

The Role of Public Opinion
in the Regulation of Genomics in the United Kingdom

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Abstract

This thesis analyses the role played by public opinion in the regulation of genomics, and conversely the role that regulation plays in shaping public opinion. It is argued that there has been an over-emphasis on the use of public opinion by regulators, and that this is a rhetorical strategy. There are strong normative drivers behind the regulation of genomics, which include the argument that regulation has the capacity to imbue public confidence in novel technologies and that enhanced deliberation will help to placate public concerns. While not dismissing these arguments, the thesis shows that in practice the interaction between regulation and public opinion is not so clear. It is argued that both regulation per se and the very existence and visible presence of independent regulatory agencies overseeing genomics can help to alleviate public concern. A key finding is that although regulators refer to public opinion, in practice they actually respond to stakeholder opinion. The thesis analyses the classic interpretation of public opinion, survey data, and contrasts it with regulators' understandings of public opinion and with public opinion data collected by independent regulatory agencies. The regulators interviewed agree that the public opinion data used in the regulatory process is not representative of public opinion. However, public opinion is still used as a way of legitimating policy. It is for this reason that I suggest 'public opinion' should, for reasons of transparency, be called 'public opinion data'. Such a move would reflect its value in the regulatory process, but equally indicate that such data has inherent limitations. The argument is supported by evidence from two case-studies from genomics, both of which are significant areas of scientific and public concern. The first is prenatal testing and preimplantation genetic diagnosis (PGD) and the second is Genetically Modified foods. The thesis questions whether the sui generis features of genomics merit its special regulatory handling and the enhanced role given to public opinion in this area.

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List of Abbreviations

CORE	Comment on Reproductive Ethics
CQC	Care Quality Commission
EFSA	European Food Standards Authority
ESHRE	European Society of Human Reproduction and Embryology
FSA	Food Standards Agency
GiG	Genetics Interest Group
HFEA	Human Fertilisation and Embryology Authority
HGC	Human Genetics Commission
HTA	Human Tissue Authority
IRA	Independent Regulatory Agency
NIPD	Non-invasive Prenatal Diagnosis
PGD	Preimplantation Genetic Diagnosis
PGS	Preimplantation genetic screening
PND	Prenatal diagnosis

Chapter 1

Introduction

What is this thing called public opinion? Can such a fluid concept be ring-fenced? If not then how can we measure the role it plays in the regulatory process and conversely, the role that regulation plays in shaping public views? In this thesis I analyse the relationship between public opinion and regulation in the case of genomics. I show that public opinion has multiple definitions and understandings and it is these understandings that I attempt to isolate as the public opinion input is incorporated into the regulatory process. From the outset it is apparent that while there is an enormous business in the collection and collation of survey data pertaining to our daily lives and attitudes, it is not clear where and how this data is being interpreted and digested by the regulatory-policy process. More specifically, there is a huge amount of data relating to the public opinion of genomics. Sturgis and Allum, for example, identify 298 publications, 236 studies, 140 knowledge questions, 85 interests questions and 817 attitude questions in relation to biomedical science in the meta-review they conducted covering 1980-2006.¹ This illustrates an enormous push for data collection which is driven by the narratives relating to the potential risks and concerns seen as emerging from novel technological developments. This thesis is concerned with the paucity of discussion relating to how this data is being used, and to issues of consistency. While survey data per se is referred to in the regulation and policy documents, it is more often the results of consultation exercises which are discussed. This raises the question as to why and for what purpose the survey data is being collected. Further, there is, I argue, an enormous gap between these two gauges of public opinion (survey data versus consultation exercises) in terms of the way the resulting data is utilised. It is both this gap, and the utilisation and response to the public opinion data, which I am studying in order to shed light on the function of public opinion as an input into the regulatory process. It is not simply a one-way process however, and the interaction between regulation and public opinion is additionally viewed from the perspective of how regulation per se can alleviate public concerns. The idea that regulation has the capacity

¹ Sturgis, Patrick and Allum, Nick, 'A Literature Review of Research Conducted on Public Interest, Knowledge and Attitudes to Biomedical Science', prepared for the Wellcome Trust, August 2006, at p.2.

to bring resolution to the public over the use of genomic technologies is examined and interrogated in the thesis.

The thesis focuses on two case-studies from the regulation of genomics: Genetically Modified (GM) foods and prenatal testing and preimplantation genetic diagnosis (PGD). The original reason why two areas of biotechnology were chosen was to generate data which might shed light on the role of public opinion in this area of regulation. This area of regulation has been selected because it is important to determine whether these two areas of genomics have a sui generis regulatory style. The thesis argues that the idiosyncratic features of genomics as a regulatory object has led to an increased resort to public opinion data by the regulators. Indeed, public opinion has been viewed precisely as a means to advance the credibility and legitimacy of the regulatory bodies in this field. The unique nature of the regulatory and institutional design in the regulation of genetics is supported by Black who describes it as ‘a morass of regulation’ made up of ‘an enormously complex set of advisory bodies, regulatory bodies, committees, professional bodies and industrial associations’.²

In the next section of the chapter an overview of the thesis research questions is given. This is followed by the central justifications for the research topic and the contribution of this thesis to the current literature. The thesis is situated in the socio-legal literature and this is discussed in terms of the interdisciplinary nature of the work. The chapter then describes the methodology and the decision to adopt a mixed methods approach involving a combination of diverse sources of data. The principal data sources, survey and interview data, are then discussed in terms of the strengths and limitations of each. A section is included on researching observable and non-observable interactions as this is considered particularly pertinent in terms of analysing the relationship between public opinion and regulation where many interactions are not explicit. For instance, significant decisions may be made in committees and not added to the meeting minutes. Finally a chapter-by-chapter overview of the thesis is given.

