthritis and their conclusions could not be applied to the general healthy

population(Gilsenan, 2011). In contrast, claims relating to the consumption of calcium and child bone growth have been approved.

Notwithstanding the question of scientific evaluation, there are five general principles which must be followed in relation to all health and nutrition claims. The claim must not:

- i) be false or ambiguous
- ii) give rise to doubt about the safety and or the nutritional adequacy of other foods
- iii) encourage excess consumption
- iv) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general
- v) refer to changes in bodily functions which could give rise to fear in consumers

(EC,
1924/2006)

The decision making of the Panel differs from adjudication by a self-regulatory body like the ASA or a court in some important respects. The process has very much been a case of 'learning by doing', not something that regulators or courts typically do, or at least admit to doing. The guidance for substantiation is evolving and EFSA has also committed to more dialogue with stakeholders by consultation. In fact, there is a thirty-day period from the issue of an opinion by EFSA when anyone may comment on the proposal and further comments are invited on the draft legislation following an opinion.

Court cases often arise as a result of ambiguity in the law. The result of the Article 13.1 procedure of adopting permitted claims or a 'white list' may be that there is less ambiguity and that consequently there will be even fewer cases. This will have implications for enforcement which should also involve a preliminary check by authorities to enquire whether a claim is among the permitted claims. On one view, this should be a more straightforward exercise and remove the ambiguity and judgement that may then need to be made. In spite of this, recent court decisions seem to indicate a less than supine attitude of the courts;

In two decisions dated 12 March 2008 (MD2008,p 533) and 11 September 2008 (MD2008 p 1344), the Higher Court of Schleswig addressed the issue of prior effect of the Community list. The court held that the inclusion of a health claim on the list had no legal effect and that the list merely contained proposals.

(Meisterernst, 2010).

Challenges under the Regulation, where they are made, may involve a challenge of the procedure used by EFSA for approval and about other parts of the Regulation.

However it is 'imperative that the Commission and the Member States, as the responsible risk managers and the institutions entitled to decide on the authorisation of health claims, regain control over the interpretation and application of the Regulation'(Meisterernst, 2010).

2.29 Research questions

A number of research questions arise from the literature which aim to seek to account for differences in enforcement style from members of a single profession: regulatory enforcement, who are tasked with enforcing the same legislation but who work in different areas and are subject to varying political control.

The research questions might be:

What is the level of awareness in the business of the Regulation and how they might expect it to be enforced? If there is widespread ignorance how has this come about and are there some types of firms who are more aware than others? To what extent is this due to the complexity of the law and Regulations? Are larger food businesses more knowledgeable than smaller independent ones or are they better equipped to deal with investigation and are they treated differently based on enforcers' preconceived notions of their character? Do businesses make a rational calculation of the costs and benefits of compliance versus non-compliance and deliberately decide to breach the law in the hope of a financial benefit? Alternatively, do they comply with legislation as a matter of moral principle? This question affects our view of an effective enforcement strategy, as to what reliance may be placed on deterrence measures such as criminal penalties and how much compliance might happen in any event, independently of any sanction. Where firms comply with law as a matter of respect for the authority of the law, how is the way in which some firms observe stricter standards than those required by law explained? Is this simply a matter of cautionary practice or zealous protection of their reputation driven by self-interest? Finally, in a political environment of deregulation, is extensive enforcement of regulation employing a command and control instrument possible where there have been severe cuts to funding? What role does the provision of advice play in the relationship between enforcers and business? Does this point towards a future of greater

reliance on self-regulation given the coincidence of interests between businesses and consumers as envisaged by some business strategists, for example Porter and Kramer? (Porter and Kramer, 2002).

2.30 Conclusion

The literature review above has examined the justifications for regulatory intervention in food markets for the provision of information regarding nutrition and health claims. The latter part of the chapter reviewed enforcement theory and practice by reference to the policies and operations of regulatory enforcement agents and the broader theoretical studies of enforcement. The multi-disciplinary nature of the research question of how do enforcers enforce the Regulation on Nutrition and Health Claims means that literature draws from economics, law, political science and consumer behaviour.

This chapter provides the basis and context for the methodology proposed and justified in the next chapter of conducting in depth semi structured interviews with enforcement officers.

Chapter 3

Methodology

3.1 Summary

This chapter explains the methodology adopted in the research. The research was conducted in two distinct stages. The first stage of the research was the review of the existing literature on regulation and enforcement in general and in particular in relation to nutrition and health claims, as set out in Chapter 2. The second stage gives an account of the research based on primary data providing a detailed description of the work done along with justification for the approach taken including an explanation of the ontological position or the philosophical basis underpinning the research. Primary data collection was carried out by semi-structured interviews of the key actors in enforcement: local authority enforcement officers employed in trading standards or environmental health. A qualitative approach was adopted in an attempt to gain insight into the norms and behaviour of enforcers and to explore the overarching research question; how are nutrition and health claims enforced? The question demands an explanatory approach rather than an empirical one that seeks to find causal links. There is a justification of the purposeful sampling strategy employed and an account of the process involved in structuring and conducting interviews including the transcription of speech to text. The data were collected from in depth interviews with 18 enforcement professionals with data saturation being reached at an early stage. Finally, the ethical issues arising from, and limitations of the research are acknowledged, including the reflexivity of the researcher.

3.2 Review of the existing literature

The first step in the study was a review of the literature relating to regulation and enforcement followed by a review of the literature specific to health and nutrition claims. The review identified the models of how regulation in general seeks to achieve its aims and of how the Regulation of nutrition and health claims seeks to achieve its related aims of a functioning market and consumer protection. The literature enabled the identification of two broad approaches: that which draws from economics and particularly, behavioural economics and that which is drawn from political science. The literature review was a means to 'identify language and phrases that would be meaningful to those involved in regulatory enforcement'

(Hutter, 1988). However the writer's experience of legal practice specialising in consumer law in the past and presently of academia as a lecturer in consumer law for students on trading standards and environmental health programmes meant that he was already familiar with the discourse. The review was carried out using the library of Manchester Metropolitan University which provides registered students with access to a broad range of materials including relevant journals and texts as well as to online subscription services such as Reuters LexisNexis. The library has its own search service, 'Find It' and provides access to consolidated services such as Science Direct, JStor and individual institutional libraries. An exhaustive selection of search terms was created with the assistance of the librarian and key papers were identified based on their summaries. There were multiple terms and phrases used in searches but the key ones which recurred were: 'nutrition', 'health', 'claims', 'regulation', 'enforcement'. These were combined with modifiers such as: 'behavioural economics', 'law', 'food', 'theory', 'practice', 'reform' etc.

In addition to the academic literature, the discussions between enforcement officers on the Local Government Knowledge Hub is a forum for enforcers to raise questions about their practice. The forum is not accessible to the public and membership is closed and by invitation only. The researcher was successful in being nominated for membership of the Food Standards and Labelling area of the Knowledge Hub which gave an indication into the key concerns around the Regulations. The discussions informed the research about the issues arising from the Regulations; for example, members shared their exasperation about the delays in the issue of the list of authorised claims by the European Union. The researcher did not contribute to the discussions as it was felt that it was more important to hear the unprompted and uninhibited views of those involved in enforcement practice (The Knowledge Hub, 2014). There are no quotes used in the study that are drawn from the discussion as the researcher had not obtained the permission of any of the participants.

3.3 Research philosophy

The ontological position suggests that enforcers' knowledge, views, understandings, experiences, interpretations are meaningful properties of the social reality which the research questions are designed to explore. The epistemological position provides that speaking interactively with enforcers and asking questions and gaining access to their accounts is a meaningful and legitimate way to generate data, while bearing in mind and acknowledging that interviews rely heavily on the interviewee's capacity to verbalise, interact, conceptualise and remember their experiences and thoughts on enforcement of the Regulations. The interview process is understood and acknowledged as subjective and that as knowledge may

not be separated from the knower, that subjectivity is an integral part of understanding the work. Consequently the researcher's values are inherent to all phases of the inquiry process (Creswell, 2012). Interpretivism relies on the phenomenological understanding of reality gained intrasubjectively from sensory experience expressed linguistically from moment to moment and day to day and that without interpretation there can be no understanding (Mishler, 1990). In the words of Angen (2000) 'what we can know of reality is socially constructed through our intersubjective experiences within the lived world, which results in a form of truth that is negotiated through dialogue'. (Angen, 2000). In relation to the interpretation of data from enforcers, 'valid knowledge claims emerge as conflicting interpretations and action possibilities are discussed and negotiated among the members of a community' (Kvale, 1996). Objectivity from an interpretative perspective is provided not by measurement of results or isolation of causative factors but from a faithfulness to the phenomena (Colaizzi, 1978). In doing so, the research question is carefully framed and the inquiry is carried out respectfully with due reverence to processes designed to ensure its integrity.

It is integral to the chosen methodology that the ontological perspective of the work is established early in the process as it forms the logical underpinning to the study. The ontological perspective of the research is determined by interrogating the nature of the phenomena under investigation. It involves asking what is regarded as the very nature and essence of things in the social world (Mason, 2002). The ontological properties in this work include: people (enforcers), practices (their professional practice in relation to the NHCRs), experiences (how they have enforced the Regulations) interpretations of their duties as enforcers, legal and administrative structures and social processes.

This is a social science study based on the idea of empiricism, i.e. that knowledge is gained from experience or observation of the world rather than theory (Aspin, 1995). Therefore the question of how enforcers enforce the law is approached by obtaining direct observable information about the world or data. The data collected was used to answer the research question posed by this study and to test the ideas or theories found in the related literature.

Empiricism is one of several possible approaches used in social science research. Other examples are theoretical, conceptual or analytical research. This is a study on the enforcement of law rather than a legal study that might be expected to be found in, say, a doctorate of laws. This is an important distinction that needs to be made at this early juncture as legal research traditionally relies on the analysis of rules. Moreover, legal research rarely makes use of primary data and research methods, in the sense that the subject is understood by social scientists, is not ordinarily taught to law students who do not generally undertake dissertations.

Therefore, research methods do not occupy the position in law that they enjoy in social science. Instead legal research, and, indeed, practice is driven by the application of deductive reasoning and drawing from analogy aimed at answering the question ‘what is the law?’ when faced with what Hart & Hart describe as the ‘open texture of rules’ (Hart and Hart, 2012). The collection of data has nothing to offer in respect of this question.

Generally, lawyers are not concerned with why people behave in a particular way. Legal academics and practitioners are concerned with predicting the outcome of ‘hard cases’ based on recognised patterns of reasoning. It is not, as academics from other disciplines, unfairly claim, ‘a series of intellectual puzzles scattered among large areas of description’ practised by the ‘vociferous, untrustworthy, immoral, narrow and arrogant’ (Becher, 1981).

The theory of law or, jurisprudence, finds that lawyers approach questions with certain assumptions about the nature of law. Legal theorists are further divided between natural lawyers who hold that there is a connection between law and morality and those who believe that law is founded on human reason: positivists. The distinctions are illustrated by the difference in which the key concept of evidence is viewed by lawyers and by scientists. For lawyers, evidence is anything, which is probative of an assertion regulated by set of man-made rules created to determine the admissibility and weight of information; whether that is oral testimony, real evidence or other information. For a scientist and social scientist evidence is data collected in accordance with scientific method, which may support or refute a theory.

3.4 Gap in literature and contribution to knowledge

The efficacy of a regulation in delivering the outcomes that were intended depends to a significant extent on how regulators enforce legislation. The outcomes are often described in economic terms of markets, effective competition and efficiency and regulatory intervention is justified by seeking to correct market failure (Posner, 1974) and to deliver consumer protection considered to be socially desirable (Ramsay, 1985).

The question of how regulators actually behave in the real world has been approached from distinctly divergent disciplinary slants: as informed by political science (Weingast and Moran, 1983), economics (Stigler, 1971) and behavioural theory and regulatory design (Thaler, 2008). The literature contains few studies based on how local government officials carry out their duties in obtaining compliance with their regulatory objectives. The apparent discretion that enforcers enjoy presents interesting but difficult choices about what action, if any, to take in particular cases. Save for the notable contributions that have focussed on the political factors

(Weingast and Moran, 1983; Olson, 1995) on regulatory actions, enforcers' actions have come under relatively little scrutiny. However, a study by Harrison et al which explored the regulatory contentions of the 1990s in food policy and the nature of food regulation did so by observing the nature of food law implementation at a local level and the basis of the discretionary enforcement decisions made by trading standards and environmental health officers in their everyday working lives. 'The intention was to get as close as possible to those involved in local-level food regulation to see how they give meaning to regulatory processes or 'live them out'.' The study involved interviewing local officers at a single London borough (Harrison et al., 1997).

The methodological approaches in the literature have ranged from experimental and theoretical work in political science to the application of complex modelling techniques in economics. There are no studies that are based on the qualitative analysis of interviews with trading standards and environmental health officers. This study focusses on the enforcement of the Regulation EC 1924/2006 on Nutrition and Health Claims based on interviews with practising enforcement officers. As such, it represents a contribution to knowledge and a refinement and development of the current literature.

The research question for this project may be 'an investigation into the factors influencing the enforcement of health and nutrition claims under the NHCR 2007'. The overarching research question from which subsequent questions flow is:

- How are nutrition and health claims made for food enforced?

The subsequent, or sub-questions which flow from this are:

- What kinds of ideas, norms and practices operate concerning the enforcement of health claims?
- How are matters related to the decision to enforce negotiated and how do these link with other responsibilities of enforcers?
- What is the interface between enforcement of food safety and health claims legislation?
- Is there an underlying tension between the duties on enforcers to take action and the complexity of the issues, the size and resources of the food co and the application of the home authority principle?

The research questions are aligned with the chosen methodology and specific research methods and techniques by considering what data sources and methods are available and how they might address the questions. This is illustrated in the table below:

Table linking research questions and methods

Research questions	Data sources and methods	Justification
1. How are nutrition and health claims made for food enforced?	<ul style="list-style-type: none"> • Trading standards officers (TSO): interviews <p>Also possibly:</p> <ul style="list-style-type: none"> • Case reports: analysis of reported cases • Industry: compliance managers in food businesses: interviews • Solicitors and other professional advisors: interviews 	<ul style="list-style-type: none"> • Interviews will provide TSO accounts of how they have handled enforcement based on their own experiences • Analysis of cases will reveal how cases are dealt with by the courts • Interviews with compliance managers and solicitors and other professional advisors will provide their accounts of how enforcers handle nutrition and health claims
2. What kinds of ideas, norms and practices operate concerning the enforcement of health claims?	<ul style="list-style-type: none"> • TSO: interviews <p>Also possibly:</p> <ul style="list-style-type: none"> • Industry: compliance managers in 	<ul style="list-style-type: none"> • Interviews providing TSO accounts and reported experiences and their judgements will reveal something of the kinds of ideas, norms and practices they operate in relation to enforcement.

	<p>food businesses</p> <ul style="list-style-type: none"> • Solicitors and other professional advisors: interviews 	<p>From this we should be able to discern whether enforcers have ideas about appropriate behaviour</p> <ul style="list-style-type: none"> • Interviews with compliance managers and solicitors and other professionals may provide data on these issues as they will have experiences of representing their clients as defendants in enforcement action
<p>3. How are matters related to the decision to enforce negotiated and how do these link with other responsibilities of enforcers?</p>	<ul style="list-style-type: none"> • TSO: interviews 	<ul style="list-style-type: none"> • The accounts and experiences reported by TSO will reveal something of how they negotiate their own enforcement experiences in the context of their other duties
<p>4. What is the interface between enforcement of food safety and health claims legislation?</p>	<ul style="list-style-type: none"> • TSOs: interviews • Secondary sources: reports of cases of food safety actions 	<ul style="list-style-type: none"> • Interviews with TSOs will tell us something about their experience in dealing with and about the allocation of their resources between the two types of cases and the extent to which food safety may take precedence over nutrition and health claims enforcement • Case reports may yield data on the focus on such

5. Is there an underlying tension between the duties on enforcers to take action and the complexity of the issues, the size and resources of the food co and the application of the home authority principle?

- All methods used in the study

cases by comparing and distinguishing between enforcement action related to safety and that related to nutrition and health claims

- A comparison of similarities and differences between the data yielded from the different sources will help to build a picture of whether there is a fit between the intended policy outcomes of the regulation and the enforcement infrastructure and practice

Factors that influence the actions of enforcers may range from awareness of the regulation and the potential breach of the same. Regulators need to know about, understand, assess and act on the cases in relation to which they have powers. There is a cognitive process which takes place where a person is exposed to information, forms an assessment or evaluation that may or may not result in a behavioural response. The response may be systematic or heuristic (Chaiken and Maheswaran, 1994). Models of choice take into account how much thinking individuals are likely to do before making choices (Petty and Cacioppo, 1986). Examples of the factors that may be found to influence the enforcement decision making process include; awareness, motivation, time, financial resources, confidence, experience, attitude to risk or whether such action fits with managerial targets or alignment with departmental goals. These requirements are cumulative so that all of them are required to be in place before any action might be taken.

The term 'enforcement' is used to refer to all activities that a regulatory agency engages in to promote compliance with regulatory objectives (Law, 2006). This is broader than the economic approach to enforcement which adopts a cost benefit analysis approach where economic actors will comply with regulation if, and only if, the benefits of compliance exceed the costs (Mishan and Quah, 2007; Becker, 1974; Stigler, 1971). Enforcement in the economic view entails the setting of the optimal levels of monitoring and fine so ensure the desired level of compliance. However, this does not adequately characterise the enforcement practice of most regulators. Enforcers rely on the deterrent effect of the threat of prosecution in the courts. However, this is generally disproportionately expensive and necessarily only takes place ex post and therefore raises questions about its efficacy as an enforcement strategy. If enforcers such as trading standards or environmental health can offer benefits to business by helping firms achieve compliance than market failures may be overcome ex ante and court action may be avoided (Scholz, 1984).

Having defined enforcement, and demarcated the issues arising from this study, it was necessary to determine the basis of the research in order so that the data may be classified and anchored in the scheme of knowledge epistemologically. This concerns the principles and rules by which it is decided that social phenomena under investigation here can be known. A study of enforcement of the NHCRs suggests an ontological position which says that individuals (enforcers) make decisions and hold attitudes and that those decisions and attitudes are meaningful components of the social world. This represents the ontological position in this research and encompasses the epistemology that individuals' decision-making and attitudes are knowable.

Determining the choice between paradigms of say, positivist and interpretive thought affected the choice of research method and data collection and in doing so articulated the purpose of the research (Van-Maanen, 1989). The purpose of the research was to examine the basis of enforcement of the law relating to health and nutrition claims and to establish what influencing factors and potential constraints exist on the enforcement of the law.

This study is concerned with examining how enforcers act when faced with cases of non-compliance and the theoretical aspects such as, the contrast between deciding between enforcement action designed to provide a deterrent or taking an advisory approach, derive from the data. As such, an inductive research strategy linking data and theory as associated with qualitative work is implemented.

3.5 A quantitative or qualitative approach to the research question?

Empirical data may be characterised as quantitative or qualitative; in simple terms, the former is numbers and the latter words (Punch, 2013). A qualitative or quantitative approach might have been adopted in relation to this research question. A quantitative approach to the question might have involved, for example, a survey of enforcers to measure the levels of enforcement action. Such measurement would claim robustness and this 'hard' data would be unambiguous (Bryman, 2012). A common quantitative approach in social science research of this nature would be the use of questionnaires administered by a trained researcher. If a quantitative approach was taken, the questions for enforcers would be related to actions taken to enforce nutrition and health claims with the specific goal of measuring the action taken. Quantitative research aims for objectivity by maintaining a distance between the researcher and participants which allows it to be replicable. In doing so it claims reliability and with careful representative sampling it allows the results to be generalizable. Therefore, a quantitative approach would allow broader conclusions about enforcement across England and Wales to be drawn based on the behaviour of enforcers in the sample.

The generalizable nature of a quantitative approach may, at first sight, seem attractive; however, such a methodology carries with it some inherent weaknesses and risks when applied to the research question here. For example, a simple tally of the number of prosecutions that appeared to show an increase in the number of actions would not necessarily allow any useful conclusions about enforcement to be drawn as it may show that there are more nutrition and health claims made or on the other hand, it may show higher levels of breach.

In the light of this, a qualitative approach was adopted. The potency of the qualitative approach is that it provides insights into the beliefs of enforcers and the logic they use when considering the enforcement of a nutrition and health claim. In comparing the responses of the various enforcers across a range of local authorities, it may be possible to assess the behaviours, perceptions and rationales that are specific to a particular culture, individual, department or organisation against those which appear to be more widely held. This is particularly relevant in the context of legislation implemented at a European level but enforced locally within a small area. In this way a qualitative approach provides contextual understanding derived from the rich data derived from the prolonged exposure to the participants in an unstructured natural environment (Bryman, 2012).

The overarching research question; how are nutrition and health claims enforced demands an explanatory approach rather than an empirical one that seeks to find causal links or correlation in support of a theory which might go on to predict analogous or future behaviour. The concern

here is to understand social interaction rather than large scale trends; a 'micro' rather than a 'macro' picture (Bryman, 2012). This does not exclude a quantitative analysis. Indeed, it is possible to conceive of how a quantitative approach might be applied as described above. But as stated by Mason (2006) '[t]he particular strengths of qualitative research lie in the knowledge it provides of the dynamics of social processes, and in its ability to answer the "how" and "why" questions'. The research questions and the data generated is concerned with the significance of context, in this case the professional working practices of enforcers. A distinctive strength of qualitative research lies in its intimate and habitual concern with context, with 'the particular', and with understanding of the situatedness of social experience, processes and change (Gillies and Edwards, 2005). The explanatory potency of a qualitative approach to the research questions here is furnished by 'placing explanation at the centre of enquiry reflect[ing] an interest in the complexities of how and why things change and work as they do in certain contexts and circumstances (rather than, for example, what causes what)' (Mason, 2006). Moreover the rationale of qualitative inquiry is based on the understanding that not all aspects of human experience may be understood through the reductionist measures of quantitative research (Giorgi, 1992).

Interpretive inquiry may claim legitimacy including rigour and validity without bowing to the authority of positivism (Angen, 2000). 'Instead, what we require is an interpretive approach to social enquiry that will enlarge and deepen our understanding' (Angen, 2000). In this regard, the use of causal explanation is inappropriate to the goal of understanding and interpretation required for the study of human experience. The goal here is to understand the choices and decision making process of enforcers.

3.6 Validity of the research

While the systems of determining validity in quantitative analysis are well established, the questions about the scientific value of qualitative research and challenges to its legitimacy at least, until relatively lately, remained open and controversial (Bailey, 1997).

In establishing validity, some qualitative researchers refuse to adopt quantitative measures or terminology claiming that it is a more creative process than the statistical analysis found in quantitative work. However, this is not to say that it is antithetical to creativity, insight and depth to address issues of validity and reliability. Qualitative researchers instead seek 'qualitative equivalents that parallel quantitative approaches to validity' (Creswell, 2012). Creswell suggests a number of criteria and techniques for validity in a qualitative study. Of those criteria, the ones applied here are prolonged engagement i.e. the significant time spent

with each subject, and, triangulation, testing rival explanations and thick description. These criteria were applied in the course of the interview process and subsequent data handling and analysis.

In the case of the first of these, the prolonged engagement and triangulation, the researcher spent between 45 minutes to one and a half hours with interviewees. In the course of this time, the interview discussion was concerned with the key research question related to the enforcement of NHCRs. In raising questions about the respondent's professional practice, the researcher would approach the same questions from different angles and thus provide triangulation. For example, respondents would often say that the enforcement of NHCRs was not a high priority for their authority because non-compliance did not present an immediate risk to health. A further question was then raised about the resource allocated to such work and interviewees would admit that there was no specific agenda to carry out such enforcement and no resource attached to such work.