² Black, Julia, ‘Regulation as Facilitation: Negotiating the Genetic Revolution’, p.29 in Brownsword, Roger, Cornish, W.R., Llewelyn, Margaret, ‘Law and Human Genetics: Regulating a Revolution’, Hart 1998.

1.1 Analytical Framing and the Research Questions

The central research question of this thesis is ‘how does public opinion interact with regulation in the case of genomics?’ This question is complicated by the fact that the relationship between public opinion and regulation is two-directional and possibly even three-directional. Thus the research considers two correlate questions: what is the impact of public opinion on the regulation of genomics? And what impact does regulation have on public opinion in the case of genomics? Below, these two questions have been further broken down in order to illustrate how the thesis has gone about answering them.

1. What is the impact of public opinion on the regulation in the case of genomics?

- (i) How is public opinion understood?
- (ii) What is the difference between the rhetoric surrounding the use of public opinion in the regulatory process and its role in practice?
- (iii) Has public opinion been given a privileged role in the regulation of genomics?

2. How does regulation impact on public opinion in the case of genomics?

- (i) Can the regulation of genomics be deemed a discrete area or is it better regulated in terms of product?
- (ii) What is the capacity of regulation to alleviate public concerns over GM foods, prenatal testing and preimplantation genetic diagnosis (PGD)?
- (iii) Does the structure of the regulatory bodies, the Independent Regulatory Agencies (IRAs), have the capacity to reassure the public in terms of novel genetic technologies?
- (iv) Does the knowledge that public consultation processes are inherent in the regulation of genomics lead to a symbolic role for the consultation processes which helps to reassure the public?

Evidently these questions are fairly wide-ranging and equally very ambitious in terms of the expectations of a PhD thesis. However, these issues will be addressed to the greatest extent possible given the inevitable limitations in a study of this nature. I

contend that the argument given that public opinion enhances regulatory output has little or no empirical basis, and while it is democratically laudable it does not lead to more effective regulatory output in this field. However, if one measure of effective regulation is the impact upon the public, which in the case of genomics may be to reassure them that safety standards are devised to alleviate concern, then it is critical that a reliable gauge of public opinion is devised.

In relation to the issue of the impact of regulation on public opinion, the question of whether genomics can be classed as a discrete area of regulation will be discussed in chapter 3. It is argued here that the products, techniques and devices which have resulted from the techno-science of genomics are regulated more stringently than comparable products which result from different arenas of techno-science. This argument posits that this is ineffective regulatory practice, and while it is often supported on the grounds of a risk-based approach, there is no evidence for the inflated risk arguments. The thesis explores the role played by the consultation process, asking: how does one measure in practice the symbolic role that regulation fulfils? The research undertaken here shows that instances of enhanced deliberative practice in the regulatory process lead to greater public acceptance of the technologies regardless of the level of responsiveness of the regulatory agency to the public opinion data findings. This is something which is intimated in policy formulation in genomics. Levels of responsiveness to public opinion by the regulators are examined in the thesis, but the central thread is concerned with analysing what is understood by public opinion and how representative are the sources of public opinion data used. Within the thesis it will be asked whether enhanced responsiveness to public opinion leads to an increased public acceptance of the regulatory object in question.

1.2 The Contribution of the Study to the Field

The choice of the regulation of genomics as a case-study for an examination of the interaction between regulation and public opinion was made primarily as a response to the argument that there are high levels of regulatory responsiveness to public opinion in this area. Indeed, Lezaun and Soneryd talk of ‘the new centrality of the public to science and technology policy’ and argue that the vox populi has become a ‘new

orthodoxy'.³ In the following chapters this argument will be examined in relation to the case-studies. In the course of reading the literature relating to regulation of genomics and attending conferences on genomics in society, I have collated the principal reasons given for the enhanced role of public opinion in this field and they are:

1. The regulatory arena

Regulation in this area is characterised by Independent Regulatory Agencies (IRAs) and advisory bodies who operate at arms-length from government and use public opinion data gathering as a means to gain credibility and legitimacy in their decision-making. In this thesis I will address the weighting that public opinion is given in the regulation of genomics, both rhetorically and in practice, to determine whether a privileged position has been attributed to it. In each of the case-study chapters the regulatory field is mapped out and I investigate the hypothesis that the regulatory set-up per se has an impact on how public opinion data is utilised in the regulatory process.

2. The 'risk' factor

An additional feature is that the increased perceived or actual risk from genetic technologies leads to an enhanced rationale for increased responsiveness to public opinion by the regulatory agencies over and above the cabinet Code of Practice on Consultation in such situations. This Code has been in place since 2000, and sets out guidelines on when to consult, the duration of consultation exercises and the responsiveness of regulators to the findings of consultation exercises.⁴

3. The absence of categorical precedence

At the heart of any discussion about the regulation of genomics is the argument that this is an area where there is an absence of categorical precedence. To put succinctly, if there is an absence of categorical precedence then policy makers are unable to draw upon policy learning and to manage it as they have done in the past or in relation to a

³ Lezaun, Javier & Soneryd, Linda, 'Government by Elicitation: Engaging Stakeholders or Listening to the Idiots?' CARR Discussion Paper No:34, May 2006 at p.1&2.

⁴ HM Government, Code of Practice on Consultation (3rd Version) 2008.

similar issue.⁵ The argument that there is no categorical precedence is critical as a major justification for the high levels of political attention given to genomics. The idea is that the issues raised in the regulation of genomics are singularly unique and pose problems which regulators have not encountered before in other fields of regulation. As such the regulators cannot draw upon the rule learning of their past experience. Combined with the lack of rule learning is the fact that the technology is creating very critical social and ethical dilemmas and there are no frames of reference that can be drawn upon. It is thus concluded and argued by the regulators that genomics needs novel and special regulatory handling as it is testing the cognitive limits of the existing structures. One response advocated by regulators has been to give a heightened or enhanced role to the public in policy deliberation relating to genomics. This policy position has been accepted as a *fait accompli*, yet I believe this assumption should be open to debate and this is the central justification for this thesis.

Thus this thesis shows that the regulation of genomics is already endowed with a strong rhetorical push which arises from the nature of the issues, the moral and ethical implications, and the contested science. On these grounds it is argued by policy makers that there is a need to both educate the public through deliberation and to engage with the public in order to obtain their views.

I do however wish to stress that while the reasons above are arguments for the increased centrality of public opinion, we should not conclude that an increased responsiveness to public opinion data by the regulator is the result. It is critical that a distinction is made between the collection of the data on public opinion and its utilisation within the regulatory process. It is also important that any gap between the rhetoric in the policy documents, that public opinion is central to decision-making, and the attention that is actually devoted to the public opinion input is examined. This examination is on two levels, in that it needs to address both whether public opinion data is used in the regulatory process and subsequently to measure the level of responsiveness of the regulatory agencies to this data. This issue is critical in order to assess whether a more responsive regulator leads to more effective regulation. While discussion of effective regulation will be introduced in this thesis it is not a central concern, and more pertinent

⁵ Felstiner, Abel & Sarat refer to the concept of the absence of categorical precedence as a generic term and not in connection with genomics. They are cited in Cobb & Ross 1997: TR doc

to the current discussion is whether regulation *per se* has an impact on public opinion and whether the public are more complacent, placated, or less hostile towards a technology as a consequence of the regulation. Perhaps this type of thinking equates to the traditional idea of public engagement; one where it is viewed as a mechanism to educate the public which in turn can lead to public acceptance of the issue debated.

Thus as stated above, the significant role given to the views of the public in the deliberation of regulatory decisions has been accepted as a *fait accompli*, yet I believe this assumption should be open to debate, and this is the central justification for this thesis. The role of public opinion in relation to regulation has not previously been examined in this way by mapping different gauges of public opinion data, including the views of regulators themselves. Also, in response to the cries for the increased centrality of the public in the regulation of genomics it is necessary to analyse what is exactly taking place in order to establish whether it is a justifiable procedural development. Thus, if there is evidence that a greater role is being given to the public, then what is the effect of this in terms of regulatory output and public opinion? These last few questions have not been asked or addressed in the existing literature.

A contradiction arises in that such a fluid concept as public opinion often has different meanings, understandings and applications, and yet references made to public opinion in the regulatory discourses give the impression that this is not the case. The methodological approach taken here has been to use survey data as one indicator of public opinion and to examine it in contrast with other measures of public opinion which principally have been the results of consultation exercises carried out by regulatory agencies but have also included analysis of the influence of non-governmental organisations (NGOs). Such a method has been chosen with the aim of providing insights into the role played by public opinion data in the regulatory process. In addition to the quantitative element of the thesis, nine elite interviews were conducted with regulators. The interview data gives insights into the regulators' attitudes surrounding the significance and representativeness of public opinion data. What emerged from the interview data is that there is a consensus from the interviewees that public opinion data is an important input into the regulatory process, but the interviewees held that this data equally cannot be taken as truly representative of the views of the public, suggesting a rather paradoxical view of public opinion within regulatory organisations. In spite of the strong arguments made about the importance of

public opinion in the regulatory process by social scientists, scientists and regulators alike, I argue that in practice the regulator, and regulatory agencies, are using inconsistent measures of public opinion. This does not negate the significant role of such data in the process. While regulators accept that the public opinion data used is partial, they continue to portray it as representative of public opinion, and such data retains a significant influence, both rhetorically and in practice, within regulatory decision-making.

1.3 Situating the Research in the Socio-legal Literature

This study is situated within the literature on socio-legal studies or law-and-society scholarship because this literature and approach illuminates the interactions which take place between regulation and public opinion. Socio-legal studies centres on the analysis of the gap between the black letter of the law, the legal text, and the impact of the law in practice by looking at ‘law in context’ or ‘law in action’.⁶ While socio-legal studies offers wider angles than taken in this thesis, what is gained from it here is one of its central motifs which concerns the ‘theoretical and empirical analysis of law’s social consequences and origins’.⁷ Socio-legal studies crosses disciplinary divides, and this thesis also encompasses literature from political science, law and sociology.