The ideal of triangulation is that the same phenomenon is explored when using different data instruments. Here the problems associated with interviews such as biased or leading questions or partisan responses might be tested by reference to the actual behaviour of the subjects, for example by exploring the reports of cases and actions taken by enforcers. It is serendipitous that the work of food law enforcement is public and it is therefore widely reported in news media, by consumer groups and in legal reports. This observational data when compared with interview data provided a way to cross check the consistency of the data.

The online forum for enforcers to exchange ideas of professional practice and to raise technical questions, *The Food Standards and Labelling Section of the Knowledge Hub*, (The Knowledge Hub, 2014) was also reviewed for consistency. Some of the respondents in the research are regular participants in this active forum. Therefore, reference to the data on the forum provided a direct way to triangulate the individual responses to specific questions with the way in which that particular individual had dealt with the same issue in the forum. It provided a way of comparing what the respondents say online when in discussion with their peers with what they said to the researcher in the privacy of a one-to-one interview. It is not possible to provide an example of this without revealing the identity of the subject. However, this anonymous example serves to illustrate the principle. A respondent is asked about the extent, if any, latitude is provided in relation to goods which are already labelled and are being sold and which have some time remaining before their use by date. The response in interview was that a pragmatic approach would be taken so that the supplier would not be required to withdraw and re-label or destroy all products with a non-compliant label. Equally, the period of

grace would not automatically be extended to the expiry of the shelf life simply because it was in the financial interests of the supplier and that it was inconvenient to recall the product. This was a matter which was discussed in the forum and the same issues and responses were found. Another example of such triangulation in practice is the issue of the scope of home and primary authority. When considering a claim for a beef product the prospective primary authority was prepared to allow another authority who was investigating the matter to proceed and merely asked to be kept informed about the outcome. This appears to contradict interview data where it was found that general practice was to defer to the primary authority. This does not weaken the credibility of the data but it rather offers the opportunity to understand the issue more deeply. It also acknowledges that 'different kinds of data yield somewhat different results because different types of inquiry are sensitive to different real world nuances' (Patton, 1999). Overall it was found that there was a high level of congruence between the accounts of the respondents so that material which might at first sight appear impressionistic is in fact grounded in the lived reality of the enforcement community.

The most germane opportunity for triangulation arose during the course of this research in 2012 with the publication of *Spurious Claims for Health-care Products: An Experimental Approach to Evaluating Current UK Legislation and its Implementation* in the *Medico Legal Journal* Volume 80 p.1 (Rose et al., 2012). In this study, twelve volunteers submitted 39 complaints about products which appeared to have health claims for which there was no evidence. The complaints were submitted to Consumer Direct, the government funded online consumer advice service which closed in 2012, and the responses of the various trading standards departments to which they were referred were followed. The study concluded from the varying outcomes, ranging from no response to amendment or withdrawal of the claim, that the regulation was ineffective. In fact, it is possible to draw entirely different conclusions from the study; for example, that the referral system between Consumer Direct and individual trading standards departments was flawed. Nevertheless, the study provides a different approach to the question; how do enforcers discharge their duties in relation to the NHCRs? The Rose study provides an opportunity to compare observational data with interview data. The findings of the study were not inconsistent with the findings in this research but it is interesting to note the differences in approach: where the Rose study with its focus solely on outcome was critical of enforcers' responses to complaints, the interview approach provided an opportunity to probe in depth the decision making process of the enforcers and gave voice to their explanations for their actions which the Rose study did not do. As noted above, different kinds of data will yield different results as they reflect the complexities and nuances of the methodologies employed in each instance.

3.7 Data collection instrument – semi structured interview

The focus of the study was to explore the attitudes, values and practices of enforcers when faced with the problem of non-compliance with the Regulation. Therefore, it was decided to interview those engaged in the day-to-day enforcement of the Regulation: namely trading standards and environmental health officers. It might be apposite to seek to interview those who are subject to enforcement action: namely food businesses. This would provide corroboration or contradiction of the enforcers' accounts particularly in relation to questions of reasonableness and proportionality. Such a proposal presents challenges of identification of willing participants who are likely to be sensitive about discussing matters in which they are involved and where there has been enforcement action. However, it would provide an interesting alternative perspective on the question of the enforcement of the Regulation.

The interview process used open-ended questions which were aimed at allowing respondents to engage in wide ranging discussions. A semi-structured interview of enforcers was employed as the key method of data collection to provide respondents with the latitude to articulate fully their responses to complex issues. The interviews were arranged by email and by telephone and they took place mainly at the respondents' offices. However, in one case the respondent visited the researcher at home as this was the most convenient arrangement available. In two other cases, the respondents were working away from their offices and meetings were arranged in hotels. Therefore, in most cases the interviews took place in council offices that were familiar to the respondent. And where the interviews took place in other locations, this was at the specific request of the interviewee. In all cases the interview was carried out in an informal but professional style with a view to showing an appreciation for the interviewee's cooperation and respect for their time. The atmosphere for all of the interviews was convivial and comfortable and therefore the respondents were open and honest rather than guarded and circumspect. In fact, this gave rise to the problem of respondents speaking about matters that were not strictly relevant to the research question. Where this happened, the researcher, allowed them to finish their point before lightly bringing the focus back to the matter in hand by putting a new question to them.

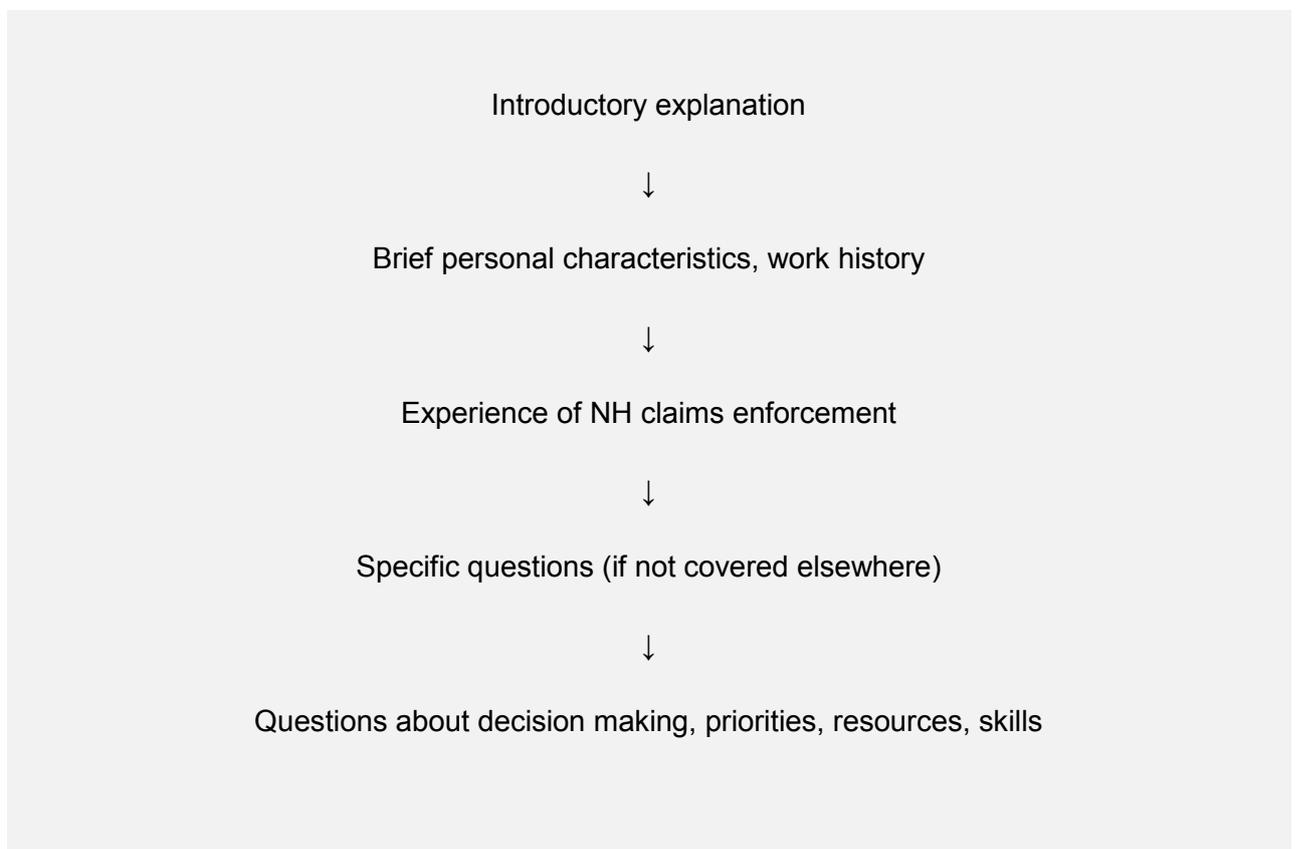
All of the interviews were recorded using a digital recorder after obtaining the express consent from each interviewee. By recording the interview, the researcher was able to focus on the conversation rather than have to concern themselves with making notes.

An interview guide was created for the interviews so to ensure a consistency of approach and to ensure that all the key areas were covered in all of the interviews. The interview guide was

not a list of fixed questions to be asked in a predefined order as this would be inflexible and could result in an artificial and stifled exchange. However, each interview was different in reflecting the differences in the experiences, language, articulacy, candour and values of the respondent. It was important to explore the contextual nuances of a response by following up initial responses. In all of the interviews, the respondent is allowed to speak for most of the time, only being directed towards a general area with open questions. The interviewer listened carefully to the response and affirmed it by summing up the point made. This often led automatically to a second more revelatory response from the interviewee who felt more comfortable and confident in sharing their views. The interview guide is reproduced below. It should be noted that the interviewer learned the structure and questions to allow the smooth flow of the conversation rather than allow it to be interrupted by referring to the guide during the interview process.

Table 2 *The interview guide*

Loose structure/format of interview



Specific topics and issues

Experience of enforcement: as a trading standards officer; advising business, dealing with complaints, prosecutions, routine inspections

NH claims enforcement and other aspects of TSO duties; enforcement of NH claims, application of home authority and primary authority principles

Barriers to enforcement: Risk, large business and small businesses , confidence, skills, resources, support

Interview Guide with questions

Enforcement of the Nutrition and Health Claims Regulations

Introduction

The purpose of this interview is to get information that will help me to understand how the NH claims are enforced. As a TSO you are in a unique position to describe how the NHCRs are enforced from your point of view. And that's what the interview is about. I'd like to know about your experiences and your thoughts about your experiences.

The answers from all of the people we interview will be combined for the report. Nothing you say will be identified with you personally. As we go through the interview, if you have any questions about why I am asking about something, please feel free to ask. Or if there is something you don't want to answer, just say so. The purpose of the interview is to get your insights about how the enforcement of the regulation is working.

I'd like to record the interview so that I don't miss any of it. Is that ok with you?

Any questions before we begin?

Brief personal characteristics of interviewee

Section 1

What is your job title?

Describe your main duties

How long have you been involved in the enforcement of food law?

Are you involved in the enforcement of food law generally?

What other areas of food law enforcement are you involved in? E.g. food safety

Section 2

Research questions to which this part of the interview relates

- How are nutrition and health claims made for food enforced?
- What is the interface between enforcement of food safety and health claims legislation?

The next questions are about your experience of enforcement of NH claims...

What experience do you have of enforcement of NH claims?

Have you been involved in the prosecution of a NH claim? Please describe your experience in relation to the case(s) you have been involved with.

How does the home authority principle affect your enforcement of the regulations?

Suppose you received a complaint about a NH claim. How would you respond to such a complaint?

Have you felt unable to act in response to a breach?

What are the constraints on your being able to take enforcement action if there are any?

What can be improved...

Resources?

Time?

Risk?

Support?

Expertise?

Section 3

Research question to which this part of the interview relates

- What kinds of ideas, norms and practices operate concerning the enforcement of health claims?
- Is there an underlying tension between the duties on enforcers to take action and the complexity of the issues, the size and resources of the food co and the application of the home authority principle?

The next questions are purposefully vague so you can respond in a way that makes sense to you. They are aimed at getting your perspective...

You say that you are familiar with the regulation...

What do you think about the enforcement of the regulation of health and nutrition claims?

Based on your experience, if none, your opinion, what problems are there with enforcement?

The regulations came into force in 2007. What difference have the regulations made? For example, are you more or less likely to take action for NH claims since the regulations came into force.

Probes for getting the interviewee to elaborate...

- Would you elaborate on that?
- Could you say more about that?
- That's helpful. I'd appreciate it if you could give me more detail
- I'm beginning to get the picture.
- I think I'm beginning to understand.
- Let me make sure I've got down exactly what you said, then I'd like to ask you to say some more on that.

The interviews had a more informal conversational style than would be found in a highly structured process. As a result, the precise wording and order of the questions in each encounter varied depending on the direction of the conversation. The differences in the order and wording were felt to be costs worth paying in return for the conversational flow, openness and in-depth reflections of the interviewees.

A further advantage of open-ended questions is that such an approach paid due respect to interviewees' opinions and their professional experience. As Aberbach & Rockman (2002) note 'elites especially – but other highly educated people as well – do not like being put in the straight [sic] jacket of close-ended questions. They prefer to articulate their views, explaining why they think what they think.' (Aberbach and Rockman, 2002). Moreover, open-ended questions allowed respondents to organise their answers within their own frameworks and thereby enhancing the validity of the responses.

There was a sharp learning curve for the researcher in the interviewing process whereby the later interviews were more fluent when compared to the more self-conscious efforts at the start of the process. After the first few interviews, the interviewer had grown in confidence and had honed in a style that was informal but focussed. As such, the later interviews were more efficient and focussed but equally thorough. As the interviewees are all busy enforcers who were interviewed on their work time, it was important that the duration of the interview was kept to a minimum necessary and that the interviewees were able to appreciate the relevance of the questions that were put to them.

It should be acknowledged that interviewing subjects carries inherent challenges in that the data cannot be easily measured and assessed. Such a qualitative approach leans towards an interpretive method (Van-Maanen, 1989). The aim of interviews would be to illuminate and grasp the logic of enforcers' decisions in relation to the enforcement of the NHCRs. This would be a step towards measuring the effectiveness of the regulation by an improved understanding of the appropriateness of the enforcement regime for nutrition and health claims.

The interview has been described as a 'conversation with a purpose' (Burgess, 1988). The purpose being 'to allow us to enter into the other person's perspective'(Patton, 1990). A qualitative approach to the choices of the enforcers examines those choices from the enforcer's point of view using a range of approaches which might include observation as a measure of what action is taken by enforcers. 'The issue is not whether observational data is more desirable, valid, or meaningful than self-report data. The fact of the matter is that we cannot observe everything. We cannot observe feelings, thoughts, and intention'(Patton, 1990). Such a method may be impractical and limited. Observing the actions of the enforcers

may prove haphazard in that there would be a high risk of not seeing anything that added to the picture and as a result it would yield a poor return for the investment of a large amount of time.

The semi-structured interview provides an organised but informal approach to data collection and attempts to distinguish between what individuals think, what they say, and what they do. It tries to unravel the normative responses where respondents tell researchers that which they feel the interviewer wishes to hear and what they ought to say to present the desired image of themselves or their organisation. The approach is aimed at uncovering actual behaviour and the reasons for it.

A pragmatic justification of the use of the use of semi-structured interviews is that the research question; how are nutrition and health claims made for food enforced? , can only be answered by interviewing enforcers. Although other methods shown in the table may provide corroboration, the core data sought may not be available by any means other than interviewing enforcers. Therefore, as shown in the table, interviewing enforcers is a necessary but not exclusive means by which the research questions may be answered.

Most studies based on self-report data collected as a result of interviews acknowledge artificiality of the forced response in the interview (Becker and Geer, 1957). In this case, this may be the difference between what enforcers claim in interview and what they actually do in practice. The responses of interviewees may be based on their own experiences or a professional view that is reinforced by perpetuation and repetition filtered through managers and colleagues. Finally there is a risk that the answers from respondents may be entirely capricious, a view that is not reflected on or considered and at all and provided spontaneously and which may not be repeated (Conrad and Blair, 2004).

The main limitation of the research is that which is common to all qualitative research; that the results are based on detailed analysis of a relatively small number of subjects when compared with the numbers of respondents involved in quantitative studies. The question of the number of interviewees is determined by the research question; there should be access to enough relevant data so that the research question may be addressed and to develop theory and descriptions that take into account specific contexts (Berg and Lune, 2004). It is stated that 'interviews with 15-30 carefully selected respondents is usually enough to identify most of the beliefs and representations that will be found in the whole population'(Leathwood et al., 2007).

3.8 Reflexivity and the role of the researcher

The responses of the subjects in qualitative studies, in this case, the enforcers, may be specific to their own cultural context, therefore it is necessary to avoid preconceptions and prejudicial judgements about the data (Creswell et al., 2007). Interviewing in a qualitative study involves the interviewer in an active and reflexive role. The researcher is the instrument in qualitative enquiry. It is important to analyse the data and draw conclusions from it rather than to be influenced by the prejudices of the researcher. It is not possible to eliminate entirely the researcher's influence but a high level of self-awareness is required in respect of that influence and its impact on the data collection, analysis and interpretation which serves to enhance the understanding of the discussion (Maxwell, 2005). For this reason, it is important to outline the experience and training the researcher brings to the field.

The researcher has a strong legal background of having spent 15 years in legal practice as a solicitor specialising in consumer and business law. This legal perspective brings a deep understanding of the substantial and procedural legal issues and the benefit of an analytical approach. It also brings with it some preconceptions about the nature of postgraduate research. The researcher finds himself at the intersection between research in law and the social sciences and there are sufficient differences between these worlds to hamper communication and for each to regard the other with a little suspicion. While this did not materially affect the research, it was helpful for the researcher to be aware of such differences between disciplines.

Since 2006, the researcher has been employed as a senior lecturer at Manchester Metropolitan University. In this post, the researcher has taught on the BSc and postgraduate Trading Standards and Environmental Health programmes. This experience has provided an insight into the work of enforcers and it also provided a starting point for access to respondents. Indeed the University is known among the profession as a key source of undergraduate recruits and a significant number of the respondents are graduates from the programmes. In the interests of transparency, the researcher should make clear that two of the respondents were graduates from the University and were taught by researcher while working at the University. It is not felt however that this has made any difference to their responses.

A standard interview guide was prepared in advance to reduce variation arising from the circumstances of the individual interviews and to enhance legitimacy and credibility by collecting the same information from all respondents. The topics and issues to be covered were notified to the respondent in advance and this increased the comprehensiveness of the data and made the data collection systematic and allowed for improved analysis and

comparison between responses. However, comparisons were not at the level of quantification of responses to particular questions or contrasting the differences in enforcers' answers to the same questions. The points of comparison were conceptual; drawing on and identifying themes in the data and determined by the research questions. At the same time, the semi structured approach of interviews allowed for more flexibility and exploration of issues which were not set out in the guide. The data were derived from the interaction between the researcher and the interviewee in the interview process. The analysis seeks to understand the complexities of the interaction rather than to minimise bias by standardisation.

The questions posed to enforcers were about their behaviour and experience and their opinions of the past present and future for enforcement of nutrition and health claims. To place those answers in context there are further questions about background and demographics e.g. age and the length of time working in an enforcement role.

Asking questions is an art as Payne (1951) observed. 'The way a question is worded is one of the most important elements determining how the interviewee will respond' (Patton, 1990). The wording of the questions has been considered so that they are open-ended, neutral, singular and clear (Fontana and Frey, 1994). Dichotomous and leading questions that suggest answers were avoided however, the presuppositions are used to enhance the quality of the descriptions responses particularly where such a response may be critical of the regulation or the infrastructure for enforcement, and, by implication of employers. In all of the interviews the researcher was unaware of any reason to question the honesty or integrity of the respondents' answers and felt that the responses provided were genuine.

3.9 Sampling

The recruitment of participants and sites is purposeful in that they are chosen because they can inform an understanding of the research problem and the central phenomenon in the study. The participants will be those who are best placed to provide meaningful answers to the research question based on their knowledge and expertise. There are 353 local authorities in England (HM Government) most of whom have a trading standards or regulatory department within them. There are several thousand trading standards officers. The sample of interviewees here has a regional bias towards the North West of England. It is opportunistic in that it is influenced by the constraints of resources such as time and travel costs. It is also determined by who was available and willing to be interviewed; a self-selection process is at work where those who come forward and provide substantial responses are those who are involved in the enforcement of nutrition and health claims rather than other trading standards

work. This may result in a bias towards enforcement action and such positive bias along with geographical factors must be considered in reviewing the results (Williams Jr, 1964).

Trading standards officers are from a wide range of backgrounds, varying in age and education and both male and female. The specific personal characteristics of enforcers for example, their age or sex, were not deemed to be relevant factors in influencing the responses relevant to the research question. However, the experience of officers, and in particular their involvement in challenging food claims may be expected to determine the data collected.

There are thousands of trading standards officers, some of whom who may be at any one point in time, involved in the enforcement of nutrition and health claims. It is not practical to interview them all. Nor is it desirable to do so if the study is to be focussed, seeking depth and complexity. In the words of Mason (2002) 'the concept of sampling from a wider universe implies that selections other than the ones you have made would have been possible, and this means you need to have and to demonstrate a clear sense of the rationale for your choices'. As this is qualitative work, the logic of probability and empirical representation of a wider group is substituted by a strategic approach to sampling. The sample captures the relevant range of constituent who might provide data that addresses the research questions or intellectual puzzle of how a social process works, here the enforcement of the regulations, rather than seeking to represent the wider universe. The sample was selected because it developed and tested the theory and the argument of the thesis and enable comparisons to be made to test the argument. In this respect interviewees who are known for their expertise and experience in enforcement of the regulations or in food standards were chosen. The purpose of the sample here was to illustrate or evoke the relationship between the contexts and the phenomena that were sampled rather than to seek to represent the wider population.

3.10 Sample size, selection and choice of subjects

Unlike with quantitative research methods where a power calculation based on the total number of potential respondents may provide a way of deciding the sufficiency of a sample size, with qualitative research there is no such equivalent and precise way of determining the sample size (Morse, 1991).

In the course of this research, twenty semi-structured interviews were conducted with respondents. According to Morse the sample size depends on; 'the quality of data, the scope of the study, the nature of the topic, the amount of useful information obtained from each participant...'

In the light of the clearly defined and narrow scope of the research as an investigation into the practices and norms applied in the enforcement of the Regulations, the number of respondents was felt to be sufficient. A non-probability purposive sample was chosen to capture those who are most likely to provide useful insights to the practice of enforcement in the relevant area. In addition, the interviews were intended to maximize the quality, richness and usefulness of the interviews. The questions were direct rather than aimed at probing at a phenomena beneath the surface intention was to optimize the efficacy of the interaction and this requires fewer interviews.

Table 3 showing names, roles and level of seniority of respondents

Name	Area of regulation	Officer, team leader or management responsibility
Chloe	Trading Standards	Supervisor
Millie	Trading Standards	Manager
William	Trading Standards	Supervisor
Ethan	Trading Standards	Officer
Jessica	Environmental Health	Supervisor
Julie	Trading Standards	Officer
Sophie	Environmental Health	Manager
Scarlett	Trading Standards	Officer
James	Trading Standards	Officer
Charlotte	Environmental Health	Officer
Jacob	Environmental Health	Officer
Dexter and Theo	Environmental Health, Trading Standards	Director, Manager
Isaac	Trading Standards	Officer
Mia and Cate	Trading Standards, Trading Standards	Officer, Supervisor
Ruby	Trading Standards	Supervisor
Sienna	Trading Standards	Officer
Samuel	Environmental Health	Manager
Amelia	Trading Standards	Supervisor

- *Table showing names, areas of responsibility for regulation and level for interviewees*
- *Total number of interviews: 18*
- *Total number of respondents: 20*
- *Of whom employed in Trading Standards: 14*
- *Of whom employed in Environmental Health: 6*
- *Number of respondents employed at officer level: 9*
- *Number of respondents employed in supervisory positions or above: 11*

NB real names have been substituted with fictional names

3.11 Data saturation

The most important determinant of sample size in qualitative research is that of data saturation; 'when the collection of new data does not shed any further light on the issue under investigation' (Glaser & Strauss 1967). The point at which saturation is reached depends to a large extent on the aim of the study and that a study with broader general aims might require a larger sample than one with more precisely defined aims. A small study with 'modest claims' would achieve saturation more quickly than a more ambitious project (Charmaz, 2011).

In the study by Condon-Paoloni et al (2015) which involved a qualitative analysis of interviews with environmental health officers in Australia, the authors described how interviews ceased when 'no new themes and ideas were being reported' (Patton, 1990). In both cases, the interviews were restricted to practising food law enforcement specialists only. It is posited that the deliberate and highly selective process applied so that only the most knowledgeable candidates were interviewed, has the effect of reducing the required number of participants in the study.

From a professional point of view, and in other respects such as education, training, experience and social background the participants are a reasonably homogeneous group, which also reduced the requirement for a larger group of participants. In addition, the researcher's expertise in the field of consumer law enforcement and therefore ability to direct the interview process to provide the most relevant and high quality information have the effect of reducing the number of participants needed in the study (Jette et al., 2003).

Given the importance of saturation as the key determinant of sample size in qualitative research the concept is worthy of closer examination. In applying the concept in this study of the enforcement of nutrition and health claims, it is possible to claim saturation early, particularly, in the light of the factors described above. However, it may also be possible to explore the context of the practice of enforcement in more detail and what it means to each of the participants. In this respect, it may be that the longer that data are examined there will always be the potential for the 'new to emerge'. (Corbin and Strauss, 2008). Therefore a 'tighter' approach to the concept of saturation is needed and this is proffered as the idea that saturation is reached when 'the new' may emerge but which does not necessarily add anything to the overall story, model or framework (Corbin and Strauss, 2008).

The approach adopted in this study was that of saturation and therefore it was not possible at the outset to decide on a sample size prior to data collection. It was found in the literature review that similar qualitative studies ranged from 15-30 interviews with subjects and this finding is corroborated by the findings of Mason in '*Sample Size and Saturation in PhD Studies Using Qualitative Interviews*' (Mason, 2010). From this, it was possible to envisage the range but not the precise number of interviews that would be required. Data saturation is easily claimed but difficult to prove. This researcher's experience was that there was a steeply diminishing return after each interview and that new information that was relevant to the study had been reduced to the very occasional idea around the mid-point of 10 interviews. The researcher was confident that data saturation was reached by the twelfth interview. This view is based on the fact that coding the data was well underway by this stage and it was not necessary to create any new categories for classification when analysing the data. In fact, no new codes were returned after the analysis of the twelfth interview. According to Guest et al (2006) a study with a high level of homogeneity among its population 'a sample of six interviews may be sufficient to enable development of meaningful themes and useful interpretations' (Guest et al., 2006). This finding is consistent with the statement that; 'the experience of most qualitative researchers is that in interview studies little that is 'new' comes out of transcripts after you have interviewed 20 or so people' (Green and Thorogood, 2009).

At the time of the interviews, the respondents were all employed as either trading standards or environmental health officers within the regulatory services of local authorities located predominantly, but not exclusively, in North West England.

The work of trading standards and environmental health covers a broad range of areas and regulatory services departments are organized so that staff will specialize in a particular type of work. For example, some officers might work on food whereas others will work on housing or counterfeit goods. However, the duties of individual officers would be reflected only in the internal organization of the department and would not be apparent to anyone outside of it. The challenge for this research was to ensure that the interviews were conducted with respondents who would have a sufficiently detailed knowledge of food law enforcement and, in particular, of the Regulations to be able to provide informed and detailed answers to the questions raised and thus ensuring the quality and richness of the data required. In this respect all of the respondents were specialists in food law enforcement and were qualified to carry out food law enforcement under the regulatory requirements of their professional bodies; either the Trading Standards Institute or Chartered Institute of Environmental Health. Each of the respondents had high exposure to the task of the enforcement of the Regulations as part of their everyday

duties. In addition, 11 of the 20 had responsibility for the supervision of others in their teams who were also charged with the enforcement of the Regulations.

3.12 Access

The researcher had some access to the sample frame by their position as an experienced consumer lawyer who has worked in the field for some years. More specifically, since 2006 the researcher has been employed as a lecturer on the BSc Trading Standards and BSc Environmental Health programmes run at Manchester Metropolitan University, one of the key providers of training to the enforcement professions. Therefore, when corresponding with the subjects the researcher's identity and that of their workplace was recognized and this allowed the subjects to trust the researcher and to grant the interview. The researcher is of the opinion that, in most cases, access would not have been granted to someone without similar credentials.

The researcher approached known contacts within the professions who held senior management positions within local authorities and their professional statutory and regulatory bodies for advice about how to identify the key specialists in the enforcement of the Regulations. In following this advice the researcher was able to identify the leading specialists. Some of the respondents are formally recognized as leading authorities in food law enforcement. The initial subjects were identified by this method of selection. Many of the subjects were involved with the work of a specialist food law enforcement forum aimed at developing approaches to enforcement and sharing best practice and influencing the development of enforcement policy at a national level.

Once the key individuals were identified, the researcher approached them individually by email. The email is reproduced at **Appendix x**. It will be noted that the area of the research is identified and that assurances regarding confidentiality are provided in that email as well and a request for the recipient to contact the researcher is made. There were few responses to the email. This is consistent with the experience of most researchers where the response rate to requests for an interview is generally low. However, the approach did allow for the initial access to the key individuals.

3.12.1 Snowballing or chain referral of interviewees

The interviewees were selected by a system of referral. On identifying an officer specializing in food law enforcement at the time of interview and at the subsequent correspondence the interviewee was asked for suggestions for names of other enforcers who might be in a position

to provide similar data. This 'snowballing' or chain referral is an established and widely used method of sampling in qualitative interviews, particularly when the interviewees are difficult to identify and there are difficulties in gaining access to them (Biernacki and Waldorf, 1981). Finding respondents presented no difficulty, in that, as enforcement officers employed by local authorities, they were a clearly visible group. However access to the group was more difficult due to the political and sensitive nature of their duties and the scrutiny and criticism to which they are subjected, as described below. Each interviewee was asked to nominate one or more other officer specialising in similar work who they felt would be able to provide answers to the questions under investigation. It turned out that many of the respondents were members of a specialist food law enforcement forum and who therefore got to know each other through this shared interest in their specialism.

The referrals made were predominately to other enforcers based in North West England and this was due to networks which operated across the region. The interviews were carried out face to face at the respondents' offices and therefore it was valuable for the researcher to be able to travel to and back from the interview within a reasonable time, usually within 2-3 hours in total. Had the respondents been located in more distant locations, the costs in time and travel expenses of attending the interviews would have been prohibitive.

That said, there were key individuals who were based in other parts of the UK who were interviewed because of their status as known experts. The locations of those experts are not provided to safeguard their anonymity.

While the researcher relied upon the referrer to nominate a person whom they thought to be suitably qualified, the verification of the respondent's qualifications and eligibility to provide useable data was carried out by setting out the purpose of the research in the email request and asking questions about their work by telephone when arranging interviews. Furthermore, at the start of the interview process, the respondents were asked about their current work and their past experience of food law enforcement and particularly about the enforcement of nutrition and health claims. In this way, several potential respondents were excluded at an early stage as having insufficient relevant knowledge and experience of the area under investigation.

3.12.2 Difficulties in obtaining interviews - the effect of horsemeat 2013?

During the period of the data gathering the work of enforcers was under intense scrutiny in the media which reached a peak with what is generally known as the 'horsemeat' scandal. This coincided with severe austerity measures at local authorities and the swinging cuts to their

budgets were most keenly felt among regulatory services. One respondent reported that the service was reduced to 25% of its pre-2007 capacity. At the same time, the political environment changed from 2010 with the election of a coalition government with a clear deregulatory agenda and a view perpetuated at ministerial level of local authorities as a barrier to business (Government, 2013). In the light of this, there was some trepidation and suspicion among interviewees and this presented problems of access notwithstanding the high levels of trust and familiarity enjoyed by the researcher.

At the start of the interview process in July 2012 the interviews with the subjects were organized and conducted quickly and without obstructions. However within six months the researcher began to experience serious difficulties in obtaining the agreement of subjects to take part in interviews. The subjects were found to be reluctant to take part and would often not respond to repeated attempts to contact them by telephone or by email.

It is suspected that the reason for this apparent reluctance to be interviewed arose from reasons connected with the meat adulteration scandal, which was first reported on 16 January 2013. The Food Safety Authority of Ireland announced that it had discovered the presence of equine DNA at varying levels in a number of the products, which it had tested in particular in ready meals, and burgers, which were being sold in large supermarket chains across Britain and Ireland. The revelation resulted in an enormous amount of media coverage and subsequent enquiries and investigations. Of course, food standards enforcement officers were at the forefront of such investigations and amongst other things, questions were raised about the efficacy of the methods and system of enforcement of food law in the UK and Ireland.

The researcher suspects that at this stage, trading standards and environmental health officers were required to ensure that their operations would stand up to the intense scrutiny that they were put under and in the light of this attention the media relations and communications departments of the local authorities in which they worked sought to control communications which might in any way be seen as potentially harmful to the reputation of the organization and which may lead to criticism of their work.

It is the view of the researcher that the horsemeat scandal led to a feeling of distrust among subjects who were advised against speaking with anyone who might seek to probe into their work. Of course, it is not possible to attribute the lack of responses to requests for interviews directly to the horsemeat scandal, it may have been a coincidence. But there was certainly a period from January 2013 to May 2014 when there was a *froideur* in response to requests for interviews. Notwithstanding efforts to provide assurances about the differences between providing assistance with academic research and speaking with media it was impossible to

arrange an interview during that time. The daily onslaught of media stories about food adulteration meant that enforcement professions had become acutely sensitive of the scrutiny which they had come under, and it was proving impossible to coax them into providing any sort of assistance. It seemed that the trust, which had previously existed between the regulatory services and media, had dissipated. At the start of that period, the researcher transcribed the interviews which had been conducted and began the process of entering the data into the qualitative data analysis software, Nvivo.

However, as far as gathering new data was concerned the research had come to a halt at that stage and discussions were held with the supervisory team about the possible alternative approaches that might be applied and how the lack of response to requests for interviews might be managed.

A breakthrough came in May 2014 when the interviewer received a recommendation to interview a particular person who by virtue of their position was widely perceived to be a leading figure in food law enforcement. (The researcher is unable to describe the basis of this assessment without disturbing the assurances of confidentiality that were provided to all subjects. It would not be possible to provide more information about this person without the risk of revealing their identity and therefore compromising the ethical standards under which the research was carried out).

The interview with this subject was carried out and during the meeting the researcher explained the difficulties that were faced in obtaining interviews. The subject offered to assist and in doing so sent a request to their counterparts in other local authorities. The request elicited the sort of positive response that the researcher had been unable to secure without their assistance. The interviewee acted as a *de facto* research assistant who was able to use their position to make contacts with respondents more effectively than the researchers could (Biernacki and Waldorf, 1981). The subject acted as a locator or significant informer who by reason of their experience was able to act as a reliable source of referral to 6 of the interviewees. In considering the risk of this one subject influencing the sample, there were no observable differences between this sector and others in the whole sample.

As a result the researcher was able to carry out a series of subsequent interviews. The researcher is of the view that without such assistance it would have been impossible to complete the project in the way it was planned. In addition, that it was the highly trusted status of the individual subject and the high regard in which they were held as professionals that facilitated the subsequent interviews to be held and the data to be gathered. The particular

methodological problems that are encountered and resolved reflect the singularity of the phenomena being investigated (Becker, 1996).

3.13 Transcription

The researcher has personally transcribed 13 of the 18 interviews. The transcription afforded the opportunity to become close to the data and as the transcription was carried out immediately after the interview, it consolidated the researcher's understanding of what was said. The transcription would take place in the intervals between interviews. This allowed the researcher the opportunity to understand the nature of the dialogue and which questions worked best and therefore to hone in the interview to make it more effective. However, the process of transcribing is extremely time consuming and the researcher was fortunate to be able to sub contract the later interviews to an experienced transcriber employed at the University.

The transcripts were checked by the researcher and it was interesting to note the difference in the transcripts. On comparison of the transcripts it was found that the researcher's transcripts took a more interventionist editorial approach by omitting words and phrases which were considered to be irrelevant to the overall research questions. Also, where there were words and phrases that were effectively pauses for thought or represented the breaks and flow between sentences, and were therefore fillers, in that they were not purposeful or contain any meaning, these were readily removed by the researcher when transcribing but they would be retained by the contracted transcriber who was more reluctant to take such editorial decisions without consultation. These approaches reflect the differences between the 'two dominant modes: naturalism, in which every utterance is transcribed in as much detail as possible, and denaturalism, in which idiosyncratic elements of speech (e.g. stutters, pauses, non-verbals, involuntary vocalisations) are removed' (Oliver et al., 2005). The justification for a naturalist approach is that it preserves the integrity of the data and the voice of the respondent. The denaturalist approach is focussed on extracting meaning from the speech and translating it to the text.

Most researchers, including this one, use a hybrid of naturalism and denaturalism making decisions based on their epistemological position and their assessment of how their research objectives are best served. In this research the concepts and questions arising from them are explicit and manifest and while there was some sensitivity on the part of some respondents in providing detailed answers about their way of working, generally the researcher sensed that the respondents felt comfortable and able to provide open answers to the questions raised.

As such the researcher was justified in employing a process of condensing, that is, 'shortening while preserving the core' (Graneheim and Lundman, 2004). In the light of this context and the fact that there was little latent meaning or interpretation to be read into what was left unsaid that would inform the research question the researcher was able to justify the intervention. For consistency and for confirmation of the credibility of the approach the researcher carried out the editing of the contracted transcriptions at the analysis stage.

3.14 Thematic analysis

Once the data were collected and transcribed from the interviews the transcripts were uploaded into the QSR NVivo data management programme and a thorough process of data coding and the identification of themes was then commenced. The coding process involved recognition of a significant statement and encoding it (Boyatzis, 1998) and a useful code was one that captured the qualitative richness of the phenomenon.

Thematic analysis involves the search for themes which emerge from the data that are relevant to the research question. This was done by the close and repeated reviewing of the transcripts to find patterns in the data where emerging themes become the categories for coding and analysis. This is the data driven inductive approach of Boyatzis (1998). Examples of the codes that were generated in this way are; the use of risk assessment in determining enforcement action; the influence of the central government organisation and support and references to resources. Such codes were then further split into 'child nodes' and, from there, further grandchild nodes might emerge. By encoding the data it was possible to organise it to identify and develop themes.

As each interview transcript was encoded, further interviews were being undertaken and more data were gathered. As the data collection and analysis were carried out concurrently it was possible to review the interview process in the light of the analysis in order to ensure that the themes did emerge from the data.

3.15 Limitations

The interviews were carried out during the period from June 2012 to May 2014. Therefore, strictly speaking, the interviews provide a snapshot of enforcers' experience during that period. When interviewed respondents are most influenced by their most recent experiences which are still vivid in their recollections. In addition, people, including enforcers tend to attach most significance to matters that are reported and which receive most attention and that may not

actually reflect actual risk of detriment to consumers. Even though it is hoped that this study accurately reflects the present position, circumstances may change, even at the time of writing. There will be new cases of commercial communications which potentially infringe the Regulation on nutrition and health claims which enforcement officers are responding to that might be reshaping enforcement practice. A single event, for example, a court ruling on the application of the Regulation or a media focus on nutrition and health claims may change the enforcement landscape. In particular, it may push nutrition and health claims higher up the regulatory agenda when compared to other areas such as food safety. However many of the most important theories of regulation underpinning this study were first promulgated in the 1970s and 80s and they are clearly relevant now.

Qualitative research aims to obtain evidence about attitudes, opinions, beliefs and behaviour but these are subject to change over time. The research presents a picture of those officers who participated in it. The study does not claim to be representative of the hundreds of councils or thousands of enforcement officers throughout the UK so it cannot be assumed that the conclusions of the study will apply to all local authorities.

3.16 Ethics

The study received ethical approval on acceptance of the research proposal in 2009. Since then the highly experienced supervisory team and the researcher have maintained a watching brief over ethical issues and there have been no unanticipated concerns regarding the ethics of the study. Also since the initial approval there have been no changes to the study which required a reconsideration of the ethical issues by the University Academic Board Ethics Committee. The code applied to the research is the University's Academic Ethical Framework 2011 (Manchester Metropolitan University, 2011).

The participants were all employed as enforcement professionals working as trading standards and environmental health officers within the regulatory services department of a local authority. As such they are public servants who are accountable in their work, in the first instance to their employers and managers but also in a wider sense to the communities they serve. The interview was concerned with their professional life as opposed to their private life and as such it was not 'sensitive' in the usual sense. Nevertheless there were sensitivities that arose from a concern about identification. The most serious concern for participants was as employees who might face negative consequences as a result of speaking openly about issues which are not ordinarily discussed publicly.

The interviews were carried out on the understanding that the identities of the participants and of anyone else who was identified in the interview would remain confidential and would not appear in the final published work. By providing the assurance of confidentiality the participants were able to speak openly about their practice without fear of exposure and criticism and it was felt that this provided greater credibility to the data.

To this end, the participants were emailed with an assurance of confidentiality when the initial request for an interview was made. An oral assurance of confidentiality was provided again at the start of the interview. Many of the participants expressed their concern for the confidentiality of the businesses with whom they had had dealings as these were ongoing relationships which required mutual trust and professional dealing.

It was made clear to the participants that their participation was entirely voluntary, that they were free to discontinue the interview at any time, that they could decline to answer any of the questions and that they could withdraw their data at a later stage as long as the final work had not been published. The final condition allowed for a long 'cooling off' period as there was at least one year between the final interview and the first draft thesis. The participants were asked for their consent to record the interview and they were assured that only the researcher, the transcriber, the supervisory team and examiners would listen to the interview. All but one of the participants agreed for the interview to be recorded. Where the participant objected to the recording, a contemporaneous note was made of that interview to substitute for the recording.

It was felt that in the light of the fact that the interviewees had agreed by email to a meeting with the researcher at their place of work, that there was no need to request a signed consent form as well. This was a deliberate choice because requiring a consent form would potentially create a greater formality and inhibit the interviewee from speaking as freely as they might and raise concerns where in fact none existed.

A particular concern in this study is the risk of deductive disclosure where insiders within a group may recognise each other from the identifying information provided in an interview specified as confidential (Tolich, 2004). The group here is enforcement officers employed by local authorities. By identifying the region, where most of the participants work as North West England, it might be possible for someone with knowledge of the profession to identify individuals from their characteristics such as age or gender and their account of their practice. As the information provided in this study contains rich descriptions of the work of participants it was not difficult to envisage that there was a risk of a breach of confidentiality. This was limited to some extent by the fact of participation being known at the outset as a result of the

chain referral or snowballing sampling method. Therefore, during the interview, it was not uncommon for an interviewee to mention their counterpart in a different local authority, particularly if that person had made the referral. As a result of participation in knowledge sharing groups, it was also common for an interviewee to speak about the experience of another colleague. In these circumstances it was not possible for the researcher to disguise the *identity* of the other participant, nevertheless it was still important avoid disclosure of the *substance* of the interview to the later participant. The researcher was conscious of the risk of the breach of confidentiality and therefore was deliberately circumspect where the interviewee would touch upon the experiences or views of others.

In respect of the confidentiality of participants, the identifying information such as names and addresses were removed after transcribing the interviews from audio recording to writing. The removal of identifiers allowed the creation of a 'clean' data set (Kaiser, 2009). This was done by using the 'find and replace' feature in word to ensure that all references to real names were removed and replaced by pseudonyms. However, the transcripts also were checked manually as well to remove third party names such as those of businesses which could not have been anticipated and therefore removed automatically.

Data cleaning can remove personal identifiers such as names but individuals remain at risk of identification where their story is in some way unique. As such it was important to consider whether the quotations or examples presented might lead to participants' identification by deductive disclosure. Where this was possible, details in the data were changed. Of course the decision about which identifying features of a person's account needed to be removed for fear of disclosure was taken by the researcher and this carries with it a responsibility for ethical decision making in rendering the respondent unidentifiable without changing or losing the meaning of the data. This gives rise to the question of how participants would feel about having their data altered. As Corden and Sainsbury found, respondents may have strong views about how their words or their personal characteristics are altered in research reports (Corden and Sainsbury, 2006). It was felt that on balance protecting the identity of the participants should take precedence over fears about changing the authenticity of their voices. Therefore, where there was a risk of identification then that material was changed but if that could not be done without significantly altering its meaning then it was removed altogether. The disadvantage of this approach is that the responsibility for deciding what to change or remove lies with the researcher and the reader cannot see what has been changed or removed and assess the significance of the amendment for themselves.

In considering the issue of confidentiality it is worth determining the plans for dissemination and the likely audience for the research. The research is undertaken as part of a PhD so that the immediate audience will be supervisors and examiners. The final thesis will be published and a hard copy will be held in the library for a limited time. It will also be available online at the British Library Electronic Theses Online Service (Ethos) which provides a free download for a registered user. It is intended that the work will form the basis of a follow up to the article *Nutrition and Health Claims: An enforcement perspective* published in Trends in Food Science and Technology in 2012 (Patel et al., 2012). The work may also form the basis of a conference presentation. In this respect, the work will be publicly available but the audience is likely to be limited to other academics, policy makers and enforcement professionals including the respondents themselves.

It was not felt necessary to seek approval of the drafts from the respondents prior to publication. The respondents were professionals and impervious rather than vulnerable and they came across as confident and safe in the interviews. They were not exposing their inner vulnerabilities and therefore seeking approval for drafts would serve only to raise alarm when in fact there was no cause to do so.

The researcher is aware of obligations on those who hold personal information about others as set out in the Data Protection Act 1998. Of the eight principles in the Act the most relevant ones to this study are: the data is processed only for the purpose for which it was provided; that it is relevant; not retained for longer than is necessary and that it is secure. In this respect, the questions raised in interviews were limited to information about enforcement practice. The data are not to be processed beyond the purposes of research and care has been taken to ensure that audio and document files are retained within the secure encrypted University information technology systems and they are not copied or moved to any other computers.

Finally, the most important issue here is that the participants have taken part voluntarily and have freely given their informed consent. It is worth reiterating that they are professionals who are being interviewed about their work and not their personal lives.

3.17 Conclusion

This chapter describes how the research was carried out and it explains why it was conducted in that way. In doing so, it demonstrates the appropriateness of the method to the aims of the project by reference to the research questions. It justifies the use of semi-structured interviews as part of a qualitative methodology which were analysed by applying codes using a thematic

approach. The limitations and the ethical considerations raised by the research are considered at the end of the chapter.