1.4 Methodological Approach

In responding to the research questions the thesis has become very data-rich in that it maps out different sources of public opinion data across time in order to establish the representativeness of the data and the role specific sources of public opinion play in the regulatory process. Within this context a greater depth of analysis has been devoted to survey data and specifically the British Social Attitudes (BSA) Survey as this data has been used as a comparator against which the public opinion data collected by the Independent Regulatory Agencies (IRAs) has been analysed. This methodological approach is not intended to suggest that the BSA survey is deemed more representative or robust than the public consultation exercises, which is a claim made by Sturgis et al.

⁶ Selznick, Philip, ‘Law in Context’ Revisited’, *Journal of Law and Society*, Volume 30, Number 2, June 2003, pp.177-186 at p.177.

⁷ Cotterrell, Roger, ‘Subverting Orthodoxy, Making Law Central: A View of Sociolegal Studies’, *Journal of Law and Society*, Volume 29, No.4, December 2002, pp.632-644 at p.632.

Sturgis et al state the following in relation to the cache of genomics questions contained in the BSA survey:

‘While we make no claims to having fostered a public dialogue by administering the questions in this survey, we believe that our findings are a good deal more robust and representative of public preferences on these issues than can ever be produced by such exercises in public ‘consultation’’.⁸

This claim is examined in the course of the thesis, although it is difficult to directly contradict because the questions posed by the survey do not directly correspond to public consultations.

A mixed methods approach has therefore been adopted as a means to address the research questions. This method is defined as ‘integrating quantitative and qualitative data collection and analysis in a single study or programme of inquiry’.⁹ A large range of data sources are drawn upon and these are:

1. Secondary analysis of British Social Attitudes (BSA) survey data and the Eurobarometer. Additional survey data will be discussed and referred to but this will be primarily from published findings. The latter includes a survey conducted by the Food Standards Agency which includes attitudes to GM food (The Consumer Attitude Survey).
2. Nine elite interviews conducted with senior regulators. The interviewees were officials from the Directorate General for Health and Consumer Protection (DG SANCO) at the European Commission, the European Food Standards Authority (EFSA), a member of the GM Policy and Regulation team at The Department of Food and Rural Affairs (Defra), a member of the Novel Foods, Additives and Supplements Team at the Food Standards Agency (FSA), Members of The Human Fertilisation and Embryology Authority (HFEA), The Human Genetic Commission, The Genetics Interest Group (GiG), a member of The National Consumer Council who additionally chaired the FSA’s Advisory Committee on

⁸ Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, ‘Genomic Science: Emerging Public Opinion’, From Park, A., Curtice, J., Thomson, K., Bromley, C. and Phillips, M. (Eds) (2004), *British Social Attitudes – the 21st Report*, London: Sage at p. 121.

⁹ Cresswell, J.W., Plano Clark, V.L., Guttman, M., Hanson, W. ‘Advanced Mixed Methods Research Design’ in Tashakkori, A. and Teddlie, C. (Eds), ‘*Handbook on Mixed Methods in the Behaviour and Social Sciences*’, Thousand Oaks, Calif: Sage Publications, 2003, pp. 209-240.

Consultation and Engagement (ACCE) and an academic who had extensive involvement in consultation on GM including sitting on the FSA steering group on UK GM dialogue in 2010.

3. Mapping of Regulatory Organisations. In order to contrast product and process regulation and to assess whether the regulation of genomics should be viewed as discrete area or whether it is better viewed as application relevant.
4. The regulation pertaining to the two case-studies
5. Human Fertilisation and Embryology Authority (HFEA) Consultation Documents relating to PGD.
6. The Cabinet Office regulations on consultation which outline the duties placed upon IRAs to incorporate public opinion into regulation.
7. Media counts relating to numbers of stories in the press about GM foods which were undertaken on Lexis.

Brannan argues that mixed methods research may lead to new perspectives and innovative insights on the subject of study.¹⁰ It is hoped that this the case in this thesis and that the choice of methods is a good fit with the research questions posed. The use of each data set can be justified on the basis of the need to investigate the different understandings of public opinion. For example, the interview data shows the regulator's perception of public opinion and how s/he uses survey data.

Triangulation is often purported to be the purpose of using mixed methods, based on the idea that different methods corroborate or validate each other. There are however a number of possible outcomes in addition to this view of 'triangulation' as corroboration. It is hoped that the methods used for this research will achieve the outcome which Brannan describes as complementarity, that is, the qualitative and quantitative data sets are treated as 'different beasts' and each enhances the other: 'the data analyses from the two methods are juxtaposed and generate complementary insights that together create a bigger picture.'¹¹ It is an unusual approach to analyse and refer to such a wide range of data sources but it allows original insights into the research questions in terms of added depth to the study and greater subtlety to the findings.

¹⁰ Brannan, Julia, 'Mixed Methods Research: A Discussion Paper', ESRC National Centre for Research Methods, NCRM/005 at p.9

¹¹ Brannan, 2005 op cit. at p.12.

The thesis thus analyses an array of survey data, public opinion data collected by IRAs, and regulation, and additionally draws on a number of elite interviews conducted with senior regulators. A thematic analysis was undertaken of the interview data which allowed themes to emerge from the data without being predetermined. This lent itself well to the study since the mapping of public opinion data through the regulatory process demanded a fluid and flexible approach. In addition, an in-depth document analysis of the regulations relating to GM food and prenatal testing and PGD was conducted. A further area of analysis is the secondary data which includes the survey data and the reports on the public consultation exercises. The overall aim was to map out the regulation for each case-study and to map the public opinion inputs into this while also gauging public opinion measures across the time-frame. The time-frame extends from the first BSA survey data which included the cache of questions relating to genomics in 1999 until 2010 when an extensive Eurobarometer survey was conducted covering this area.