Chapter 4

Findings

4.1 Summary

This chapter analyses the enforcement of the Regulation on Nutrition and Health Claims following interviews with enforcers about their practice. The questions raised in the interviews were informed by the literature relating to a binary approach to enforcement of accommodation and deterrence and about the strategies adopted by enforcers in the face of the challenges posed by such a strategy.

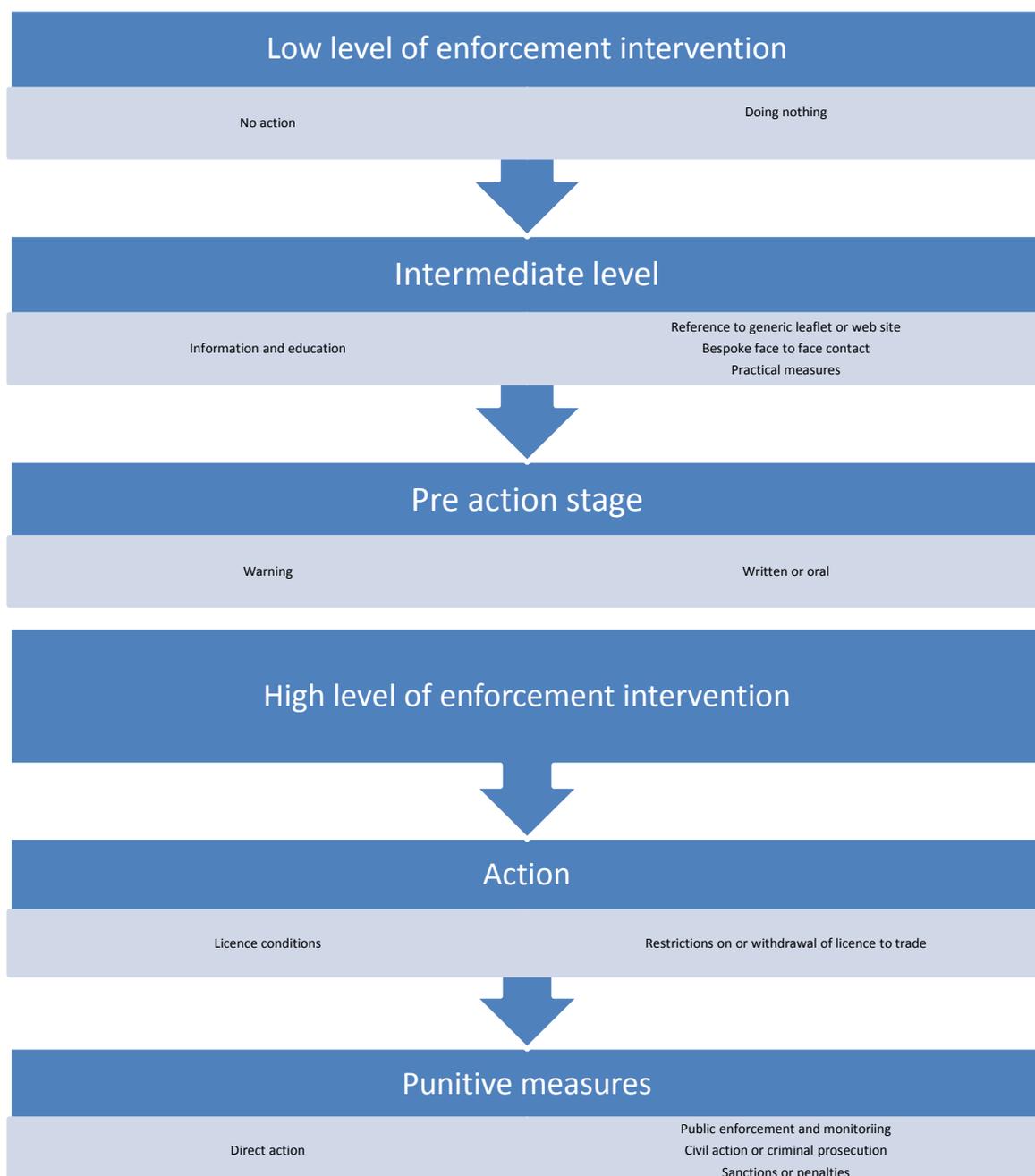
4.2 Introduction

Local authorities may choose whether and how to enforce the Regulation and this discretion allows enforcers to selectively enforce or not to take action at all, even where regulatory enforcement might be considered apt (Davis, 1969). Officers enjoy a high level of autonomy in their work only rarely being given specific direction by a supervisor. This is consistent with the findings of a recent study of environmental health officers in Australia which shares a similar organisational model for enforcement to that of the UK (Condon-Paoloni et al., 2015).

The importance of the role of officers is derived in part from their role as the 'first stop' for enquiries, concerns and complaints from the local population (Condon-Paoloni et al., 2015). Not all cases that come to the attention of the enforcer result in enforcement action and there are cases where it is appropriate for there to be no action taken. The discretion allows authorities valuable flexibility but the result is greater unpredictability for those businesses who are subjected to such regulation (Cranston, 1979). That enforcers enjoy a large level of discretion be able to choose whether to issue proceedings where there appears to be a prima facie case, is supported by judicial authority in the judgement of Viscount Dilhorne in *Smedleys Limited v Breed* (1974). In this, and in other cases, judges were keen to support actions which were justified to be in the consumer interest and were prepared to countenance the decision not to take action in cases where the consumer interest appeared unclear. The way in which the discretion is applied represents the operational policy of the authority affecting those who are subject to the regulation allowing them to be able to gauge what is expected of them by regulators and the efficacy of the Regulation (Dearlove, 2011). Condon-Paoloni found that

'environmental health officers, through their work practices and especially their enforcement role, have the capacity to affect the implementation of policy at community level and to optimize or lessen the benefits to consumers of policy and food regulations, such as nutrition and health claims' (Condon-Paoloni et al., 2015). The findings of this study appear to support the application of this conclusion to trading standards and environmental health officers in the UK. As such this may risk undermining the behavioural changes which are sought by the implementation of new food labelling law and policy.

Table 4 illustrating the options for regulatory enforcement and their levels



It is difficult to assess the success of a particular regulation and the enforcement measures associated with it (Hutter, 1988). There are numerous factors involved: for example, consumer trends in shopping, changes to the way in which products are marketed and the price of a product. These commercial factors will influence consumer behaviour so that the effect of any regulation and enforcement are difficult to isolate. However, the stated aim of the Regulation is consumer protection and making markets work and it is against these benchmarks that the efficacy of the Regulation may be judged.

It was clear from speaking with the respondents and from a review of available local authority guides and other documentary evidence that, notwithstanding the importance of enforcement, no formal policy specific to food law enforcement exists within councils. Therefore, each local authority is able to apply its own policy and practice and this research aims to uncover insights from the data into how this function is fulfilled.

4.3 Data analysis - emergent themes

A number of themes emerged as a result of the analysis of the interview data. Some of the themes are explored in detail, based on their relevance to the research question of how enforcers enforce the Regulation on Nutrition and Health and their use of discretionary powers in taking enforcement action.

A striking theme which emerged from the data is the enforcement officers' identification of themselves as prosecutors with sole and direct responsibility to the public: a view consistent with the deterrence model presented by Reiss (Reiss, 1984) and developed by Hawkins and Hutter (Hawkins and Hutter, 1993). A further related theme was a view of enforcers as advisors to business. Such an approach is rooted firmly in the accommodative model of Braithwaite et al where officers seek to 'educate, persuade and cajole' (Braithwaite et al., 1987). In this capacity, the enforcer adopted techniques such as education, persuasion and negotiation to deal with cases. In this role, enforcers' tactics were more informal.

Further themes emerged from the data such as the influence of elected councillors on local authority enforcement policy and the effect of enforcement action on the rights of those subject

to enforcement. These are discussed but they are corollary themes *relevant* to the matters in issue rather than the actual matters in issue.

4.4 Enforcer or advisor?

Ethan captures the duality of his position as an enforcer and how he reconciles the functions:

We always have to play two roles. Supporting businesses and the enforcement but they do tend to blend together quite well I find. And most businesses want to be compliant, and they know that, so if you can help them be compliant then they'll you know, go with you.

Traditionally enforcers have had an arm's length relationship with business. However, Ethan, like his contemporaries, is not uncomfortable with modern enforcement practice where enforcers play a role in supporting businesses in their efforts to ensure compliance with the law. This would support the notion that 'an advisory approach to regulatory enforcement may be a necessary component of an effective enforcement strategy' (Law, 2006).

Similarly, at the start of the interview where the enforcement officer is invited to describe their role and main duties, Chloe describes her view of her role primarily in terms of enforcement as her main purpose:

Well, enforcement is our main, we are regulators, enforcement is our main business advice and primary authority advice is probably secondary to that.

From Chloe's initial answer, it appears that she views her role as that of an enforcer and that even primary authority advice, where she is *contracted* to provide advice to a business, is secondary to that role. (Under a primary authority relationship, a firm will pay the local authority to meet the costs of providing advice in order to assist with compliance.)

It is notable how Chloe distinguishes between the roles of enforcer and advisor. She sees herself as an advisor but able to switch from that to regulator. This is at odds with the theory that advice is an *integral* part of the compliance strategy as described by Law (Law, 2006) but compatible with the regulatory pyramid of Ayres and Braithwaite (Ayres and Braithwaite, 1992; Braithwaite, 2002; Healy and Braithwaite, 2006) actions where enforcers move up and down the range of possible regulatory measures.

However, later within the same interview, Chloe seemed to shift her position to say that in fact her primary duty was to business. She described this more nuanced view of her role:

What business advice, especially what businesses need; always put businesses advice as the top, consumers tend to put that at the bottom, but they don't see that link in with food standards. The business advice improves the food standards. We use the questionnaire to get a full idea of businesses advice, some consumers will say, what are you helping them for? They don't understand that the business advice will prevent the problem with all the other areas.

Chloe's comments now appear to provide evidence of the business advice aspect of her role as integral to her enforcement activity. That for ex post enforcement, compliance with regulation is more readily achieved when the enforcer is engaged in an advisory capacity. Analysing this enforcement perspective is important because Chloe's beliefs about achieving compliance will determine policy making at her local authority and beyond (Chloe holds a supervisory position and hers is an influential voice in the food law enforcement community.) It will also directly influence agency and her own enforcement practice.

Chloe appears frustrated at the public perception of the relationship of enforcer and business as necessarily adversarial and her providing assistance to business with compliance as rather disloyal. The implication was that individual consumers would seek to use reporting to environmental health or trading standards as part of a strategy to settle private disputes with traders. In a similar vein, consumers might threaten to report matters to the local press:

Consumers would threaten companies by saying that they would report cases to us or that they would call the xxx News [the local newspaper]. Environmental health stories would often be front-page news. And if we didn't take the action they wanted, they would report us to the paper

In her view, there is a public perception that she should be taking a deterrence-based approach as described by Reiss. It is not clear why Chloe feels that public expectations would require that she does not provide advice to business. This may be due to a failure by the public to appreciate the nature of the enforcer's role and in turn, this may be attributed to the lack of communication by enforcers about their duties. Certainly, Chloe's remark regarding consumers indicates that she faces some resistance to the idea of helping business and that she ought to police and prosecute non-compliant business. However, in her practice Chloe actually adopts an advisory role. In fact Chloe goes much further when she actually speaks of promoting economic growth as an objective in itself and part of her work rather than as a

means of securing compliance: *'we'd give assistance with small businesses because we've got obviously priorities to promote prosperity and business growth in xxxx.'*

The role of economic regulators to deliver a competitive marketplace in order to provide an environment for business growth is well established (Beesley and Littlechild, 1989; Helm, 1994). The literature on enforcement practice does not however document the role played by a consumer protection enforcement agency in delivering business growth. To a degree, this may arise from the unique nature of local authority work where the authority has a duty to promote the welfare of its local residents including job creation. The political dimension where elected councillors influence enforcement practice and who seek election on a mandate to promote local jobs will enhance this aspect.

Whereas there has been a general move towards the deregulation of markets marked by the dismantling of the apparatus of government controls, beneath this picture, social regulation aimed at consumer protection has grown while economic regulation has been pared back (Hamilton and Viscusi, 1999). The Regulation may be justified as a consumer protection measure on the one hand and on the other, one aimed at delivering economic efficiency, 'a long standing rallying point in economic deregulation' (Hamilton and Viscusi, 1999). In this way, the goals of efficient allocation of resources and a strong level of consumer welfare can be reconciled via the paradigm of the informed and self-interested consumer.

Charlotte revealed that the provision of advice can provide the initial engagement between enforcer and a firm on the subject of the application of nutrition and health claims. When asked what experience, if any, she had of nutrition and health claims, she responded:

Some of the food manufacturers based in this area or other food businesses will ring up saying I want to make a claim on my label and I'll give advice.

Amelia went on to provide specific instances of the cases of such advice:

We have provided advice to a sports supplements importer...We have also been involved in giving advice to an internet trader for vitamins.

The reference here is to advice provided in response to a request for assistance from a firm. In their paper *Really Responsive Regulation* Baldwin and Black stress the case for regulators to be responsive to not only the attitude of the firm but also the 'operating and cognitive frameworks of firms' (Black and Baldwin, 2010). In responding to the specific request for advice, enforcers or regulators avoid the 'expensive process of shooting in the dark' (Black

and Baldwin, 2010) as the advice is targeting to meet an expressed need.

Health supplements and functional foods are, of course, the products where nutrition and health claims are most critical, as the product has no intrinsic value and without the claim and there is no reason for consumers to purchase such products in its absence. Unsurprisingly, it was in the promotion of health supplements where claims for health and nutrition were most commonly found and most strongly contested.

In both deterrence and accommodative approaches, the enforcer sought to achieve the same goal: compliance with the regulation and therefore to stop the offending behaviour in the case in hand and to deter such behaviour in other cases. The roles of enforcer and advisor were not mutually exclusive; in fact, it was common for the enforcer to move from the position of advisor to prosecutor in the same case as lower level action failed and the case escalated to stronger measures. *'Initially advise them, yes. I mean if they don't listen to advice then you can take more formal sanctions but most of them will comply'* Ethan. This confirms the notion of escalation up the regulatory pyramid of Ayres and Braithwaite et al (Ayres and Braithwaite, 1992).

4.5 The enforcer as advisor: the nature of the relationship and its defining characteristics

This section describes the advisory function of an enforcement officer as revealed by the data.

Mia alludes to an established relationship between the enforcer as advisor and the business as client: *'Because we do have a number of manufacturers that we do advise generally on labelling.'*

When asked about the significance of nutrition and health claims as part of the day-to-day work, Jessica, perhaps surprisingly, accords the claims real importance:

Right, I would say now that they [nutrition and health claims] are usually at the forefront of a lot of complaints and enquiries that we have because we record how many new businesses that contact us and for last year we had 30 odd start up, what we call start-up businesses, brand new businesses. And the thing is with when people start up a new business we say right, what are you looking to sell and they'll tell us, it's a muffin, and it's absolutely fantastic and it's going to be low fat, it's going to be high in fibre, it's going to blah blah blah,

In their study of the Irish market for food, Lalor et al found that a significant number of products had nutrition and health claims (Lalor et al., 2010) and Jessica's comment appears to confirm the popularity of such claims for marketing.

Jessica refers to small businesses who may not yet appreciate the controls applied to the making of such claims and who may subsequently decide not to make the claims or act in breach of the law. This is supported by the fact that Jessica then goes on to describe the attraction as well as the misunderstanding surrounding a claim such as 'gluten free':

Well how are you going to market it? What claims are you going to make? And they'll say, well, it's got, it's going to have oats in, so it's going, we can say it's gluten free. Well, can you say it's gluten free, because it's got oats, because there's a debate at the moment as to whether gluten free, low gluten, coeliac information, so we say you can't just go ad hoc and make these claims.

Kagan and Scholz, in their work *The Criminology of the Corporation*, theorise about the reasons for non-compliance with the law by small business but conclude that there is no single theory which will adequately explain such behaviour (Kagan and Scholz, 1984). More specifically, following an empirical study of small business compliance, Yapp and Fairman find that:

Whilst some of the barriers identified within other research were present within food businesses (specifically time and money), there were also a number of complex, underlying issues that prevented compliance with regulatory requirements and which have implications for regulatory and enforcement policy. These barriers included the lack of trust in food safety legislation and enforcement officers; a lack of motivation in dealing with food safety legislation; and a lack of knowledge and understanding (Yapp and Fairman, 2006).

Similarly, Harrison *et al* found that educative function 'is increasingly focused upon the lower tier of food retail establishments, such as a butcher's shop or a bakery' (Hutter, 1989). There are now very few independent butchers and bakers on high streets. In the light of the change in this composition of the high street the current independent food businesses which are most prevalent are fast food takeaways and it was apparent from the data that these are now the focus of educative efforts of officers.

As with retained advisors like lawyers or consultants, the enforcer may be involved at an early stage in the life cycle of the product and be asked to advise about the label design:

Some of the food manufacturers based in this area or other food businesses will ring up saying I want to make a claim on my label and I'll give advice.

Charlotte

We've had it with a company XXLtd who came to us before the products were launched and asked for our advice. It's a bit like a cereal bar and it's got loads of claims on it like it's gluten free, and it's suitable for everyone and it has all these different properties in it and it's quite difficult because you have to say you can't have this but you can say that. But they wanted to keep everything. But we were involved from the start so that helped reach an agreement.

Mia

The act of seeking advice is not an artless activity and food businesses may approach the topic armed with their arguments, and with a view to obtaining advice that best suits them. They may, for example have seen what they consider to be a similar claim being used by another firm. As a result they have reached the view that they can do the same. The outcome as described by Mia is positive and the supplier accepts the advice. Where suppliers are very attached to the claims to the extent that they have even designed a product around a claim, it can be difficult to provide helpful and constructive advice in such cases. In cases where advice is sought on label wording and design the role of the regulator is significantly different to the policing role which is traditionally invoked.

Amelia describes how she is faced with a proposed claim based on what the firm has witnessed in the market:

Sometimes we get an enquiry which says they want advice about labelling which refers to [the practice of] xxx [major supermarket chain] or yyy [another major supermarket chain] and they ask which they can follow, and we know that they know that xxx or yyy are not doing it right.

This is an obvious challenge to the regulator, impliedly saying that, 'if you are prepared to tolerate the claim from another which we both know to be unlawful, I will do the same.' Such a challenge may force the officer's hand and require that action is taken against the business who already use the claim. Alternatively, it may, in the interests of consistency, require that the regulator ignore a claim by the firm seeking advice. In either case, it represents a defiant

challenge to the regulator's operational working.

One response to the challenge might be to say that fairness or consistency of treatment is not the measure of effective regulation and that the enforcement action is best assessed by judging the total harm prevented and the benefits to society overall. Notions of fairness are secondary in this model of the economic analysis of regulation (Hahn, 2004). Such an approach may also be justified on consumer protection grounds to ensure the maximum welfare to the maximum number of consumers.

Charlotte provides an example related to the attempt by a manufacturer to use the term 'healthy':

One of the manufacturers wanted to launch a healthy range so they were going to put the word 'healthy' in the label so I had to advise on that. I just needed to see why they thought the products were healthy and advise them accordingly. 'Healthy' is a general claim which will need to be accompanied by a specific claim. And all the other things which have to appear on the label. It was the marketing department which wanted to do it.

Charlotte distinguishes between the circumstances in which the Regulations will apply and where they will not. Using the term healthy as a general claim is not covered by the Regulations unless there is a specific claim which accompanies it. In her account, Charlotte also demonstrates an appreciation of the commercial imperative applied by the organisational structures within a business. A single definition of the term 'healthy' is impossible to agree. An example to illustrate this would be cheese: it may be rich in a desirable nutrient such as calcium but contain high levels of fat. Nutritional profiling provides a clear way to communicate the nutritional qualities of a food by translating this information into colour coding where a quantity and proportion of a single nutrient within a food is clearly signalled. In their study of the effects of nutrient profiling as a way of categorising foods according to their nutritional quality, Lobstein and Davies found that this information might be a practical way to communicate complex dietary information to consumers (Lobstein and Davies, 2009). This is the underpinning of the traffic light or colour coding systems in place on food labels and the basis of the restriction of advertising of unhealthy foods to children.

Dexter describes the challenges of providing practical advice based on complex legislation, which might be translated into action by the recipient:

I think understanding the accuracy of the health claims is complex. It's not as easy as just looking and seeing oh that label needs to have a best before

date or the use by date is wrong, it's looking at the whole thing, and (a) it's a health claim and (b) I need to go and check that to see if it's correct so I need to go back onto the website so it's not immediate. You need to go back and double check, the local website is (a) it's a valid health claim and (b) it's authorised and then go back to the business and say well we need to make some changes.

Any corporate lawyer will be familiar with the problem of translating complex legal rules into helpful advice for a business client and then to go on to make recommendations. Often the position is unclear and, at best, advisors provide an assessment of the risk rather than a definitive answer. When retained advisors give advice, which, when things go wrong, may lead to a financial loss, they are potentially liable to pay damages for breach of contract or negligence. Solicitors are obliged to take professional indemnity insurance to deal with any potential claims under the Solicitors' Regulatory Authority Indemnity Insurance Rules 2013 Rule 4 (Solicitors Regulatory Authority, 2013). The provision of advice, albeit without charge, would potentially give rise to liability to the local authority for which it may be prudent to obtain such indemnity insurance or ensure that it is protected under the terms of its existing cover. This raises the question of whether this might have the effect of formalising the relationship between enforcers and the regulated firm and inhibit the provision of advice. It would certainly put to the test the circumstances in which liability might arise.

The issue is most acute where the regulated firm is an SME which does not have the knowledge or awareness of the laws which apply to it and therefore are unlikely to have in place the resources such as financial commitment and management systems in place to ensure compliance. They are also unlikely to be able to afford hire such expertise. SMEs do not have the personnel or time or availability to be able to monitor compliance and to interpret law (Hillary, 1995). In such cases, the firm is reliant on the free advice provided by the local authority. If such a service is stopped or restricted to avoid liability for negligent advice than this may lead to more non-conformity in a sector where there is already significant breach.

We can see from below that Jessica appreciates the importance of consistent advice for businesses, particularly where they operate across local authority boundaries. Yapp and Fairman found that where there was a follow up visit to the same premises and there was an inconsistency between the advice provided on each occasion that this would lead to a lack of trust:

EHPs were seen to act inconsistently, both within the individual business and between businesses. SMEs complained that different food safety requirements were made each time the premises was inspected, despite conditions remaining the same and the same EHP visiting. SMEs also believed that EHPs would forget or fail to enforce requirements made previously and therefore failed to take action...

(Yapp and Fairman, 2006)

Yapp and Fairman were concerned with inconsistency between repeat visits to the same business. A similar concern was also raised by Cranston in 1979 at the general level of the exercise of unconfined discretion in *Regulating Business: Law and Consumer Agencies* (Cranston, 1979). The risk of inconsistency between different officers operating in different local authorities is significantly greater.

One of the mechanisms that was used to ensure consistency of enforcement practice between different businesses is by the issue of guidance from the Local Authority Coordination of Regulatory Services (LACORS). The role of LACORS was to issue guidance aimed at coordinating enforcement practice. However LACORS was replaced by the Local Government Association in 2010. The coordination role has been replaced with a web site for users to share practice known as *the knowledgehub* (TKH, 2014).

Providing advice to business entails a responsibility, which is not borne easily without the assistance of LACORS the central coordinating body, as Jessica explains:

That's what that's all that the manufacturers want, a consistent approach. We do our best, we try to, that's why we go through home authority and primary authority but it would be better, you know it's different me, I feel that the responsibility is too much on local authorities because most primary authority and going and speaking to a multi-million pound business and they are relying on my advice, that's a massive responsibility for me. I would rather have checked it out with LACORS and LACORS had come out with the advice, and for me to say this is what LACORS have said, this is what you should follow.

There are formal processes in place to ensure that the local authority advice across boundaries is consistent. A recurring theme was how businesses feel an acute sense of unfairness where it appeared that a competitor was able to make claim which they are advised not to, *'They will say, x, y and z are doing this and we want to do it as well. How come they can do it, and we can't?'* Jessica. By having advice and following guidance from LACORS an enforcer was able to provide authority for their action. Now that LACORS or its equivalent is not available to provide such assistance, enforcers risk being exposed and having to respond in a defensive manner.

One of the methods used by local authorities to ensure consistency is the setting up of a primary authority relationship which provides notice to other authorities that advice has already been given. Interestingly, here Chloe also speaks of being a burden on business; not a position that one might ordinarily associate with an enforcement official:

*There's a section just for regulators on the BRDO [Better Regulation Delivery Office] website so I can go on that register and look for like a national supermarket and see if they've been advised on health claims. If I was to go and visit that supermarket, I have to look at the primary authority register to see if they've got a primary authority and I have to have regard to advice that's already been given. **We do burden a business**, so like at xxx (major supermarket), if they've got 422 local authorities all going in, taking up the time of store manager, their primary authority could say, 'no need to look at this area, we've audited it and we're happy with it. All the primary authority partnerships across the country are listed on this website and regulators have a special log in to check what advice has been given. So if I was to do, say a xxx [name of major supermarket] inspection, I'd have to go and look at their inspection plan, any advice that had been given, to know where to direct my resources when I go into my local store.*

Chloe seems concerned that the regulation is not optimal rather than that there is any at all. The research points to inefficiencies in command and control systems of regulation and a preference for market based regulation. Therefore, the questions are around when and how to regulate and how to avoid problems of regulatory capture (Helm, 2006). Chloe's suggestion is aimed at avoiding the inefficiencies of the regulation of individual outposts of a business with multiple branches.

The primary authority relationship where business receives advice in return for payment, may provide a level of indemnity which commercial advisors cannot provide, as Chloe explains:

And as much as we wanted to be able to say, yes, we couldn't so we've not heard from them since. And the primary authority has gone, because that was, to be fair, I did say to them, if we can't approve and give primary authority advice to say that you can use that, there's very little point in us actually being the primary authority.

Where enforcers can provide an indemnity against action from either their own authority or from another authority, this provides a valuable benefit and assurance to business. This goes beyond the benefit that might be provided by an independent professional advisor such as a lawyer while raising the issue of liability for advice provided and the provision of a benefit which cannot be matched by any other provider. It also raises questions of the conflict of interest between the provision of advice and assistance on the one hand and the duty to enforce on the other.

Enforcers can demonstrate a surprising level of involvement with the commercial aims of the business as Scarlett shows:

I'm trying for them not to change their trademark, I know they want to keep their trademark. How can we go round – not circumvent the legislation obviously, but get to a point where they can continue to use it

There are specific provisions in the Regulation which make it clear that a claim contained within a trademark is subject to the same control as if it were made without the trademark. In other words, that the registration of a trademark does not provide immunity to a claim made within it. Local authority enforcers do have experience and knowledge of law for business. However, it would be unusual for that to extend to providing advice relating to intellectual property issues arising from the protection of trademarks and to provide advice about how the trademark might be protected.

4.6 The limits of the advisory function

At times, there was an expectation from a business that enforcers would be on hand to provide advice whenever it was required. James describes that expectation:

certain companies would be phoning you all the time so you felt like you were doing their work for them which is ok but when we are stretched it's not possible to do that as much so it's something that's in formation at the moment with primary authority, so we'll see how it works out.

Enforcers would need to adopt strategies to manage the expectations of businesses because they were unable to deliver the service levels which business would have liked and possibly had become accustomed to from other providers. There is no fixed service level agreement in the provision of advice from the enforcer to the business. There are general turnaround times for responses used by local authorities to deal with enquiries from the public. In the absence of specific response times for business enquiries, these are likely to be applied. However, this is speculation and the issue was not explored with interviewees. The problem of managing business expectations was most acutely felt following the severe cuts to budgets imposed from 2009 onwards. James described the circumstances:

We're short staffed now but we used to have a chap who was office based and people would send their labels for approval and raise issues they have and he could spend quite a lot of time doing it. We don't provide that service any more.

It will be instructive to see whether the withdrawal of a label copy clearance service will lead to more ex post liability breach and with enforcers playing a lesser role in the provision of ex ante advice. The effect of withdrawing 'free' advice may implement a cost structure and more efficient distribution of resources and avoid the waste associated with services provided free at the point of use. Alternatively, it may result in greater non-compliance and problems of consumer detriment that might have been avoided more cheaply by providing advice. This was raised as a concern by more than one of the interviewees.

The number of products which might potentially contain claims and therefore may be caught by the Regulation is vast and it is impossible for an enforcer to review each one individually. As Charlotte explains, *'we can only advise on what the law says rather than each specific claim.'* This is a reasonable, as well as necessary, way to limit the volume of requests for advice. It also provides a method of limiting liability for any advice proffered by framing it in terms of general rather than specific guidance.

Charlotte refers to another means of limiting the amount of time spent on enquiries by

signposting enquiries to publicly available resources:

You do refer them to the guidance so you wouldn't necessarily have to deal with each potential claim. Every time they want to make it in relation to every product line. Which potentially could be a lot of claims.

Charlotte is referring to the general guidance available from the Food Standards Agency web site and the *Guidance to compliance with Regulation 1924/2006 EC on nutrition and health claims made on foods* (Department of Health, 2011). Millie makes reference to her obligation to provide advice and the limitation on that obligation and how that might be extended in the case of a primary advice relationship:

Following the regulator's code, we are required to provide basic advice. I do not think intricate labelling of products is basic advice, it would require my officers to carry out additional work and that additional work would not be covered unless they had formed a primary authority relationship with us, therefore we wouldn't get involved. It's the responsibility of the company.

The lack of time was found to be a barrier to compliance by 54% of SMEs in the study by Yapp and Fairman and businesses did not see the identification and interpretation of regulations as part of their business operation. Instead, they preferred to rely on assistance from the environmental health officer during inspections (Yapp and Fairman, 2006). Therefore, by fulfilling the advisory function there is a risk that small business in particular will rely on advice from enforcers in order to achieve compliance. Where there a lack of time or resources to deliver such advice, businesses may feel that they are not obliged to take proactive measures to seek compliance.

4.7 Advice as a preliminary step to enforcement action

It was clear from all of the data that advice represents the first step in the 'enforcement ladder' with further steps becoming more formalised as Ethan says, *'Initially advise them, yes. I mean if they don't listen to advice then you can take more formal sanctions but most of them will comply.'*

In the majority of cases, matters will not proceed any further than the advice, *'most businesses are reasonable. We advise them 'you must get rid of this' and they do or are in the process of doing so'* Ethan.

Ethan explains the broader position:

All enforcement tends to be a hierarchy of actions, we decide the proportion as best we can. And it ranges from just, you know, simple verbal advice up to a full prosecution. It sort of increases in more formality if you will, as you need to, if somebody doesn't listen to written advice you give them, sorry verbal advice, then you tend to give written advice, then formal written advice...prosecution is the final resort.

Attempts to capture and illuminate the negotiation between enforcers and regulated firms have found this hierarchy of actions (Braithwaite et al., 1987; Hawkins, 2002; Hutter, 1997) . The theory of the 'regulatory pyramid' of a hierarchy of actions from negotiation to prosecution provides strategic level guidance on how enforcers should carry out their duties. This is consistent with the way in which enforcement is implemented as described by Ethan. Such a responsive approach to regulation is commonplace and involves regulators who enforce 'in the first instance by compliance strategies, such as persuasion and education [but] apply more punitive deterrent responses (escalating up a pyramid of such responses) when the regulated firm fails to behave as desired' (Black and Baldwin, 2010).

In the pyramid of responses, as one regulatory intervention fails, the regulator moves upward to the next more serious level and as the risk subsides, the regulator should move back down to a lower level. In this way, the pyramid provides an inherently proportionate and reasonable exercise of power the justification of which is based on the failure of the less serious previous action.

The commercial response to the advice demonstrates the level of reliance placed on the officer's judgement as shown by Charlotte:

The first step would be advisory. Then you would ask them to change the label. And most of the time they do. Sometimes they stop making the product altogether.

It is unclear whether the advice to change a label resulting in the withdrawal of the claim, and finally to stop making the product altogether, is wholly dependent on the opinion of the enforcement officer or whether the opinions of others have been sought. It is clear however, that business can place great reliance on the opinion of the officer and it plays a significant role in influencing the decision.

4.8 The decision to prosecute

The alternative to advice, or where advice has failed to realise compliance, is prosecution. The interviews made clear that the decision to prosecute is not taken easily and that it represents the last resort in relation to all regulations, when all other options have failed as Scarlett says, *'prosecution is the last resort right across the board, not just with NHCRs.'*

The fact that there are very few reported prosecutions for breaches of the Regulation is unlikely to be the result of there being few breaches. In fact, the ASA casebook of adjudications shows that cases of breach do exist. It may be that trading standards and environmental health officers do not view prosecution as an efficient means of securing compliance. While prosecution does represent the strongest sanction in the regulator's toolkit it is viewed as a means to the end of compliance as set out in the regulator's code rather than being a goal in itself:

Generally, now as well it's about compliance. The regulators' code, since that's come in, and I think here and a lot of good places anyway, it was about compliance, it wasn't about just going in and just slapping on a prosecution,

Millie

The decision to prosecute here does not provide evidence of a preference for the use of the deterrence model over an accommodative approach, rather it highlights the role of prosecution within the latter (Reiss, 1984). In the deterrence approach the methods of enforcement are penal and adversarial and prosecution plays an important role and there is greater reliance on imposing sanctions (Hutter, 1989). The emphasis here however is on seeking compliance rather than punishing wrongdoing. This way, prosecution is less a means of retribution for actions carried out in the past or notions of justice found in the punishment of 'mainstream' criminal offences of violence and dishonesty and more aimed at ensuring compliance and minimising consumer detriment.

In explaining the lack of prosecutions, Jacob refers to the political climate as an influence:

There are fewer prosecutions now for a number of factors. Cuts is an obvious one. But also the direction from central government away from prosecution. Those who deliberately flaunt rules can still be dealt with but at the same

time some companies may see infringement as a commercial risk and they may factor in the cost of dealing with a prosecution against the benefits.

Hutter found that political factors have not played a significant role in food law enforcement with the political complexion of any council providing no indication of the enforcement action which might be taken in that authority (Hutter, 1988). As Jacob indicates, the politics of prosecution are more likely to be internal to the organisation where there may be tendency to vie for control of food law enforcement between trading standards and environmental health. This is likely to be intensified under the climate of severe cuts in local authority spending. There is also a pressure felt by enforcers that they must act in a way that is consistent with the wider government deregulatory agenda; 'There are strident demands...for the 'regulatory burden' to be reduced. National governments and the European Commission have responded with large scale commitments to reduce the regulatory burden' (Helm, 2006).

Jacob refers to how some businesses may view legal action as a 'commercial risk'. This is consistent with the idea of business as 'amoral calculators' motivated entirely by profit-seeking, and non-compliance stems from economic calculations of costs and benefits of compliance.' (Yapp and Fairman, 2006). Under the economic approach to regulation actors will comply with regulation if, and only if, the costs of compliance with regulation are exceeded by the benefits (Law, 2006). This means that the size of the sanction and the risk of being caught must be such that together they amount to a sufficient deterrent to make a rational business comply with the regulation (Becker, 1974; Stigler, 1974; Polinsky and Shavell, 1999). Jacob's statement appears to support this theory but it would be unwise to infer a widespread practice of economic calculation from the comment.

In contrast to food safety, when it comes to the compliance with the Regulation, Amelia goes so far as to claim that in her authority; *'food labelling generally isn't something we prosecute on'*. Notwithstanding that, it remains a real possibility and it cannot be dismissed:

So we don't prosecute very often and it's not a resource, and I absolutely fundamentally will stand by that, I've never turned down a prosecution because I thought it would cost the authority money. That does not come into it. I have to be pretty damn sure if I put it forward! But it would never, ever be spiked for lack of money

Amelia

When asked if he would receive the necessary support to bring an action, William is

unequivocal:

And if you had to take that one to court, would you get the support and resources that you need to take it all the way?

Oh yes, I mean if it meets the evidential and the public interest test.

Both Amelia and William provide assurance that where necessary, prosecution will be pursued and that resources will be made available for important actions. There is something of a mismatch between the costs and benefits of a prosecution. The costs are borne by one local authority but as a result of the deterrent effect of the legal action, the potential beneficiaries are the entire population who benefit from compliance by other suppliers and as a result are not misled into buying products bearing false claims. As with 'public' goods generally, 'no 'market type' solution exists to determine the level of expenditure on public goods' (Tiebout, 1956). This is a familiar problem when considering public goods as memorably illustrated by Ronald Coase in describing how a good such as a lighthouse needs to be provided by the government rather than through markets (Coase, 1974). Similarly, the benefits of food law enforcement are allocated in a non-optimal way when compared to other goods. The example of the mismatch between costs and benefits of the enforcement of the Regulation here is instructive.

In addition, when considering the benefits it is unlikely that the authority will consider the wider effect of action or engage in a comparison between ex post and ex ante costs. This is described by Innes albeit in relation to accidents, but the principle of the wider good remains the same:

'the direct ex-ante regulation of care can be more efficient than imposing ex-post liability for harm even when the government's cost of monitoring care (as required under ex-ante regulation) is significantly higher than the cost of monitoring accidents (as needed under ex-post liability).'

(Innes, 2004)

In the one case where a prosecution had actually been taken under the nutrition and health claims regulations, the enforcers, Mia and Cate were asked; *'So when did you decide to take legal proceedings?'* They replied; *'We tried everything else. We tried to contact her by phone, email and hand delivered letters. It got to such a point when we had no alternative.'*

4.9 Factors involved in the decision to prosecute- the evidential and public interest test

A number of the interviewees refer to the evidential and public interest tests as applied by the Crown Prosecution Service as factors involved in deciding whether to prosecute a case:

We would go through the process and ask do we have the evidence and can we prove it? We put it to our legal team, we make a decision based on the code for crown prosecutors so we apply the evidential and the public interest tests.

Jacob

We have our enforcement prosecution policy so that there's things that we have to go through, public interest, likelihood to reoffend, likelihood of penalty, if they've had previous advice, what groups of people are affected, if it was premeditated...

Chloe

We have an enforcement policy. The policy mirrors Home Office guidelines so we look towards public interest, likelihood to reoffend etc. everything that's in that. So we'd always consider all of those aspects of a case.

Mia and Cate

Under the Code for Crown Prosecutors, the Full Code Test, specifies in relation to the evidence in a case that:

Prosecutors must be satisfied that there is sufficient evidence to provide a realistic prospect of conviction against each suspect on each charge. They must consider what the defence case may be, and how it is likely to affect the prospects of conviction. A case which does not pass the evidential stage must not proceed, no matter how serious or sensitive it may be. The finding that there is a realistic prospect of conviction is based on the prosecutor's objective assessment of the evidence, including the impact of any defence, and any other information that the suspect has put forward or on which he or she might rely. It means that an objective, impartial and reasonable jury

or bench of magistrates or judge hearing a case alone, properly directed and acting in accordance with the law, is more likely than not to convict the defendant of the charge alleged.

(Service, 2014)

This does not mean that the prosecutor needs to be satisfied that the case will succeed. It is for the court to decide whether the criminal burden of proof of 'beyond reasonable doubt' is satisfied. The evidential test appears to require that the court is 'more likely than not to convict the defendant'. A standard more akin to the civil burden of proof of a 'balance of probabilities' and that this would provide evidence of a realistic prospect of conviction.

Whereas the application of the evidential test maybe a relatively straightforward legal technical matter based on ensuring that there is prima facie evidence of each of the elements of the offence, the public interest element is a more complex matter:

Yes, that's all clear it needs to meet that criteria, and evidentially with this particular one, it's there. The claims we've got, the analyst report we've had done ourselves and what the claims are, downloads of the pages and the dates they were up there with the claims. So we've got all of that evidence, that's not the question. It's then: "is it in the public interest"

William

William then goes on to describe how ensuring a level playing field for competition might be a determinant of public interest:

The kind of things we look at for the public interest are in our enforcement policy. And one of them is that they are trying to gain a competitive advantage. Well, they are because if all the other suppliers of that product are having to comply, this person is making these additional claims, then clearly he's trying to put himself at a competitive advantage, my products do this, so that's the kind of thing you're looking at in terms of public interest.

Once the evidential test the code makes clear that, 'it has never been the rule that a prosecution will automatically take place once the evidential stage is met.'

A prosecution will usually take place unless the prosecutor is satisfied that

there are public interest factors tending against prosecution which outweigh those tending in favour. In some cases the prosecutor may be satisfied that the public interest can be properly served by offering the offender the opportunity to have the matter dealt with by an out-of-court disposal rather than bringing a prosecution.

(Service, 2014)

The public interest is determined by a utilitarian approach that requires balancing the harm and the benefit. The Code goes on to describe the factors to be taken into account when deciding if a prosecution is in the public interest. The factors include; the seriousness of the offence, the culpability of the offender, the harm to the victim etc. They appear to be markedly different to William's interpretation of public interest as ensuring fair competition. The factors in the Code are more suited to the types of crimes for which the CPS, rather than the local authority, is responsible. It is noteworthy that the 'culpability of the offender' brings with it a moral framework and judgement that may assist the CPS in dealing with the crime but, which, one might argue, has no place in consumer protection.

4.10 Enforcement policy or code

Prosecution represents just one of many tools in the regulator's armoury and one that is, of course, rarely used. In determining the correct course of action in individual cases, enforcers are guided by their own employer's enforcement policy or code and this is based on the Regulators' Compliance Code and Enforcement Concordat as issued by the Local Better Regulation Office.

The Regulators' Code came into statutory effect on 6 April 2014 under the Legislative and Regulatory Reform Act 2006. As such, local authorities have a statutory duty to adhere to its principles to guide their regulatory activities. It replaces the Regulators' Compliance Code and Enforcement Concordat. It provides a clear, flexible and principles based framework for '*how regulators should engage with those they regulate*' (BIS, 2014). The code says that Regulators should carry out their activities in a way that '*supports those they regulate to comply and grow*' (Section 1). This is a clear statement that regulators should assist those whom they regulate. This is a positive obligation which represents a recalibration of the relationship between the enforcer and firm in the context of local authority food law enforcement.

The code goes on at Section 2: *'In responding to non-compliance that they identify, regulators should clearly explain what the non-compliant item or activity is, the advice being given, actions required or decisions taken, and the reasons for these'* (BIS, 2014).

As well as the code itself, each local authority publishes its implementation of its enforcement policy based on the Regulators' Code. Local authorities have such guidance in place, as William describes:

I guess like all local authorities we have a food enforcement policy, a written policy, and that's on our website. With this as well as all enforcements, I do a graduated approach which is expected from us both morally and politically, that that's the approach that you take.

It is notable from William's description that the local authority provides this information upfront on its website for transparency and his reference to 'morally' may be interpreted to mean fairness and 'politically' that the approach should be ethically and sensitively applied. These matters combine to provide greater accountability in regulatory services' decision-making.

Scarlett describes the way in which a 'tick list' scoring sheet is used to determine the appropriate course of action:

We follow an enforcement policy, there's a tick list scoring sheet that we go through. We then have a choice of no action, formal caution or prosecution.

Scarlett

The phrase 'tick list' has taken on a pejorative meaning to signify a bureaucratic approach to decision making however here it is used by Scarlett without guile to denote the application of a systematic method.

In applying such a systematic approach, William describes the stages, each marked by increasingly serious actions:

So if you come across a breach of the legislation, based on obviously the severity and the risk that you deal with it informally in the first instance. You may write to them and give them an opportunity to put things right, if they have been told about it before and they don't do that, then you would go to improvement notices. I mean you do have prohibition power if something is

an imminent risk to health then you could actually prohibit it, either close the place down or prohibit it.

Of course, in relation to nutrition and health claims the closure of a business is a highly unlikely outcome whereas the prohibition of the use of a claim would be quite feasible.

Millie refers to some businesses who are going to be recalcitrant and how she has something of an enforcer's nose for identifying them; *'let's face it there are, there are some that are just never going to comply, and you know that pretty much from the start I think.'*

The idea of regulators acting on instinct is not discussed in the literature. The phenomenon exists in relation to law enforcement by police where police refer anecdotally to acting on their instinct to apprehend crime rather than in relation to the work involved in investigation of a crime and gathering of evidence.

4.11 Risk

Risk plays a large role in influencing food law enforcement determining the level of scrutiny on a particular activity, for example, meat production or independent businesses run by an individual or small group are generally considered to be high risk and will invite closer examination. The significant role played by risk is reflected in other studies of how environmental health officers prioritise their tasks: '[a]ll officers, regardless of position, reported that the most important factor influencing their work practice was the assessment of risk to public health and they would respond first to incidents posing the highest danger' (Condon-Paoloni et al., 2015).

Risk may be subject to economic analysis and in doing so, it is possible to arrive at an 'optimum' level of risk where the marginal costs and the marginal benefits are equal (Henson and Traill, 1993; Antle, 2001).

In practice, the application of regulatory impact analysis allows for the systematic quantification of the costs and benefits of the enforcement of a regulation. Such an approach is endorsed by the OECD and its members apply regulatory impact analysis in some shape or form (OECD, 2015).

The application of a risk rating to the actions of the enforcer provides a valuable insight into their enforcement strategy and how it determines the action which will follow - including the frequency of visits:

We actually do the scoring ourselves. The businesses will not see this but they have knowledge of how it all works. It's like a list of questions; what sorts of products they're making and that will generate a score and depending on what that score is, dictates how often you inspect the business. So low risk business is once every five years, and high risk are every year, and medium risk in between.

Charlotte

Risk based regulation provides a systematic approach that allows regulators to relate their enforcement activities to their objectives and the basis for evaluating new risks. Hampton advocates targeting resources based on an assessment of risks that a firm presents to the objectives of the regulator. In order to do this, the risk needs to be evaluated based on the evidence (Hampton, 2005). Risk based regulation has the most impact on inspections which move from routine visits to risk rating firms according to the possibility of non-compliance and the potential impact of such breach. The frequency of visits is determined by the assessment of risk associated with the actions of the firm as described by Charlotte.

The view of risk, particularly where environmental health is responsible for enforcing food standards, is skewed heavily towards hygiene enforcement and food safety:

none of the environmental health officers had anything to do with food standards at all. They couldn't see the problem and I can understand that because safety is the top priority. You don't want to be dropping dead from food poisoning. If you are a little bit mislead it's not so significant. They are low risk as far as EH are concerned. Because it's not chilled product it's low risk.

Amelia

In a similar study the authors found that the role played by risk had a similar effect when officers were faced with the competing demands of safety on the one hand and false claims on the other; 'local government officers placed monitoring health claims below the most highly prioritised matters of public health risk.' (Condon-Paoloni et al., 2015). A respondent from that study echoes the views of Amelia: '...looking at a label claiming fat free, I just don't think that the risk posed by that particular issue is going to take precedence.'