The method adopted of mapping the sources of public opinion data and examining the inputs of this data into the regulatory process is original in methodological approach. Originality is additionally derived from the subsequent data findings. The methodological approach has led to interesting findings in relation to the influence of public opinion on the regulatory process. One such finding is the significant impact on public opinion of the moratorium on GM products which is discussed in Chapter 5. The findings of this thesis are not intended to be ‘grande generalisations’ but ‘petite generalisations’¹²; they are significant, but the aim is to offer a nuanced account of the interplay between public opinion and regulation. One very significant problem in this study is that of when and where causal inference between the variables (public opinion and regulation) is appropriate. As Steel opines:

‘Given the general impossibility of performing experiments and the difficulty of knowing whether all possible causes have been taken into account, one is faced with a serious challenge to the possibility of making reliable inferences about the causes of social phenomena’.¹³

¹² Stake, Robert E. (1995) ‘The Art of Case Study Research’. Thousand Oaks, CA: Sage

¹³ Steel, Daniel, ‘Social Mechanisms and Causal Inference’, *Philosophy of Social Sciences*, Vol. 34, No.1, March 2004, pp.55-78 at p.55.

While the problematic nature of causal inferences is acknowledged here, this thesis does make knowledge claims and in doing so it contributes to the field of study.

As already acknowledged, the public opinion data is analysed in this thesis in order to identify points of convergence and points of data divergence across the sources and additionally to examine changes in public mood over time. A longitudinal study was not possible due to the data limitations: the data points of the BSA data were sporadically and not annually conducted in relation to specific techniques. The mapping of public opinion and regulation over time was necessary in order to show the interchange of public opinion data and how it has been both used and viewed from within the regulatory process. The large number of sources of empirical data analysed here is justified on the grounds that it is the best means by which to gain an overview of the public opinion data collected. The overview was a necessity in order to gauge the understandings of public opinion utilised in the regulation relating to the case-studies, and for the cross-analysis of the data to assess representativeness.

As already noted, the study undertakes a comparison of the regulation in two fields of genomics: genetically modified (GM) foods and prenatal testing and preimplantation genetic diagnosis (PGD). There are a number of benefits from this comparative approach which include the applicability of the findings. The reason for using two case-studies in the study has been that the data findings may have significance or resonance for other areas of genomics, although the findings should not be deemed representative across the board for the regulation of genomics. The latter argument would lead us to conclude that genomics regulation is best viewed in terms of product rather than process regulation. I will return to this point in Chapter 4. A discussion of the survey data follows, after which the interview procedure is outlined.

1.4.1 The Survey Data

The survey data utilised in the thesis, the BSA and the Eurobarometer in particular, benefit in terms of force and enhanced robustness from the large sample sizes. A number of on-line databases were used in the course of this research and these include: EurLex (Europa), BAILII, Butterworths Legislation Direct, and LexisNexis. ENDS Europe Daily proved very useful in terms of highlighting legal and policy developments at both national and EU level. The data discussed here is drawn from three principal sources: the British Social Attitudes Survey (BSA), the Eurobarometer and the Food

Standards Agency Consumer Attitude Survey (CAS). The first of these, the BSA survey, is designed to produce annual measures of public attitude and is intended as a means to measure attitudinal change across time on a very wide range of subjects from opinions of marriage to views on smoking. A cache of questions relating to genetic technologies was included from 1996-2003. However, the areas of genetic technologies covered were included in a random fashion, which poses difficulties in terms of any kind of longitudinal study. For instance, survey questions on GM foods were only included in the years 1999 and 2003 and for prenatal testing and PGD in the years 1998, 2000 and 2003.

I analysed the BSA data-sets in SPSS and the findings have been presented in the form of pie-charts, tables and graphs. The BSA data imposed limitations in a second way because for GM foods, six questions requiring a likert response were asked in the two years they were included in the survey. Fortunately, five of those statements remained the same across the years and a similar pattern emerged for prenatal testing, where the same questions were posed in both 1998 and 2000 (see appendix 4). I also examined the reports on the BSA surveys produced by Sturgis, Cooper, Fife-Shaw and Shepherd in relation to this data and GM foods.¹⁴ These reports are produced by the academics responsible for the design and collection of the data relating to attitudes to genetics in the BSA surveys. The sample sizes varied in relation to the questions; for the 1999 attitude statements it was small at only 833. For the 2003 attitude statements the sample was 2,649. The BSA survey of 2003 additionally contained a quiz related to genetics (base =2,649) and a set of public trust statements which demanded a likert scale response (base =3,272).