Risk based enforcement requires that regulators should prioritise higher risks by allocating greater resources to them. Inevitably, this means withdrawing resources from elsewhere. Risk

based regulation will tend to ignore lower levels of risk even where the cumulative effect may be considerable. In fact, it may lead to persistent non-enforcement in relation to certain activities, which once characterised as low risk, will cease to attract regulatory scrutiny. In considering the enforcement of the Regulation, given the relatively low risks associated with nutrition and health claims one might expect that the attention of enforcers might be drawn towards other higher risk areas such as food safety.

Millie explains how a business is categorised according to risk, where in food standards, ‘*a takeaway is likely to be low risk but a large manufacturer is high risk, which is the other way round to food safety.*’ As nutrition and health claims are unlikely to present an ‘imminent risk’, it is unlikely that such a matter will provide the basis for strong action such as closure or a prohibition.

The risks of misleading consumers about nutrition and health claims are latent and long term rather than immediate as with food safety. Therefore, such risks are easier to ignore:

the public have been misled, but they're not harming their own health unless it's their mental health because they have issues with, and they're relying on that product. But we won't know that, will we? I think that's where the differences are a lot of the time with food, food standards. With food hygiene, we come from a background where you can usually, the consequences are immediate.

Julie

However low risks cannot simply be ignored. The harm they are designed to prevent is latent and long term and, in the case of nutrition and health claims, political concerns about public health may require that they are attended to in some way or other. Ignoring low risks will potentially simply substitute the supervision of many widely spread low risk activities with fewer larger risks which may or may not reduce risk overall. When subjected to economic cost benefit analysis risk based regulation may not lead to the most efficient use of resources. Large risks can lead to fewer very resource intensive actions which also may not lead to the greatest overall reduction in risk in return for the expenditure.

There are particular challenges of dealing with low risks, including their identification and classification and ultimately the level of failure an enforcer is prepared to accept. There are many ways in which to quantify risk, usually by reference to probability and impact (Weber et

al., 2002) but there is no single accepted method. Therefore, in practice 'low risk' is often defined by the relevant regulator itself as meaning low priority. Having identified health and nutrition claims as lower risk, the challenge for enforcers is to pick up the 'accumulations of such risks when they become an issue without expending significant amounts of resources' (Black and Baldwin, 2012).

In practice, the difference between a low risk and high risk is in the frequency of inspections or the intensity of the monitoring. This is consistent with the study by Condon-Paoloni where the authors concluded that notwithstanding that officers had a statutory duty to enforce, 'they applied their discretion to risk analysis to set the frequency of their inspections.' (Condon-Paoloni et al., 2015). In deciding what action regulators should take and how often they should take it, enforcers may directly inspect premises or use proxy indicators such as compliance history or evidence of deviation by a business from their own systems.

In the event of a low risk where there appears to have been little harm, enforcers are faced with the dilemma as to what action to take. For example, if an unauthorised claim is made on the label of a product with low sales, should enforcers adopt a more conciliatory approach than if it had sold larger quantities? Or should they take a more principled approach where they treat contraventions of the law equally regardless of the harm or potential harm that ensues.

Intelligence gathering plays a larger role in informing risk and diverting resources than simply routine inspection, *'we try and do intelligence led work...market surveillance where we purchase items, for example diet pills, rather than a scattergun approach to everything'* Mia and Cate.

4.12 Proportionality

An important factor in determining the action or sanction to be applied in a case is the principle of proportionality. The Regulators' Code refers to proportionality in section 2: *'Regulators should choose proportionate approaches to those they regulate, based on relevant factors including, for example, business size and capacity'* (BIS, 2014).

As James makes clear: *'a mistake on a label isn't really a major crime. We have to use proportionality and help promote business'*. Proportionality tempers the action which might be taken and goes further with an eye on commercial considerations as Ethan describes his approach to the problem of relabelling old stock:

But once we tell them why most, well everybody I've talked to has been compliant and changed it. They may ask for some time to change labelling, getting rid of old stock or whatever, and again we look at that and the volume of stuff they have, if it's just a small amount you'd probably let them, if it's a large amount, no, they'd have start again with new labels.

Ethan

Sunstein refers to the rise of the principle of proportionality: 'the last two decades have seen an increasing enthusiasm for cost benefit analysis for regulatory problems with a keen interest in disciplining regulation by ensuring a kind of proportionality between costs and benefits' (Sunstein, 2002).

Similarly, in the pyramid of responses, as one regulatory intervention fails, the regulator moves upward to the next more serious level and as the risk subsides, the regulator should move back down to a lower level. In this way, the pyramid provides an inherently proportionate and reasonable exercise of power the justification of which is based on the failure of the less serious previous action (Baldwin, 1990).

4.13 Resources

On the question of whether the authority was adequately resourced to be able to take cases enforcers had different views. On the one hand Ruby confirms that in her authority at least, they, '*do have the resources and expertise to be able to take cases.*' Similarly Ruby says

We do not have any real barriers to enforcement. We have the resources, the expertise and money if we wanted to take a case to court.

Ruby

On the other hand Scarlett says, '*the single most important factor stopping me from taking action is resources.*'

Where resources are tight this might lead enforcers to be more likely to take legal action as they lack the time necessary to devote to educating the businesses within their jurisdiction. This might seem counterintuitive, as legal action is generally expensive and difficult to justify in economic terms by reference to its direct effect. Rather the justification used is in the wider

effect on the market. In their study of the Office of Surface Mining in America, Shover et al. found this argument which was used to account for greater use of prosecution at the time (Shover et al., 1983).

There is some evidence of the opposite view, where constrained resources will deter the issue of court proceedings as legal action is also resource intensive and legal costs rules mean that it presents a very high level of risk and this may mean that enforcers do not have the appetite for the considerable uncertainty involved in the process (Bartrip and Fenn, 1980). The cost of prosecution will restrict prosecution in a large proportion of cases but it may not be the prime or most significant consideration. Prosecution action even if it appears to be an expensive option in a particular case, may be justified by providing a deterrent effect and acting as a warning signal to others. Those studies showed that 'it is not resources alone that determine policy', but the 'way in which they are used is determined by the interplay between their availability and other influences' (Hutter, 1989).

It appears that the lack of resources leads to action being less likely rather than more likely. Charlotte points to the reason why there is little appetite for litigation as one of resources: 'we *can't afford to lose cases.*' She implies that the cost of losing such an action entails expenditure of unrecoverable legal fees and staff time. Another interpretation is that the authority cannot be seen to lose cases for the public opprobrium such a defeat might incur. This suggests a lack of experience among enforcers.

Both Charlotte and Ethan point to the loss of a 'fighting fund' provided by the Food Standards Authority which might be called upon by an authority to fight a case which had national significance.

There appeared to be a general perception that food enforcement had suffered during the period from 2009 to 2014 as a result of the coalition government cutbacks in public spending. Dexter and Theo explain:

The food team suffered quite a few cut backs over the last few years. When I first started at trading standards there would be probably 12 inspectors pounding the beat and I was one of them visiting all food premises...[now] I've got 2 teams one of which is food and that team consists of 2.3 officers. That's all.

Dexter and Theo

The representative body the Trading Standards Institute (TSI) has warned of the risks to consumers as a result of the cuts to their service. It says that more than 70% of the trading standards services will restrict or stop some services: 'These cuts threaten consumer rights, consumer safety and the health of legitimate businesses' (Trading Standards Institute, 2014a).

As well as the adverse effect on individual consumer rights, the wider effect of poor enforcement of consumer rights will be felt by all consumers as a result of their impact on the market: 'The trading standards service plays a vital role in safeguarding consumer rights and the efficient working of consumer markets - essentials for our recovering economy,' John Bridgeman, former director general of Fair Trading. (Trading Standards Institute, 2014a)

Research carried out in 2014 by the consumer group Which? appears to support the TSI view that the number of food inspections carried out by local authority officers had declined significantly in recent years. The number of food standards interventions had dropped by 16.8% compared to the previous year. In addition, there were large variations of between authorities in the levels of enforcement carried out (Which?, 2014).

Millie sees the problems of the lack of resources as common to other authorities and not just hers, '*we're not the only ones, it's a resource issue.*' She points to the fact that issues other than labelling would attract special funding for projects such as smoking cessation or reviewing the options available for staff at a canteen, '*but not labelling!*'

Scarlett views the impact of the cuts as nothing less than devastating:

Firstly, you've got resource issues. We've lost 40% of food standards staff. We've lost hundreds of years of experience through redundancy, or natural wastage. Standards has fared much worse than hygiene.

Scarlett

Millie goes even further with the argument that the lack of resources places in doubt the authority's ability to fulfil its statutory obligations, '*we have a duty to enforce food safety legislation and some people might say we're not compliant with our statutory responsibilities.*'

Effective judicial enforcement is a condition for functioning markets (Stiglitz, 1989). Where the lack of resources will lead to the inadequate enforcement of regulations to avoid consumers

from being misled then this would result in market failure. The regulation is aimed at correcting the information asymmetry between consumers and suppliers in the food market and the fulfilment of this aim depends on the effective enforcement by regulators and enforcement officers (Ramsay, 1985).

4.14 Focus on matters other than food standards: agenda setting and conflicting priorities

Environmental health officers are responsible for the enforcement of a broad range of areas concerning the immediate environment. These include: housing, disease, air pollution, noise, working conditions, in addition to food (Chartered Institute of Environmental Health, 2014). Trading standards officers are responsible for matters which involve financial or physical risks for consumers. This requires the enforcement of an equally broad range of areas including consumer problems, product safety, fair trading and food fraud. Examples of the types of cases they deal with are: weights and measures to dealing with underage sales of tobacco and alcohol and counterfeit goods, particularly cigarettes and alcohol. (Trading Standards Institute, 2014b).

The breadth of the scope of the roles means that officers are responsible for the enforcement of a long list of legislation. In relation to the range and volume of legislation, one officer refers to ‘800 pieces of legislation’, and the number of businesses in their area means that they need to make choices about which legislation they enforce and against which businesses. They need to prioritise their work to make the most efficient use of their limited resources to deal with the problems of the communities they serve.

Since qualifying in environmental health and from trading standards is that you have such an incredibly broad range of legislation and you know areas to cover.

Ethan

My remit includes the food team but it might also involve non-food laws such as the CPRs, Estate Agents Act, energy performance certificates, Package Travel Regs. The CPRs effectively replaced the TDA so anything and everything will come to me.

Dexter and Theo

There were varying opinions on how such priorities were established. Chloe describes a consultation process using a questionnaire with local consumers and business ‘We use the

questionnaire to get a full idea of businesses advice.'

In customer satisfaction surveys, food does always come second or third, we have categories that we ask complainants to categorise, so the selection of questionnaire answers, complainants, businesses and consumers, and ask them to rank what do you think important in what we do, food always comes high up with underage sales and product safety, they're always the top three. But we don't break it down any further than food standards and labelling.

Chloe

However, Dexter and Theo saw priorities set by the local political agenda, which led to food standards being a low priority when compared to hygiene:

Everyday local politicians are making very difficult decisions about what essential services they are going to stop providing. And enforcement of food standards of which NHCs is a part, just doesn't get it on to the list. The dodgy Echinacea capsule with no Echinacea in it – nobody's going to die. Even with an Echinacea capsule with a very high level of lead in it, nobody's going to die. The emphasis is going to go on the salmonella. Somebody gets ill, the next day you can point the finger and say, it was the chicken tikka from that place down the road. If you get symptoms of high blood pressure or stroke in 20 years' time it's not appropriate to say well actually it was those takeaways I was having. Well, so what? It's too late to do anything about it. Those longer term things are not on the radar any more. And the landscape...the FSA things are changing all the time...things in 2010 that I mentioned. FSA Scotland, it's just going off on its own as of last week. We got the review of the official food control going on, but that was very much spurred by the eColi 151 incident in Wales. It was very much looking at microbiological food safety...I say there's more to this. It's not called the Food Safety Agency it's called the Food Standards Agency. These things are important for protecting the consumer. Not necessarily stopping the consumer from being ill and dying because of food poisoning. But protecting their pocket. Food has to be of the nature, substance and quality demanded. That's why we're here but it's not a priority...

When questioned about why less attention is paid to food standards, Julie points to the latent

nature of the problem, *'in terms of food standards, I think it's the poor relative and it's hidden'*.

In the event of a choice between safety and standards it appears that safety takes priority at the expense of standards:

My gut feeling having dealt with lots of home authority referrals over the years is that food standards is very poorly enforced. Understandably, they are more concerned with ensuring that people don't get salmonella food poisoning than they are being ripped off on the Echinacea capsules.

Dexter and Theo

Samuel spoke of food safety but not food standards being protected:

Food safety has been thought to be more important. We are fortunate in that food safety has been protected but the same isn't true of food standards.

However, by contrast, Charlotte highlights how standards are in fact enforced:

I suppose just taking it from the food standards point of view, working with xxx (supermarket), anything with safety implications say food past its sell by date we respond to immediately and would be top priority and anything else comes after that. But I think the rest of it is treated with the same level of priority really. At the end of the day if someone thinks a HN claim is wrong it is misleading and should be dealt with accordingly.

It would seem that food law enforcement plays a large part within departments, *'food is a big part of trading standards work...a lot of trade advice is food based'* (Ethan) and in larger departments, some officers are dedicated to only food but with generic officers in others. As Chloe says:

Proportion wise, you do quite a bit of food work but it's not our sole responsibility, everybody's generic here. So it might be 10% of your day one day, 30% of your day the next. Out of 12 of us, there's only 4 that aren't qualified for food.

It appears that where officers cover the range of matters, priorities may be set by events rather than strategic decision-making:

Because we are generic, nothing can really take priority. It's a priority of literally on a day-to-day basis which is the most essential item to do.

Sophie

Food law enforcement divides further into food standards and food hygiene. Where trading standards officers are responsible for food standards enforcement only there is no conflict between safety and standards. However, in many cases, environmental health officers were given responsibility for food standards and therefore this would need to be reconciled with their traditional focus on safety.

I think LA managers are being left to make that judgement for themselves individually. So a LA manager will have their own preconceptions of what's important and what's a priority or not. Food safety is always perceived to be important and it's always been a priority.

Sophie

In examining the potential for state influence on food law enforcement Condon-Paoloni found a confluence of politics and media where the former would exert its influence on enforcement decision making in seeking to avoid criticism by the latter: 'for the state government it's more the consequences of what the media will do if we don't respond rather than the health effects.' (Condon-Paoloni et al., 2015). There was no evidence of such an influence from the data in this case.

In some respects, until the turn of this century, the idea of food being political was new and even surprising. The first publication of Marion Nestle's *Food Politics How the Food Industry Influences Nutrition and Health* (Nestle, 2013) in 2002 marked a change in attitude so that food related disease such as obesity now ranks high in the consumer consciousness. It is difficult to assess the effect of such political sensitisation on regulatory enforcement. Dexter and Theo describe how the political process influences the setting of priorities for regulatory enforcement. Greater political awareness and concern about nutrition and health may raise an expectation that the enforcement of nutrition and health claims will rise up the agenda. However, as Dexter and Theo state, nutrition and health claims compete for the limited resources of enforcers with food safety and fact that the consequences of the lack of enforcement are latent and long term for food standards rather than immediate as with food safety appears to indicate that they remain a low priority on the political and regulatory agenda.

4.15 Lack of specialist skill and experience

There is a sense that by not focusing on food standards enforcement, that enforcers are not gaining the necessary specialist experience required and that this leads to atrophy in skill and the lack of enforcement becomes a self-fulfilling prophesy:

TSOs are not dealing with it day to day. Nutrition is not a regional priority. There are very few projects in this area. The informal economy is the regional priority, counterfeit goods is a regional priority etc. not nutrition. Management experience plays a role. Most TSOs come from a fair trading background rather than a food science background. And this affects their choice of priority. Whereas years ago, food might have been fundamental but that isn't the case anymore. It's legislated under food standards but it's not an immediate risk to health so why would it be a priority?

Isaac

The lack of involvement, allied to a lack of training may have an effect on the choice of actions to take for enforcement by officers. The interests and experience of managers is likely to influence the actions which are presented to them for approval for prosecution or other enforcement action and those which are likely to receive their support. Where managers are from a background that has not involved food and food science in particular, as Isaac says, this makes it more difficult to obtain support for such cases.

Enforcement of food standards can seem arduous with little prospect of a satisfactory result:

you can tell City of xxx that there is a x and y making claims in breach but they have other priorities. I think a lot of front line officers would turn a blind eye. It's something that will generate a huge amount of work and you will not get a legal case out of it. The prosecuting authority will just look at it and say well that's just not in the public interest. Particularly where it's not clear-cut and there's a lot of marketing puff too.

Isaac

4.16 Environmental health enforcement of food standards

The issue of the lack of expertise is exacerbated by the way in which food standards are traditionally enforced by specialist trading standards officers but how that work is increasingly

done by environmental health officers. It was clear from the data that following cuts in the trading standards services that the responsibility for food standards enforcement was ceded to environmental health officers and that respondents felt that food standards enforcement was weakened as a result:

None of the environmental health officers had anything to do with food standards at all. They couldn't see the problem and I can understand that because safety is the top priority. You don't want to be dropping dead from food poisoning. If you are a little bit misled it's not so significant. They are low risk as far as EH are concerned.

Amelia

By contrast, Scarlett feels that food standards are given priority in her authority but that this is exceptional and the result of the director's personal interest in this area:

Food standards is seen as important here because of the interest of this director but I don't think that's the case everywhere. They have other priorities. They have a limited staff and try to keep all the plates in the air. If you are in regulatory you'll have more people concerned about say, dog fouling, than NHCRs so politically you'll have other priorities as well. So NHCRs are not a priority area at all.

This lack of experience in food standards was readily admitted by Julie, 'it was decided, with the budget cuts, that in theory as environmental health officers are competent in food standards we would take that role. So, it's been a bit of a learning curve'.

Scarlett supports this view:

A lot of EH people who have the qualification actually have only a very superficial knowledge of the regs or of food standards generally. They have their eye on hygiene.

The cuts in government spending have been most acutely felt by trading standards. While this raises a question about the loss of specialist enforcement, some have gone further to say that it raises a question of the effectiveness of regulation such as the Consumer Protection from Unfair Trading Practices Regulations 2008 arguing that it makes a nonsense of the government's assurances that consumer protection will be maintained (Shears, 2012).

It is difficult but not impossible to quantify the impact of the cuts in spending in trading standards and local authority services. Those such as Shears who argue that the effect is harmful to consumers do not point to evidence that demonstrates a qualitative or quantitative difference between before or after the cuts. In the absence of evidence of a causative link between the cuts and consumer protection, it is difficult to argue the point. In the light of the highly charged political debate surrounding the cuts to public services such claims need to be treated with caution.

4.17 A proactive or reactive approach to the enforcement of nutrition and health claims

Enforcers are faced with the choice between a proactive approach to nutrition and health claims where they seek out cases from monitoring and or alternatively a reactive approach where they respond to complaints as they are made.

According to Fairman and Yapp: 'compliance is conceptualized as the negotiated outcome of the regulatory encounter. This leads to heavily reactive decision making, in which the enforcer becomes the predominant driver, which poses huge challenges for the successful implementation of enforced self-regulation, and is an explanation for the lack of empirical evidence supporting deterrence theory in business compliance' (Fairman and Yapp, 2005).

The data showed evidence of both reactive and proactive approaches being employed but with an emphasis on complaints. James refers to his experience of both approaches:

I know that my previous local authority was one of the only ones which did routine inspections and I know now that a lot of people don't have the skills or the budget to do it so they only do reactive work.

Dexter and Theo support this view while explaining their reactive approach:

The problem I have is that because I don't have officers to pound the beat we tend to be reactive. We will react to information that comes from other trading standards and EH and we will react to complaints and we will react to referrals from the FSA or any other government body.

Scarlett agrees; in her view, 'you haven't got the time to be proactive.'

However, Chloe indicates that while adopting a reactive strategy, there are likely to be few complaints about nutrition and health claims, *obviously we're responsive to complaints too, [but] we don't get that many about health claims really.*

Millie supports this view and indicates that complaints provides intelligence on what she calls 'problem' traders:

We work on problem traders, who's got the most complaints, obviously you don't get many complaints about food labelling... I'm pretty certain that we've never had a complaint about a health claim, not since the new legislation.

4.17.1 Proactive work and investigation

The interview data exposed two instances of special projects which had been set up to review the use of nutrition and health claims. Chloe describes one:

a couple of years ago we got some funding to, we did 30 samples, or 29 samples of take away meals and analysed them for nutritional content.

Chloe then goes on:

We have a business plan in place which always includes some kind of food projects as well as food we would respond to all complaints. In this year's business plan, there was, as part of Trading Standards North West, there was the health claims project

Millie also describes an instance of the funding of a similar (possibly the same) project:

And coincidentally, last year we got a fund, the North West region got funding for sampling and I did the sampling for Rochdale. So I had to take 2 samples for health claims and both were wrong.

In carrying out investigation officers are influenced by the nature and seriousness or otherwise of the claim

It depends on the seriousness of it. For example a serious claim that says this can prevent the build-up of cholesterol but there is no evidence according to the complainant. We think we might investigate this.

Jacob

An important means of investigation at the early stage is to look at the product and any claims made for it online, *'We make an independent assessment; which these days means you go to the web site and have a look.'*

On investigation, officers would sometimes find that the claims were, according to Chloe, mostly compliant:

I had a look at some claims to do with like, you know, high protein type drinks and things like that, and, they seem to be what, from my opinion, what I thought, was on some of the claims I think they seem to be complying with, mostly.

Where claims require further investigation it was important evidentially as well as for investigation to obtain samples:

We did a test purchase and brought some ourselves. They were being sold online. We got both lots sampled. The ladies who bought them had an unopened bottle so we got theirs sampled. Did a test purchase ourselves and got that sampled as well. And waited for that to come back. We got the composition and we had the labelling.

Mia

Scarlett describes how at one level an investigation may involve simply checking to see if a claim is permitted. This involves checking the list of permitted claims. The other, is where you need to carry out the research to establish nutritional content or whether the food has the claimed health effect. This is a more involved, expensive and even prohibitive process:

There are two ways to go about enforcement. One where you ask, is this an authorized claim? In which case you check the wording against what's on the list. The other is to ask does this product actually have the nutrient in it or does it have the health effect? That's a much more difficult question. And I don't have a sampling budget.

4.18 Victims: consumers or other business?

From acknowledging that the work is more reactive and that few complaints are made, arises the question of who makes the complaints. In relation to the Regulation there is no single consumer victim as such, in that there is no one person who bears the substantial cost of the breach. The quality of enforcement depends on whether there is a 'victim'. 'Enforcement is generally more effective against violations with victims because victims have a stake in apprehending violators, especially when they receive restitution' (Becker and Stigler, 1974). This theory bodes badly for the enforcement of the Regulation because, in the same way as other food and environmental law, there is no single victim who suffers a significant and identifiable loss. Therefore, there is less incentive for there to be effective enforcement.

Scarlett appears to change her position when she says that the work of enforcing nutrition and health claims is proactive but that the nature of such claims means, not surprisingly, that complaints are restricted to informed consumers:

The work is proactive so it's driven by inspection but we do get complaints as well. I have some repeat complainers from the public who are interested and informed. For example I have a lady who trawls shops and the internet for labels and where she thinks they are wrong, she lets me know.