The Eurobarometer have conducted seven surveys specifically of public perceptions of the Life Sciences and Biotechnology. The surveys were conducted in 1991, 1993, 1996, 1999, 2002, 2005 and 2010. While the surveys reflect a wider European public they additionally contain data specific to the UK. I refer mostly to Eurobarometer Reports 58.0, 63.1 and 73.1 covering the years 2002, 2005 and 2010 respectively, but which

¹⁴ Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, 'Genomic Science: Emerging Public Opinion' from Park, A., Curtice, J., Thompson, K., and Phillips, M. (Eds) (2004) *British Social Attitudes – the 21st Report*, London: Sage; Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris, 'Attitudes to Biotechnology: Estimating the Opinions of a Better-Informed Public', *New Genetics and Society*, Vol.24, No.1, April 2005, pp.31-56.

included analyses of previous Eurobarometer data from the years since 1991.¹⁵ The sample size of the Eurobarometer survey is approximately 25,000 respondents, taken to be representative of the 27 EU Member States plus Croatia, Iceland, Norway, Switzerland and Turkey. The survey examines, inter alia, trends in optimism and pessimism towards biotechnology, familiarity with specific technologies including GM foods, and support for and opposition to biotechnologies including GM foods. The Eurobarometer survey also includes data relating to public trust in the biotechnology system and specifically trust in scientists and regulators. The data is analysed as one source of ‘public opinion’. It is data which, while it is very robust as survey data, has all the inherent limitations of survey data. Survey data is an artefact of the survey design and this must be borne in mind when drawing conclusions from the findings.¹⁶

1.4.2 The Elite Interviews

‘The term ‘qualitative interview’ refers to interview techniques that provide qualitative (textually rich) data.’¹⁷ Kelly argues that due to the reflexivity and textual qualities of qualitative interviews, they are ‘appropriate to research questions regarding the meaning of events or phenomena to research participants’.¹⁸ This is a great fit therefore for a discussion of the relationships between public opinion and regulation. Following the advice of a colleague, Kelly, it was the hope that the interviews would give an insight into the regulators’ ‘knowledge, experience and perspectives’ on the role of public opinion in regulation. The semi-structured nature of the interview allowed this to take

¹⁵ Gaskell, George, Allum, Nick and Stares, Sally, ‘Europeans and Biotechnology in 2002’ Eurobarometer 58.0, A Report to the EC Directorate General for Research from the project ‘Life Sciences in European Society’, QL7-CT-1999-00286 (2nd Edition: March 21st 2003); Gaskell, George, Stares, Sally, Allansdottir, Agnes, Allum, Nick, Corchero, Cristina, Fishler, Claude, Hampel, Jurgen, Jackson, Jonathan, Kronberger, Nicole, Mejlgard, Niels, Revielta, Gemma, Shreiner, Camilla, Torgersen, Helge and Wagner, Wolfgang, ‘Europeans and Biotechnology in 2005: Patterns and Trends; Final Report on Eurobarometer 64.3’ A Report to the European Commission’s Directorate- General for Research. (July 2006)

¹⁶ In particular due to the high number of likert style questions, acquiescence response bias is a problem whereby respondents are more likely to agree than disagree with a statement.

¹⁷ Kelly, Susan, E. ‘Qualitative Interviewing Techniques and Styles’, Chapter 16 in Bourgeault, Ivy, Dingwall, Robert and de Vries, Raymond (Editors) ‘The Sage Handbook of Qualitative Methods in Health Research’ 2010, at p. 307.

¹⁸ Kelly, Susan, 2010 *ibid.* at p.308.

place rather than restricting or delimiting the discussion with preset categories.¹⁹ Nine interviews with senior regulators of GM foods, prenatal testing and PGD were undertaken. The interviewees were senior regulators from the Human Fertilisation and Embryology Authority (HFEA), the European Commission's Directorate General for Health and Consumer Affairs (SANCO), the European Food Standards Authority (EFSA), the Food Standards Agency (FSA), the Human Genetics Commission (HGC), the GM Team in the Department of the Environment, Food and Rural Affairs (Defra), an academic with a background in GM regulation as a scientist and the Genetic Interest Group (GiG). GiG is a national alliance of over 120 charities which represent the interests of people with genetic disorders. The interviews were semi-structured and ranged in length from 45 minutes to an hour and a half. The semi-structured approach enabled a flexibility to allow the interviewee to speak at length while specific questions remained at the core of the interview. The interview schedule included open-ended questions. The majority of the interviews were conducted face-to-face but 3 were telephone interviews. The preference was for face-to-face but the travel costs and time meant that phone interviews were easier when the interviewee was based for example in Brussels or Edinburgh.

The contribution of the interview data to the thesis is that it brings a level of nuance and depth to the study. It is very difficult to find regulators who agree to devote their time to being interviewed by a PhD student. While such a small sample of interviews is not, of course, representative of regulators, the value of this interview data should not be underestimated as those interviewed are very senior officials and as such are central to regulatory decision-making.²⁰

Incorporation of the realist approach tells us that the data obtained from the interviews should not necessarily be viewed as a candid account of the regulator's view of public opinion processes, but rather as a particular account of events or views. It can perhaps be best understood as the voice the regulator wishes to portray, which is nevertheless a rich source of data and gives us an insight into a somewhat idealistic view of how

¹⁹ Kelly, Susan, 2010 op cit. at p.309.

²⁰ Stephens, Neil, 'Collecting data from elites and ultra elites: telephone and face-to-face interviews with macroeconomists', in *Qualitative Research 2007*, vol. 7 pp.203-216, this article looks at the hierarchical differences between the PhD student and the elite interviewee and the problems this poses.

public opinion would work in the regulatory process. Additionally, there are other factors at play which may elude capture in the process of data collection: some observable and others which are not observable.