Amelia and Charlotte respectively, '*I envisage that after the publication of the list we will get a huge raft of business complaints*' and '*we also investigate complaints from possibly other businesses but mainly members of the public.*'

When business complains it is with a view to competitive pressure whereas consumers are directly concerned with the misleadingness of the claim and the detriment to purchasers and this provides enforcers with the means to deal with cases as Isaac says: '*complaints from other food companies is a good way to deal with cases...using competition, that can be effective.*'

4.19 The outcome of complaints

When enforcers receive complaints, it is apparent that the usual response is to provide the necessary advice to correct the misleading statement. This is discussed above. It is possible for there to be a range of outcomes including where Millie describes that no further action

would be taken:

if anybody finds anything wrong with the labelling of a product produced in xxx [local authority] they would need to refer it directly to the company now, we wouldn't deal with it. We would potentially take it for information purposes only but we wouldn't proactively do anything with that.

However Ian describes where the complaint was referred to the Advertising Standards Authority (ASA) with a successful outcome but possibly a pyrrhic victory:

in one case they did get their complaint upheld by the ASA. Though that took a long time and it was a seasonal product and that season's sales had been made.

The evidence of other studies found that investigation of health and nutrition claims on labels was generally initiated by complaints rather than routine proactive inspection (Condon-Paoloni et al., 2015).

4.20 The differences between the enforcement of nutrition and health claims and other food standards legislation

Enforcers were asked whether there were any differences in the way in which they enforced the Regulation compared to other food standards legislation. It was an area where Theo and Dexter had the most illuminating responses. The first was unequivocal:

AP: Have you found differences between the enforcement of the HNCs and the range of other regulations that you are involved with?

T&D: No not at all. NHCs are no different to any other area. We just have to measure it by the same yardstick of our enforcement policy.

Jacob agrees:

The process is exactly the same as we would use in relation to the enforcement of any of the food regulations.

As does Ruby, who confirms enforcement is: 'no different to enforcement of any other food standards.'

Samuel further confirms this view but makes the point that claims are high in the consumer

consciousness:

No different to any other types of food standards legislation. The one thing might set this apart is its conspicuousness to the consumer.

However Theo and Dexter make the point that the Regulation uses the term 'commercial communication' to encompass all promotional messages including those on web sites and not only the label. This goes beyond the usual scope of an enforcer's role:

Of course, that's the other big difference between food labelling – it applied to anything that's connected with the product so web sites included, all commercial communications not just what's on the bottle.

Theo and Dexter

There are some key differences between the Regulation and other legislation, which might be manifested in the way in which the Regulation is enforced. These are: the large number of nutrition and health claims in commercial communications which fall within the Regulation (Lalor et al., 2010); the way in which the Regulation is structured, in particular with creation of the approved list of claims where such a small proportion of the claims submitted are approved (Verhagen et al., 2010; Asp and Bryngelsson, 2007; Gilsenan, 2011). The challenges of enforcement are discussed by Patel et al. 'From the initial proposal on nutrition and health claims in 2003, the European Commission acknowledged that such claims "are often not properly enforced.'" (Patel, 2012)

4.21 Summary

The evidence of the data indicates that the enforcement of nutrition and health claims faces the same challenges as other legislation enforced by trading standards and environmental health officers. These are the limited resources, the adoption of a risk based strategic approach and the differences in the styles of enforcement priorities of various local authorities. In reference to enforcement of legislation generally it was found that 'Trading Standards Officers enjoy a high level of discretion about how to implement the law in relation to individual businesses' (Patel, 2012). The evidence shows that regulators generally deploy this discretion flexibly (Hawkins, 2002) The same maybe said for the approach to the enforcement of the Regulation on nutrition and health claims.

Findings – structural themes

4.22 Summary

This second part of the Findings Chapter, like the first, analyses the data gathered from enforcers. However, it differs from the previous part in an important respect: its focus is on what might be termed ‘structural’ or ‘systemic’ issues. There is a critical review of the issues arising from the enforcement of EU law by local agencies, inconsistencies in enforcement, the application of the home and primary authority principles in practice, the problem of the complexity of the legislation and finally the role of central government.

4.23 Local enforcement of EU law

One of the challenges faced by the enforcers is that of enforcement at a local level of legislation issued at EU level. The EU is concerned with strategic policy and harmonisation initiatives, whereas, a local authority is typically concerned with the interpretation, application and day-to-day enforcement of the law as implemented at the intermediate national level. The gap between policy and enforcement poses challenges for governance. In particular, for regulators charged with implementation of food policy there is some negotiation between the local, national and international interface (Harrison et al., 1997).

Charlotte describes this as a potential tension:

I am concerned with the fact that it's a system originating in EU law and then you have the problem of multiple authorities, is there a tension there? Between that wide multiple nature and the local nature of enforcement

This is identified by Scott and Trubek with their broader theory of ‘new governance’ which ‘accepts the necessity for coordination of action and actors at many levels of government, as well between government and private actors and...it accepts the possibility of coordinated diversity and the advantages of leaving final policy making to the lowest level when this is feasible’ (Scott and Trubek, 2002).

According to John, ‘[B]y engaging with transnational economic and political organisations, local decision-makers become part of a world that is more complex, changeable and interdependent than national politics’ (John, 2000).

There appears to be agreement in the literature with the theory that local enforcement allows the authority to calibrate its response while taking into account the character of the area over which it has jurisdiction (John, 2000; Harrison et al., 1997). This is supported by James with reference to his experience of practice:

The thing with local enforcement is that you can respond to local needs. We're in an affluent area with a foodie reputation. There will be other problems in other areas.

In a concept that is not inconsistent with the individual character of local enforcement, John refers to the 'uneven' nature of localised and delegated government. While this may allow for positive outcomes such as the ability to respond to local needs, it will necessarily lead to variation in practice. As James states, 'I think that there is an inconsistency in regulation, as we all know'. Such inconsistency will be most keenly felt at the individual firm level where it is bound to be perceived as unfairness. At the EU level, this will result in varying levels of service and protection for consumers. For business it may provide a means of being able to use the variations in enforcement to permit a choice of forum and jurisdiction that would have undesirable consequences for consumers.

James describes this risk:

Things are European based and there will be interpretation in that as well. You sometimes hear that certain manufacturers will go to certain countries because they know it can get passed they believe it's a lower standard and get to the market that way.

The position is summed up by John: 'Whereas the apex of political systems was formerly the nation-state, whose leaders could authoritatively resolve most political decisions, now many decisions lie elsewhere in the institutional mechanisms of the EU with its competencies in specified policy sectors.' (John, 2000) The position is intractable and represents a fault line in European, and particularly British, policy and politics that extends into enforcement practice. The ambitions of the international forum with its goals of removing barriers to trade that seeks simultaneously to take advantage of local mechanisms faces the challenges of consistency and the charge of legal pluralism.

4.24 Differences in enforcement policy and practice – a postcode lottery?

Where powers are awarded to local authorities who operate independently in a particular area

of decision making, in this case, the enforcement of nutrition and health claims, differences in the experiences of sections of the population who are subject to the regulation, are inevitable. Critically, this will have an impact on the experience of the service received of those consumers who the regulation seeks to protect. Sometimes, this is referred to as a 'postcode lottery', a term usually used to refer to the uneven provision of public services in areas such as healthcare (Cummins et al., 2007).

The suggestion of a postcode lottery has become a sensitive issue in respect of public service provision. In fact the phrase has emerged from the media when highlighting differences in health services dependent on location. The phrase carries with it an implication of injustice. Therefore, it was with some delicacy that the question was raised with enforcers when conducting the research. When asked if the experience of a business might differ from another depending on where they are located, Samuel responds with surprising directness: 'Absolutely yes. Without a doubt. It will do. Yes.' Samuel does go on to provide a further reason for this based on the way in which food businesses are structured; 'Because of the contracting for manufacture model, the local authority might not even know that they are there.' It's not clear how the model where the manufacturer and the licensor of a product are distinct entities should influence the uneven enforcement of law. However, it does provide a sense of the complexity in identifying the responsible party with the obvious deleterious effect on enforcement.

The idea of a postcode lottery appears to be supported by research carried out by the consumer group Which?. The research discovered 'a huge variation' between levels of food law enforcement by local authorities. It found: '[w]ork to check food standards, such as the accuracy of food labels, is particularly patchy.'

4.25 Relevant authority: home authority and primary authority

The issue of a single organisation operating across local authority borders raises questions of which authority or authorities should exercise jurisdiction over that business. The established position, in the absence of alternative arrangements, is that the authority where the business is based or 'where the relevant decision making base of a business is located' i.e. the 'home authority' is the relevant authority. The home authority will prioritise monitoring and enforcement over businesses based in its area and it will act as the principal link on regulatory enforcement matters on behalf of other authorities. The home authority may be determined by the location of the head office or main place of business of the directors or the registered address of a business. The home authority principle is aimed at offering a degree of clarity for businesses and local authorities and reducing the burden of compliance costs. It does not

however remove the responsibility of enforcement from the authority in which an infringement is found to have occurred.

There are differences between attitudes to the home authority principle. Here Dexter and Theo appear to rely on it:

We tend to concentrate on [this area] and what food we are responsible for. Our attention is turned to them. If we can make sure that everything in our patch is being enforced correctly and everyone else sticks to ensuring that everything within their patch is being enforced then the theory is that everything should be ok.

Their confidence in the principle is supported by Ethan: 'It [home authority] works reasonably well, you need to backtrack really as to how European legislation really works.' And further by Charlotte:

In terms of the trading standards element to it, it's sort of, it has worked well, because people when we were trading standards they were never afraid to pick the phone up and speak to somebody and say, I've just found this, and it's made by your company, can I just have a chat with you about it. And that worked pretty well.

Jacob explains how the principle may bestow the authority with an alternative to issuing legal proceedings and how it can also provide a database of intelligence to the home authority to inform further action:

If we find a case we investigate we can refer it to their home authority this might be an alternative to prosecution. If they have other complaints the HA can build evidence with which to approach the company to say 'we have had these complaints we need to take action.'

James credits the home authority principle as an element of the framework of food law enforcement that delivers a high level of food safety and trust in the accuracy of the label. However, problems may arise with differences in enforcement attitudes to labelling practice. James illustrates this with the example of the compliance with the regulation relating to the use of the cheese substitute 'analogue':

Overall, we probably enjoy an exceptional level of food safety, accuracy in composition in the UK. But there are problems too. For example, synthetic cheese called analogue which may be on the label but most consumers will not appreciate what it actually is. It's made from vegetable oils rather than cow's milk and I've found instances of breaches. It's cheaper than real cheese and some companies use it in pizza but call it something else, like an Italian sounding name but you must actually call it by its real name. So when challenged they say, well that other company they do the same. And there is some validity to that because they expect consistency in enforcement which seems reasonable. But there's a proper way to do it. The substance isn't banned, you can use it but you just need to play by the rules.

The home authority principle may be applied in informing an authority's choice of enforcement action. Ethan describes how the procedures work in conjunction with each other in determining where on the scale of potential responses the appropriate action should lie:

That would depend on the severity of the matter in question and whether it's a case of: here's a referral, deal with it as you wish, don't tell us. Here's a referral: we're a bit concerned to know what the outcome was and what the dialogue with the business. Here's a referral: we want to take action anyway.

The fact that a business falls within the jurisdiction of a local authority may accommodate the use of referrals for advice and guidance on the basis of ease of access:

If it's a home authority company, it tends to be dealt with by advice. I would go along and speak to them and say, because a lot of the complaints I get specifically about health claims would be from other trading standards authorities. So they'd be a referral to me.

Jessica

Therefore, the home authority principle appears to work in conjunction with the accommodative approach to enforcement. In the light of the apparent success in the operation of the home authority principle, it may be surprising that there is now a shift away from the principle and towards the promotion of primary authority relationships (see next section). This may be accompanied by the adoption of Hutter's 'insistent' approach or even the sanctioning

strategy identified by Hawkins.

In each of the interviews, it became clear that respondents were drawing from their general experience of enforcement when answering questions rather than restricting their answers to the context of the enforcement of health and nutrition claims. For clarification, respondents were asked if there were any differences between the enforcement of health and nutrition claims compared with other legislation. It was clear from the responses that there were no such differences; 'No. It's the same as food safety' (Charlotte) was a typical answer.

4.25.1 Primary authority – definition

The concept of primary authority was created in 2009 as a means of mitigating some of the disadvantages of the home authority principle. Primary authority involves creating a statutory partnership between a business and a single local authority where that authority will be responsible for providing definitive advice to the business in exchange for payment. Primary authorities provide 'assured advice' which is described as 'robust' and 'bespoke' and which 'must be respected by all local regulators.' (BIS, 2015b)

4.25.2 Primary authority in practice

Charlotte claimed that there were several primary authority relationships between businesses and her authority. When asked what precisely this meant in practice she explained that:

It gives them [the business] consistency. If your primary authority say we agree this label, other regulators have to consult that, and obviously you can challenge it, but it's not easily challenged by another authority.

The value of primary authority relationships are therefore obvious for business; as James describes: 'Primary authority gives protection to companies in that they can outlay money and finances knowing that it's not going to be challenged about the way they do things.' For local authorities faced with harsh spending cuts, they provide a valuable source of income and enable them to continue essential work.

Notwithstanding that primary authorities were created in 2009, the first ever primary authority determination came in 2015 when The Better Regulation Delivery Office made the following statement:

A dispute over different local authority interpretations of the law has been resolved in the first ever Primary Authority determination. The Business Department's regulatory delivery directorate, BRDO, has upheld advice from primary authority Newcastle City Council to high street baker Greggs Plc. about provision of toilets in its retail premises.

(BRDO, 2015a)

The important point here is not the substance of the decision but the principle that when the primary authority advice was challenged, the BRDO upheld the advice from Newcastle City Council. The decision upholds the original ruling by the council and therefore provides positive support for the concept. It is instructive to consider the rationale in this quasi-judicial role on the part of the BRDO:

1. The advice was soundly based upon the purpose and content of the disputed provision, and represented an informed and professional view of the law;
2. It was consistent with relevant case-law; and
3. Evidence demonstrated that since June 2011 the advice issued by Newcastle City Council has been accepted by other local authorities as reflecting a reasonable and proportionate interpretation of section 20 of the 1976 Act.

The direction of the Primary Authority was therefore confirmed. It is highly unusual to find the terms 'informed' and 'professional' applied when considering the reasonableness of a decision. In cases of challenges of delegated authority decision making it is more common to find the principles of administrative law, namely judicial review and natural justice applied with the focus on the way in which a decision is made rather than its substance (Bradley and Ewing, 2007).

The terms 'reasonable' and 'proportionate' used in the third paragraph are more familiar concepts in legal decision-making. They allow of differences in interpretation and it would not be inconceivable for a court or quasi-judicial authority to determine the same case by upholding the challenge and yet apply the same principles.

That the determination upheld the verisimilitude of the Council's decision and therefore providing support for both the original local authority and the business (Greggs the baker is a multiple based across the UK) is notable. It might have been more interesting to note the outcome if the BRDO had determined to uphold the challenge and therefore undermined the

decision of the local authority. This would, one suspects, somewhat undermine the expectations of certainty from business.

It is instructive to review the enforcer's understanding of the primary authority principle (made prior to the BRDO determination).

we haven't issued any assured advice for people for primary authority, and assured advice is something that the primary authority would rely upon and that another authority couldn't really challenge, to a certain degree, it's published advice and then if somebody comes along and says well we don't agree with that, we're going to have to seek permission. The trader would rely upon that advice. And if another authority wanted to challenge it, they would have to speak to us and for us to either rescind that advice or to make a change in some other way, or for us to concede, you know, we'll pull it or something like that.

Jessica

The primary authority principle may be viewed as the logical conclusion of the accommodative approach identified by Hawkins (2002). Assured advice occupies a unique position in one important respect. It goes beyond the benefit of advice from a retained professional such as a solicitor or consultant where, if such advice turned out to be incorrect the client would need to prove that the advice was negligent and that a reasonable professional exercising due care and skill would not have provided such advice. Primary authority advice goes further by providing an (albeit limited) indemnity to the business. That there is a payment made for the advice which represents a revenue stream for the local authority risks undermining the independence of the authority as a prosecutor and as such represents the strongest objection to the advice. Councils are under pressure to seek such revenue as Chloe describes: 'We do a lot of business advice. We don't have any home authority any more, from 2012 we stopped home authority'.

The provision of services by an enforcer in return for payment and how revenue generation might influence the setting of priorities is not necessarily unique to this study. Condone-Paoloni et al found that 'management and budget considerations affected work practice, so that the government policy for 'cost recovery' of (audit and other) services may have resulted in skewing of work activities to generate funds to provide the service' (Condon-Paoloni et al., 2015).

From a business point of view, there are also disadvantages; most profoundly in having to pay for a service that was previously provided free. Moreover, in this particular case where the businesses in question decide, eventually, to pay:

Because we haven't got resources to do it, so a lot of our home authority companies from April 2012 transferred over to primary authorities. Not all of them, initially because they said why should I pay for something that I've always had for free, or then we don't need it, we'll go to xxx. And then a few of them have come back, and said oh actually can you help with this?

Chloe

Sophie points to the problem of the primary authority principle where this results in a close relationship between the regulator and the regulated firm: 'It's very difficult. There are very few home authorities or primary authorities ready or willing to prosecute their own.'

However, Samuel dismisses the risk of a conflict of interest and the potential for bias in favour of a business solely because they have a primary authority relationship:

We have PA relationships here. For example, we have one with a German company but I've made it very clear that I was going to report on their labels. They didn't get any better treatment because they have a PA relationship. They changed their labels as a result of the report. They have a primary relationship for which they pay but there's no question of different treatment.

4.26 Technical barriers and complexity of the Regulation

At first sight the Regulation draws in questions of health and nutrition into the sphere of local authority enforcers who are more used to dealing with food hygiene issues and misleading claims on food standards. Other studies have shown that this can present a challenge for inspectors where they found they were uncomfortable in this area while admitting that this is an area where 'my skills aren't 100% up to scratch' and struggling when faced with the question, 'will it improve heart health?' and unable to respond with more than; 'I don't know. I'm not a doctor.' (Condon-Paoloni et al., 2015).

As Charlotte says:

when you start reading something in the nutrition and health regulations and it's going on about psychological [physiological?] functions and things, you do start thinking 'do I need to be a doctor?', 'do I need to be a scientist?'

Ruby reiterates this by highlighting the impact of the Regulation's complexity on the task of enforcement, 'It's the most technical piece of legislation and that is what makes it difficult to enforce.'

The Regulation distinguishes between nutrition and health claims by creating a distinct regime for each. The distinction is borne through to enforcement where the substantiation of a nutrition claim is a matter of compositional analysis and for health claims it is a matter of scientific evidence resulting in an authorised claim following a recommendation by EFSA. The EU publishes authorised claims on its web site <http://ec.europa.eu/nuhclaims/>. This is explained by Amelia:

With the nutrition claims because that is so clear cut we send them off to the analyst to check that what it says on there is what is in there. They are not complex in that we can get the analysis done.

But with health claims in some respects they are more straightforward. Once the list is published if it's not on the list it is not permitted. I don't feel we are at that stage yet because there are still huge amounts of decisions pending.

This is echoed by James when considering the evidential burden of proof: 'previously we had to prove that it was false beyond all reasonable doubt. Now it's a question of whether it is on that list.'

Such comments regarding the structure of the legislation and the removal of the requirement of having to make a judgement or the requirement to seek expert evidence for the prosecution of a misleading health claim might lead one to consider that the task of the enforcer had become more straightforward. That, according to Charlotte, would be a mistake. She was asked to consider the position before and after the regulation came into force:

You've been involved since before these regulations came into force. Have they made a difference?

It's a lot more complicated. The fact that the guidance is over 100 pages. Previously the claim just had to be correct. Now you have all these additional categories. Some can be used awaiting authorisation and some cant depending on the type of claim. So it's definitely more complicated now. The

legislation was brought in because a lot of claims were being made but business accepted the regs because they thought it was going to be simplified but I don't think we realised how long the approvals process would take and that's causing a lot of issues I think. And because the wording is set in stone, as it were, that's causing a problem. You don't have to use that exact wording but there are not a lot of other words you can use. I think it's categories as well where a claim might be approved for one product but can't be used for a different type. It's all getting complicated.

Charlotte

The Regulations sets out the scope of their application by reference to 'commercial communications' about foods to be delivered as such to the final consumer (Article 1). There is guidance on what precisely the term commercial communication means and how it applies. However, in practice there are questions that arise particularly with internet communications in social media and with consumer testimonials where the difference between editorial content and reporting and advertising are unclear:

The internet presents a further problem. For example a direct or indirect link to a survivor of an illness endorsing a product and saying that they got better from consuming that product. That might be 5 clicks away but the effect is just the same. If it is a testimonial does it fall within the NHCRs? Is it made by the company?... How do testimonials fit with the regs and what about where it is published by another? Is it a commercial communication?

Jacob

In relation to claims within the context of social media, Jacob raises the familiar problem: 'The NHCRs will require a scientific evidence base but what companies will do is raise the question of is it us or is it someone who we have no control over? For example through social networking.'

4.27 Central government involvement

In the period between the drafting, implementation and coming into force of the Regulation, there have been fundamental structural changes to the government affecting the ministerial

and non-ministerial responsibility and involvement with the Regulation. The most significant of these has been the reorganisation of the FSA into a single smaller organisation with the responsibilities relating to the food industry such as labelling passed to the Department for Environment, Food and Rural Affairs and matters of health now ceded to the Department of Health. The reorganisation took place as a part of the reforms of the new coalition Conservative and Liberal Democrat government in 2010 (Defra, 2010). For enforcers this meant that where there was previously a single point of reference for food within central government, there are now three; with the Department of Health responsible for nutrition and health claims. The aim according to government was to protect public confidence in food with a renewed focus on safety for the FSA.

However, in Amelia's view, 'The whole split between Department of Health, Defra and FSA is just a nightmare for us. It's not helpful to us and it's not helpful for business.' And Charlotte adds a similar view, 'instead of just the FSA, you'll have the Department of Health and Defra there. And then there's FSA Wales and FSA Scotland with different remits.' The more restricted remit of the FSA is felt by Dexter and Theo who say:

I find in my dealings with the FSA is that they are focussed on food safety from a microbiological view and they do tend to overlook the rest of the remit which hasn't been helped since the divisions made since the 2010 election with nutrition functions and labelling functions going off to other government departments. Which makes our life difficult.

Theo and Dexter go on to describe the complexity involved when a product gives rise to multiple issues which fall within the remit of all three bodies:

We need to throw into the pot the fact that the ultimate body that is responsible for enforcement is the UK Department of Health and that has certainly not helped. The fact that food has been split three ways. Between Health, Defra and the Agency. So if you have one product and three different issues. Each of which could go to a different body.

Dexter

Ethan provides a ready example of this lack of coordination by raising a question with reference to the remits of the bodies and applying the case of allergens; 'composition is now Defra, safety is FSA, and health claims are the Department of Health. So, you know, what should be included in the new consultation response about allergens?'

The issue affects enforcers when concerned with trying to obtain help and guidance in enforcement issues, ‘you don’t know whether to call the Department of Health, Defra or FSA.’

The problems are not just organisational but also problems of substance and what is regarded as a lack of responsibility, knowledge and skill in the ministerial departments. In her experience Scarlett finds that, ‘you can email DoH and Defra and you’d be very lucky to get a reply. I emailed three days ago and I haven’t even got a response to say we’ve received it.’ Jessica confirms this experience:

The Food Standards Agency local liaison officers are great and, as I say, they attend the meetings and if we’ve got an issue we ring them up and we speak to them, and we do about other issues, so we ring them up for that. So the FSA, great. Other departments, we’ve not heard a thing from them.