1.4.3 Observable and Non-Observable Interactions

There is an almost all pervading normative driver, both in the literature relating to the role of public opinion in regulation and from the regulators themselves, which argues that public opinion input into policy and regulatory decision-making is critical. This normative driver is discussed throughout the thesis, however as pertains to the methodology it is important to recognise the role that such normative arguments lend to the interpretation and analysis of the role of public opinion at the outset. There are very strong democratic arguments for the inclusion of public opinion as have been outlined yet the question has to be does the incorporation of public opinion in regulation better the regulatory output.

Cultural theorist Pierre Bourdieu talks of the ‘imposition of a problematic’ which he argues is ‘just what opinion polls do with all the appearance of ‘neutrality’’, a notion that is instructive in informing our awareness of the status of opinion data. Bourdieu widens this argument to include a similar process occurring in the research interview, where a choice is made by the researcher to attempt to act in a neutral manner or to engage with the interviewee.²¹ In the interviews I carried out for the thesis, I found that it was at times exceedingly difficult not to lead the interviewee by either the way the questions were framed or feeling that it was necessary for the interviewer to nod or make a small sound of agreement with the interviewee as a means to encourage them to continue talking. The latter point relates to the discomfort an interviewee can feel in the process of being interviewed and also to the unusual position where one does not generally produce a monologue on a subject but interacts with another person. It is necessary to acknowledge that the interview data is a product of this interaction between the researcher and the interviewee.

University ethical approval was obtained to conduct the research for this thesis. Additionally, an informed consent form was drafted (see Appendix 1) and sent to each

²¹ Bourdieu, Pierre, ‘Understanding’, in Bourdieu et al ‘The Weight of the World: Social Suffering in Contemporary Society’ Stanford University Press, 1999.

interviewee prior to the interview. This form outlined the nature of the study and anonymity and confidentiality measures to be undertaken. Subsequently, before the interview began, the details of this form were reiterated and the interviewee was asked whether they were happy with specific elements which included the confidentiality issue, and recording the interview.

The redaction of data is a necessity in the conduct of a finite research project, however this does not negate the point that it is a redaction and the findings should not be given a greater significance than reflects this. For instance in the transcribing of a recorded interview, the researcher is interpreting the data and Bourdieu argues creating a 'translation' of the interview.²² The interviewee is often viewed as someone giving an 'account' and as such it needs to be viewed as an 'account'. It is important that the researcher retains a reflexive approach in the course of the data collection and data analysis.

1.5 Thesis Overview

Following this Chapter, Chapters 2, 3 and 4 provide a theoretical background to the themes of the thesis on which the analysis of the case-studies is based. In order to discuss the role that public opinion plays in the regulation of genomics, the principal interpretations of 'public opinion' are reviewed in the next chapter. Five understandings of public opinion are given and these provide an overview for the discussion of how public opinion is captured and subsequently represented by the regulatory-policy process in relation to genomics. These five definitions form a frame for discussion throughout the thesis, but most importantly in the chapters which analyse the case-studies.

In Chapter 3 I set out the rationale for the use of a more expansive definition of regulation, including both hard and soft law, thus running from primary legislation through to guidance notes. The different understandings and definitions of genomics, regulation and the regulation of genomics are discussed in Chapter 3. The principal focus of the regulation here relates to the rules which emanate from Government, i.e., the rules which are produced by the Independent Regulatory Agencies and Government

²² Bourdieu, Pierre 1999, op cit. at p.621. Bourdieu expands this argument by discussing the constraints upon the researcher in being faithful to the interview when one cannot reproduce everything on the recording and the constraints of readability.

Departments relating to the case studies chosen in the thesis. In addition, the primary legislation is drawn on as necessary to elucidate the role played by public opinion in the regulatory process. For the case of GM foods, the principal forms of regulation I will be looking at are: primary legislation which is predominantly the relevant European Directives, and secondary rules such as product approval processes relating to the authorisation, risk assessment and labelling regulations. In the cases of prenatal testing and preimplantation genetic diagnosis I examine the primary legislation & case-law, principally the Human Fertilisation and Embryology Act 1990. In addition, I analyse the secondary rules, principally the Codes of Conduct for PGD and the large range of general guidance which exists to oversee prenatal testing.

Additionally in Chapter 3 I outline the rationale for my choice of reference to the regulation of genomics as opposed to the regulation of genetics or biotechnology. The movement from genetics to genomics is outlined and it is argued that genomics is more appropriate for this study as both a nod to the increased complexity of the technological and scientific developments in the field and as a recognition of a shift from a 'thing' to an 'activity'. Genomics embraces so much more than genetics in this respect and I argue that it is more representative of the study conducted here. For the purpose of this thesis, genomics is defined as 'the place where things happen which involve the genetic complement of an organism'.²³ The regulation of genomics is viewed in the thesis as the study of the regulation relating to the development of products from the laboratory to the consumer and as such is a fairly expansive understanding. Included in this chapter is a section outlining both the rhetorical arguments commonly given for why genomics should receive special regulatory handling and additionally an examination of whether there is any evidence that in practice genomics is being given special treatment. As such the normative arguments and justification for the regulation *per se* and the regulatory approach are outlined. What arises from this discussion is that public opinion collection and deliberation have been utilised as a response to the idiosyncratic features of genomics such as novelty, ethical issues, and the controversy over safety and risk of harm. The idea is raised that in certain cases it is not the regulation which appeases the public but the fact that deliberation has taken place: are the public aware of the state of the regulation in any case? Do the public feel more secure if they feel that a

²³ This definition is attributable to Professor Steve Hughes, Egenis, University of Exeter, in discussion and to the NIH definition of 'genome'.

fair system and process has been followed to ascertain their views? If the latter is the case then it is a sharp move away from much of the existing literature which generally examines how responsive the regulation is to the public and does not address the idea that the regulation, the IRAs or the public consultation exercises may themselves imbue reassurance and public trust.