Dexter and Theo describe the nature of the support from central government since the reorganisation in vivid detail:

I know of one incident. I’ve heard this from the horse’s mouth at the agency. That a call comes into the FSA, the person on the switchboard say oh that’s a Defra function now, this person rings Defra. The person at Defra doesn’t have a clue. So they say I’ll get back to you on that. So they ring somebody at the FSA. I have been very critical of the Agency but at least before 2010, you could generally get to speak to someone who didn’t necessarily know all about the subject but had the responsibility. With Whitehall you just get to know somebody and they move off to another job, and educating about who you are and what you do.

The sense of disappointment and frustration is palpable.

Table 5

Application of Lipsky’s model of street level bureaucrats to the data from trading standards and environmental health officers based on Condon-Paoloni et al.

Lipsky’s theory	Findings
Heavy workload	Multiple duties across a broad range of areas

<i>Unpredictable demand for services</i>	<i>Difficulty in planning for uncertain demand</i>
Direct interaction with clients	High degree of interaction with public and industry
<i>Limited resources</i>	<i>Limited resources</i>
Conflict between client needs and organisational goals	Conflicting role of enforcer or advisor
<i>Rationing of services</i>	<i>Prioritisation, particularly with reference to risk</i>

The table shows significant correlation between the results of the research and Lipsky's theory. To sum up, they are: high workload with demands from clients including from consumers and industry, a need to prioritise workload and the result being a struggle to understand and apply complex legislation.

4.28 Conclusion

This section examined the challenges of enforcement that arise from the structural issues of the legislation. The key challenges lie in the enforcement of international law (which is what the EU is in the final analysis) at a local level. The price of devolved power and local responsiveness appears to be lack of consistency of implementation and inevitable charges of unfairness. The reorganisation of responsibility for food between three areas of government has caused difficulty for enforcers who are faced with the prospect of multiple ministries and agencies becoming involved in the enforcement of various issues arising from a single product.

Chapter 5

Conclusions

5.1 Introduction

This chapter draws together the specific conclusions and findings from the earlier work in the literature review and findings into a conclusion of the study as a whole with reference to its original aims. The conclusion will connect with the earlier work detailed in the literature review by applying the theory to the practice found as a result of the data analysis. The conclusions highlight the significance of the study and its implications for regulatory enforcement.

5.2 The original aim of the study

This study explores the ways in which local enforcement officers apply their discretion to enforce the law relating to nutrition and health claims. It is one small but important part of the broader debate around the regulation of the food supply. The aim of the study was to investigate the practice of trading standards and environmental health officers in the enforcement of nutrition and health claims for food in the UK. In doing so, it is worth revisiting the original objectives:

1. To review the theoretical basis and rationale for the implementation of the regulation on nutrition and health claims;
2. To establish the practices and normative values of trading standards and environmental health officers in the enforcement of the regulation;
3. To identify the operating and cognitive frameworks of enforcers affecting the application of their discretionary powers;
4. To explore the variations in regulatory enforcement styles in the enforcement of the regulation;
5. To establish the nature of any constraints and limitations that exist on the enforcement of the regulation;

5.3 The rationale for the regulation of nutrition and health claims

The literature review investigates and explains the theoretical basis of the regulation. This regulation aspires to move towards the goal of perfect markets to ensure the efficient distribution of resources, provide optimal conditions for business, promote a high level of competition and therefore provide optimum value for consumers (Sharpe, 1964). In a perfect market, consumer sovereignty is the natural result of competition between suppliers. Therefore, well-informed and rational consumers will benefit from the strong consumer protection which results from the Regulation. The justification for intervention is sometimes framed in terms of consumer protection rather than to correct recognised market failure, in relation to nutrition and health properties of food, this is to put right information gaps between buyers and sellers (Caswell and Mojduszka, 1996). In this case, regulatory intervention directed towards the provision of information will aim to correct such distortions and alleviate their effect by allowing accurate market information signals to be transmitted (Caswell and Mojduszka, 1996).

Information is provided in two ways: first, by the requirement for disclosure of specified information, for example nutritional values of food; and second, by the control of promotional claims, for example health effect claims. Both of these forms of control are evident in the Regulation.

5.4 The enforcer's toolkit

Enforcement of the Regulation allows enforcers a largely unfettered (except for financial constraints and resulting pressures to prioritise) discretion to choose between various enforcement tools. As such, 'enforcers have the capacity to affect the implementation of policy' (Condon-Paoloni et al., 2015). The data appear to support the paradigm of the regulatory pyramid in regulatory risk differentiation where firms are treated differently in accordance with the enforcer's assessment of the risks of non-compliance. As one regulatory intervention fails, the regulator moves upward to the next more serious level and, as the risk subsides, the regulator should move back down to a lower level. In this way, the pyramid provides an inherently proportionate and reasonable exercise of power the justification of which is based on the failure of the less serious previous action. It is instructive to see that the Regulatory Enforcement and Sanctions Act 2008 to a large degree implements the Ayres and Braithwaite model with the influence of the intervening Hampton and Macrory reviews. The enforcement tools that were described by Ayres and Braithwaite ranged from the provision of advice to

prosecution with all that sits in between these two extremes. In relation to the enforcement of the Regulation the tools have changed little since that time. The innovation and creation of novel sanctions has taken place in other spheres, for example in relation to the implementation of stop now orders under the Stop Now Orders (EC Directive) Regulations 2001.

5.5 Enforcement practice – deterrence or accommodation

In relation to the enforcement of the Regulation, Hawkins and Hutter capture the central difficulty thus; ‘the task of a regulatory bureaucracy is, by various means, to induce a potentially unwilling business organisation to bear costs which it would in many circumstances not wish to assume’ (Hawkins and Hutter, 1993). The costs of compliance will not be incurred in the absence of coercion by enforcement officers. Such officers play a significant role in influencing the business to incur compliance costs and to do so in a way which provides the optimal level of protection for consumers.

The literature suggests a linear paradigm of enforcement that exists between the deterrence model (Reiss, 1984) and the accommodative model. In the deterrence model the methods of enforcement are penal and adversarial and prosecution plays an important role and there is greater reliance on imposing sanctions (Hutter, 1989). By contrast, the accommodative model of enforcement seeks to secure compliance by the remedying of existing problems and the prevention of others. In the accommodative model, compliance is achieved by cooperation and negotiation. The methods used to ensure compliance are persuasion, negotiation and education. The use of legal action, particularly prosecution, is regarded as a last resort to be used only in the event that everything else has failed (Hawkins, 1984). In this model; ‘the importance of legal methods lies in the mystique surrounding their threatened or possible use rather than their actual use’ (Hawkins, 1984).

This study found evidence for both the deterrence and accommodative approaches of enforcement. When interviewed, enforcers identified themselves primarily as enforcers whose first duty was to the public. A further related theme, which is not found in the literature, but which has more recently emerged is the view of enforcers as advisors to business. Such an approach is rooted firmly in the accommodative model of Braithwaite et al where officers seek to ‘educate, persuade and cajole’ (Braithwaite et al., 1987). In this capacity, the enforcer adopted techniques such as education, persuasion and negotiation to deal with cases. In this role, enforcers’ tactics were more informal. Such a step may be seen a further step along the

accommodative path where enforcement officers are less enforcers in the traditional sense and they begin to take on the characteristics of advisors and consultants.

5.6 Enforcers as advisors

Marc Law raises the notion that 'an advisory approach to regulatory enforcement may be a necessary component of an effective enforcement strategy' (Law, 2006). The data in this study showed evidence of the engagement in advice as part of enforcement. One might have expected there to be some angst about fulfilling what appear to be conflicting roles, however respondents appeared to be able to switch between the two without any apparent difficulty.

In examining this advisory function, the communication between the firm and the regulator is found to demonstrate an awareness of the responses required to both the needs and attitudes of firms and the 'operating and cognitive frameworks of firms' (Black and Baldwin, 2010). Examples of this are evident in the commercial nature of the advice on claims for sports supplements made by internet-based businesses.

The data from the sample interviews of enforcers in this study shows how the roles of advisor and enforcer are taken on and adapted to suit the circumstances. This supports the notion of escalation up the regulatory pyramid of Ayres and Braithwaite et al (Ayres and Braithwaite, 1992). Sometimes, even in the same case, enforcers would move up but less easily down the pyramid of regulatory responses.

The study found the relationship of advisor and firm differed from that of the retained consultant and firm in some important respects. There was a willingness to challenge the advisor based on observations of what appeared to be inconsistent practice and the tolerance of non-compliant claims in circulation. This raises questions of fairness to which there appears to be no wholly satisfactory answer from enforcers. The conflict between the role of advisor and prosecutor is felt most keenly when faced with the prospect of action from another authority which challenges or undermines the advice provided to the firm. The overriding concern from firms however is for consistency and certainty for the advice which they receive. This places great pressure on enforcers to provide independent, bespoke, complex and commercially aware advice that will face up to scrutiny and possible challenge by experienced advisors. Not surprisingly, the data showed some faltering of confidence among officers particularly when faced with the absence of the coordination previously provided by LACORS.

Under such strained circumstances, the question of liability for negligent advice arises. The precise nature of the liability for incorrect advice leading to an economic loss is unclear. In

theory the application of the principles of duty of care, breach and causation and remoteness of loss will lead to liability in the same way as for paid advice save for the absence of a contract for service (Shavell, 2009).

Many of the officers interviewed reported being subjected to increasing demands from business for advice with expectations of service levels resembling those within commercial practice. Against a background of cuts in local authority services, this represents a further strain on resources. The difficulties to which it gives rise are underscored by the fact that the advice is provided without charge in the absence of a primary authority agreement. There is a danger of overreliance by firms on the advice provided by officers and this may lead to the failure to take proactive steps to deal with regulatory risk.

5.7 Enforcement by prosecution

The data showed that prosecution was rare across trading standards and environmental health enforcement in general. Save for the case of *Wigan BC v Bodyscoop 2012* (unreported) there are no cases of prosecution under the Regulation. In the light of the fact of many thousands of claims that are actually made, it might be tempting to attribute this entirely to the lack of resources or aptitude or skill of enforcers. In fact, the explanation is more complex. The data tells a more nuanced story of securing compliance with the goal of minimising consumer detriment with prosecution as the last resort. In spite of the fact that the forum for this is the criminal justice system, there is little emphasis on retribution or justice rather on efficiency and a utilitarian assessment of the consequences of the outcome. In this respect, the enforcement of the Regulation bears little resemblance to the prosecution of most criminal offences sharing only the procedural system. This provides further evidence, if it were needed at this stage, of prosecution being firmly rooted in the accommodative rather than the deterrence model of enforcement. In accordance with Hutter's findings there was little evidence of clear political influence in regulatory enforcement notwithstanding the explicit central government deregulatory agenda. Similarly, there was only the odd voice in support for the notion of the business viewing compliance in terms of commercial risk and acting as an amoral actor prepared to breach the Regulation whenever it may be more financially beneficial do so.

While prosecution was a last resort, rarely undertaken, officers were keen to stress that it is still available and that they would be able to summon the resources of the authority and look to the support of their departments if it was felt to be necessary. In fact, there was a sense of professional pride in the ability to able to exercise power even if it was rarely called upon. The decision of whether to prosecute raises the difficulty of applying the public interest test and

how beneficiaries are widespread even although the costs are borne by a single authority. Such benefits as enforcement are therefore provided by the government rather than through markets (Coase, 1974).

5.8 Deciding to prosecute – evidence and public interest

The decision to prosecute generally involved the application of the evidential and public interest elements of the CPS test. In doing so, the evidential test was a matter of legal judgement but the public interest test might involve a balance of the costs and benefits of taking action and considering matters such as competition or the moral culpability of the defendant.

Enforcers made reference to their enforcement policy to justify and guide their decision making when considering what action to take. Such policy provided transparency and accountability in the exercise of their powers avoiding the accusation of acting like ‘little Hitlers’ as described by one officer in Hutter’s work ‘*Variations in enforcement style*’ (Hutter, 1989). Of course, the opposite of rational, open decision-making would be an ‘intuitive’ approach that relies on a gut instinct for cases. This is often referred to by detectives or police in criminal law enforcement (Wilson, 1978). While there is passing reference by enforcers in the data to having a feel or instinct for enforcement, usually based on a view of the moral turpitude of the business manager, this is not found in the literature but it may, however, represent an interesting area for further research.

5.9 The roles of risk and proportionality

The data shows how enforcers’ assessment of risk plays an important role in determining the action that is taken in food law enforcement. The attitudes of enforcers confirms the influence of risk based regulation as endorsed by Hampton (Hampton, 2005). Where the enforcer is an environmental health officer, whose duties involve food safety and hygiene enforcement, the data shows that they are much more likely to be focussed on those traditional areas of environmental health work i.e. food safety, at the expense of food standards. This confirms the findings of Condon-Paoloni that environmental health officers would give monitoring nutrition and health claims, a lower priority than their food safety responsibilities: ‘[t]hey did not believe that it was really their role to undertake such monitoring and if they did, that they were ill equipped to do so.’ (Condon-Paoloni et al., 2015)

Trading standards officers on the other hand were found to have a stronger appreciation of the risks associated with food standards and they would, therefore, consequently be more alive to the enforcement of nutrition and health claims. Therefore where regulatory services departments of local authorities were reorganised with the result that responsibility for food standards was passed to environmental health officers without adequate training, the result may well be a decline in the quality of monitoring of labels.

In their paper *'When risk based regulation aims low: Approaches and challenges'*, Black and Baldwin consider the problem of enforcement of low risk and therefore low priority cases (Black and Baldwin, 2012). The data indicate how such risks at a case level are not individually concerning but their cumulative effect represents a challenge for enforcement. Individual officers may be inclined to treat breaches of the Regulation as minor infractions and respond with conciliatory measures for fear of appearing to 'break a butterfly on a wheel.' At worst, the enforcer's response is to ignore or dismiss the risk altogether.

Closely related to risk based regulation is the application of the principle of proportionality. In advocating proportionality the Regulator's Code highlights factors such as 'business size' and 'capacity'. The interviewed officers referred to practical and commercial considerations such as the cost of relabelling stock or the loss incurred by wastage. Such factors are uncommon in the calculations made by enforcers; although Sunstein appears to equate proportionality with cost benefit analysis which is less unusual. The interaction between the Ayres and Braithwaite pyramid of responses takes into account the proportionality of the response to the infraction (Ayres and Braithwaite, 1992).

5.10 The limitation of resources

The impact of resources on the regulatory response was not easy to assess. Some enforcers claim that resource constraints had no effect and that they would be able to take whatever action the circumstances required without regard to the marginal cost of such action. Others cited it as the single most important barrier to taking action. It appears from the interview data that most viewed the risks of litigation worth taking in only exceptional circumstances. Some of the literature suggests, surprisingly, that limits on resources may actually direct enforcers to take legal action as the more cost effective alternative to education (Shover et al., 1983). However other studies indicate that the level of risk and costs involved in taking legal action is a deterrent to prosecution (Bartrip and Fenn, 1980). Recent cuts in local authority spending have had a disproportionate impact on regulatory services which may in turn have further ramifications on consumer protection and the efficient functioning of consumer markets

although this is difficult to quantify. The extent of the cuts have called some to call into question the authority's ability to meet its statutory obligations (BIS, 2015a). Shears has gone so far as to conclude that the cuts to services undermine assurances that consumer protection will be maintained (Shears, 2012). There is however no evidence to support the claim that levels of protection have suffered directly as a result of cuts.

5.11 The breadth of officers' duties and the setting of priorities

Environmental health and trading standards officers are faced with the responsibility for enforcement of a broad range of legislation which is as varied as it is numerous. They cannot enforce all the legislation equally in all cases. Therefore in exercising this responsibility enforcers must set priorities for enforcement. Condon-Paoloni found that the resulting necessary prioritisation was 'employed because officers believed it most effective in ensuring protection of the community's health.'(Condon-Paoloni et al., 2015)

Here it was found that food law enforcement forms a large part of the workload for trading standards and environmental health officers. The data showed enforcers' willingness to set their priorities by reference to direct public consultation with residents and businesses and with their political representatives, local councillors. In doing so enforcers are able to claim a mandate for their actions, justify their choices and enable transparency and accountability. Unfortunately, such consultation would result in nutrition and health claims receiving little public support because of low awareness. When set against food hygiene, the risks associated with unsafe food will invariably trump the latent and long-term harm suffered by misleading consumers about the nutrition and health properties of their food.

With the exception of special projects focussed on nutrition and health claims, it was found that most work on nutrition and health claims was reactive and specifically driven by complaints. Officers emphasised their commitment to responding to all complaints but as there were likely to be few complaints relating to nutrition and health claims this was an unlikely call for action.

According to economic theory, enforcement is most effective when there is a victim who claims restitution (Becker and Stigler, 1974). This is problematic in relation to nutrition and health claims as the Regulation is a criminal statute and does not in itself create the possibility for civil claims, which in any case would be difficult to prove. Therefore, enforcers are more likely to receive complaints about false claims from competing businesses rather than consumers.

5.12 Local enforcement of EU law

The devolution of enforcement responsibility of law and policy formulated at EU level to a local level involves 'some negotiation' between the local and international interface (Harrison et al., 1997). Allowing final policy making to be made at the lowest level accepts the possibility of 'coordinated diversity' (Scott and Trubek, 2002). The study affirms the individual character of local enforcement and the variations in enforcement that flow from its local nature and this is most acute at the individual firm level where it is inevitably perceived as unfairness. This may have a knock on effect on consumers who will experience differing levels of protection depending on where they reside.

The home authority principle was applied to local enforcement to suggest to enforcers a clear direction as to jurisdiction and responsibility for matters where more than one authority might be concerned. The principle was found to be satisfactory and workable by enforcers. There was some indication that it would promulgate an accommodative approach to enforcement.

The creation of primary authorities since 2009 does ameliorate the problem of inconsistency in advice by assigning the relevant authority. However, it goes further than determining which advice takes precedence in the event of a conflict by providing 'assured' advice. It goes beyond advice that may be purchased in the market by conferring indemnity against action by another authority. Where the original decision is upheld this will be straightforward. Where it turns out that the advice was incorrect, the BRDO will need to make the difficult choice between maintaining the certainty of the original advice or accepting that the original advice was incorrect and therefore undermining the basis of the principal authority scheme. It will be instructive to see what the outcome of such a case will be. The data indicate that enforcers appear sanguine about the risk of a conflict of interest when the firm pays for advice.

The establishment of primary authority brings a high level of certainty and even indemnity not previously found in the commercial model of advice provision. It is intended to allow business to make operational and investment decisions in the absence of the ambiguity and risk usually associated with commercial activity. However, in doing so, it changes the allocation of risk significantly away from business and places it with consumers who will face lower levels of protection. For local authorities it provides a boost to revenue.

5.13 Officers' experience and expertise in enforcing the Regulation

The sample for interviews was purposively selected for the respondents' expertise in food standards. It was evident even among such experts however, that where enforcers did not have the experience of taking action for nutrition and health claims, that there was a lack of expertise, particularly among environmental health officers. The structure of the Regulation into nutrition and health claims with the creation of a list of approved claims should make the enforcement straightforward. However, some respondents appeared overwhelmed by the Regulation. It is suggested that such a reaction is due to the lack of familiarity and a confusion between enforcement by reference to the approved list or by analysis and the review of evidence for claims which is carried out by the EFSA; not a task for enforcers.

The internet and social media in particular presented challenges for enforcers when faced with the task of determining what constitutes a 'commercial communication' under the Regulation. Consumer endorsements or testimonials or blog posts which may be commercially sponsored may be indistinguishable from content. This is a widespread issue affecting all online content and one which extends beyond nutrition and health claims.

5.14 Enforcement of the regulation and food law in general compared

The data revealed no significant differences between the enforcement of nutrition and health claims and the enforcement of other food law notwithstanding the differences in risks presented by health claims and food safety. They face the same challenges of limited resources, variations in the styles of enforcement. The evidence concurs with Hawkins' finding that regulators deploy their wide discretionary powers 'flexibly'. The European Commission avers that such claims are 'not properly enforced'. The study did not find unequivocal support for this assertion. Rather that enforcement was uneven and dependent on a range of complex factors and decision making by enforcers was a multifactorial process.

5.15 Conclusion

The Regulation is enforced by criminal sanctions. The use of criminal law in consumer protection is a contested area (Cartwright, 2003). This may be responsible for what may have been an adversarial attitude on the part of enforcers in the past. When examining current practice, there is little evidence of such methods by enforcers. In fact, food law enforcers have moved further down the regulatory pyramid towards an almost exclusively accommodative approach in the enforcement of nutrition and health claims. There has been a shift from the adversarial relationship between the regulator and firm to one that resembles more closely that of advisor and client. This is consistent with the findings by Yapp and Fairman away from

policing and towards facilitation (Yapp and Fairman, 2006). Therefore, such a change appears to be part of a progressive and enlightened attitude among enforcers.

However, this brings its own challenges and raises questions of what happens when things go wrong. For example, where the advice turns out to be incorrect. In this scenario advice and negotiation rather than litigation become the stock in trade of enforcers and while this pragmatic approach is generally welcome, it raises the question of whether 'there are certain principled and ethical limits that inform and circumscribe the limits of legitimate enforcement practice' (Yeung, 2004).

As well as enforcement practice, the study also raises further questions about the regulatory infrastructure of the use of magistrates for determining cases and the extent to which laws made European law can be effectively enforced at a local level and the potential for variations in enforcement as experienced by firms.

Too often questions of regulatory enforcement are bound up in political dogma around demands for cutting red tape on the one hand, or, an unshakable faith in solving problems with more regulation on the other. Some regulation and enforcement is needed for the efficient operation of markets. However, crude regulatory reform which does not examine the operation of the specific effects on a particular market are unlikely to lead to improvements. There is a much more subtle task of designing regulation on what Helm describes as a 'disaggregated' basis involving a detailed analysis of the effect of a regulation and its enforcement which is much more likely to yield greater efficiency (Helm, 2006). By considering the case of enforcing the regulation of nutrition and health claims, this study contributes to the evidence base of this debate.

5.16 Limitations of the research

A general limitation of this work is that its scope is restricted the enforcement of nutrition and health claims. One of the limitations of the research are those that are common to the use of interviews which rely on the uncorroborated accounts of interviewees. Ideally the data would be corroborated by review of officers' casework files. This would be further triangulated by observational research which would involve shadowing officers. An obvious problem with such an approach is the compromise of confidentiality which attaches to regulatory enforcement work. Unsurprisingly, businesses are very sensitive to the risk of their exposure and regulators are similarly reluctant to allow their ongoing investigation to be placed under scrutiny.

In this study, there were 18 interviews carried out with 20 officers. While the point of data saturation was clear within the qualitative framework of this investigation, it may prove instructive to adopt a mixed methods approach to provide a quantitative approach to inform questions around the extent and depth of officers working knowledge of the Regulation. This would seek to provide a representative picture of the role of nutrition and health claims in the range of enforcement duties of officers. This might be achieved by a widely distributed questionnaire with statistical analysis of the results.

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Appendices

- A. Regulation (EC) No 1924/2006 of 20 December 2006 on nutrition and health claims made on foods. Vol. 1924.
- B. The Nutrition and Health Claims (England) Regulations 2007
- C. Patel, A., Smith, C., Knowles, T. and Lin, Y.-L. (2012) 'Nutrition and health claims: An enforcement perspective.' *Trends in Food Science & Technology*, 28(1) pp. 15-22.
- D. Patel, A. (2012) 'The regulation of health and nutrition claims for the promotion of food.' *International Journal of Management Cases*, 14(1) pp. 340-346.
- E. Copy email sent to trading standards and environmental health officers requesting interview
- F. Poster presentation for Eurocereal 2011, Campden BRI, Chipping Campden, Gloucestershire 6-7 December 2011
- G. Sample interview transcripts