Chapter four discusses the literature surrounding the interaction between public opinion and regulation and sets the scene for the issues to be analysed in the subsequent case-study chapters. This chapter questions the rationale for public opinion as an input into the regulatory process; it asks whether regulation can influence public opinion, and whether public opinion has the capacity to influence regulation. In this chapter the role played by the regulator is introduced, which leads in nicely to the data from the interviews with the regulators which is analysed in chapters six and seven.

Chapters 5 and 6 are concerned with the project's case-studies. Both Chapter 5 on GM foods and Chapter 6 on prenatal testing and PGD follow a similar structure allowing comparisons in the regulatory developments and relevant public opinion data to be outlined. For each case-study the primary areas of focus are identified and analysed. The case studies in many ways reflect a lack of unanimity over the benefits or risks posed by the technologies: for instance, the controversial nature of the risks posed by GM foods has meant that regulators are attempting to offer consumers a choice in the purchase of the products in the form of a label. With regards to prenatal testing and more specifically PGD, it is a case of contested benefits, in that the majority of the survey respondents agree that the technologies should be made available, yet there is some hesitancy relating to the ethical issues. The prenatal testing and PGD chapter examines the difference between what people say in response to survey questions and what they do through a comparison between attitude data from the BSA and statistics for the levels of terminations of pregnancies following a prenatal genetic test.

The final chapter draws conclusions from the thesis findings in seven areas and these are: the understandings of public opinion in the regulation of genomics; the question of successful policy resolution and role of regulation in the alleviation of public concerns over genomics; issues of representativeness of public opinion data in the regulatory process; the use of public opinion as a means to boost IRA credibility and increase regulatory share; the privileged role given to public opinion in the regulation of

genomics and levels of responsiveness to public opinion; the use of public opinion by the regulator: the representativeness of public opinion paradox and the inter-changeability between understandings of public opinion; and the special regulatory handling and idiosyncrasies of the regulation of genomics. In addition a review is given of the merits and limitations of the thesis both in relation to the methodology and the choice of the regulation of genomics as an object of study. The thesis concludes with a look at future research possibilities which emerge from the thesis research, including recommendations for regulators on the utilisation of public opinion data in regulatory decision-making.

Chapter 2

The Capture and Representation of Public Opinion in Theory and Practice: The Case of Genomics

2.0 Introduction

This chapter provides an overview of the often competing and conflated definitions of ‘public opinion’. Public opinion is a slippery, fluid concept and its meaning can change in accordance with the context in which the term is used.²⁴ This can give the concept of public opinion a strong utilitarian value to regulators because it has the power to act as a ‘coat hanger’ in that different interpretations can hang on it. The purpose of this chapter is to outline the most common interpretations of the term ‘public opinion’. Once these definitions have been drawn out I will examine in the remainder of the thesis the value of ‘public opinion’ as it is used by regulators and within the regulatory and policy documents. In order to understand how the term is utilised in regulation it is important to step back and examine the principal methods of data collection used to establish a gauge of public opinion and these are outlined in this chapter.

While some understandings of public opinion are underpinned by normative motives inherent in the regulatory process there is also an operationalist perspective which posits that public opinion equates simply to the thing that surveys measure. I develop this position by arguing that the normative argument concerning what public opinion *should* be can rest with the operationalist view that public opinion is what a survey measures. Indeed, the normative element is critical if the measurement techniques of public opinion are to be continually reviewed and improved upon in line with reflexive policy making. In this chapter I make the case that although there are evident and widely acknowledged limitations to any measurement of public opinion, there remains a role for the findings of such data collection exercises. Why should this be if the object of study eludes capture so effectively? It is, I argue, because the ‘object’ or ‘entity’ which policymakers and regulators call public opinion is both purposive and leads regulators to use it in a self-referential manner. Regulators use the concept of ‘public opinion’ to support a policy position and the act of collecting data and calling it ‘public opinion’ is

²⁴ Glynn et al 1999 op cit. at p.33.

taken as a given. A difficulty arises in that regulators agree that public opinion is an important input into the regulatory process, yet they admit it is also partial. It is argued in this thesis that regulators persist in using public opinion data in a way that does not belie their feelings that the data may not accurately represent the actual public opinion. If then there is a general consensus that public opinion is an artefact, it raises the question whether it should be renamed 'public opinion data' when referred in regulatory policy documents, and whether more circumspection should be used in discussion of public opinion data. However, this is a moot point as the thesis shows that public opinion carries agency and has an impact upon the regulatory system regardless of its potential lack of accurate reflection of the public's views. Is it more realistic to accept that regulators attempt to collate the most robust data on public opinion that they are able and that the data gathered retains a value in the regulatory process? Added to these thoughts, in relation to surveys per se, is that in this thesis the British Social Attitudes (BSA) Survey is analysed and the role of the survey is given a greater emphasis than, for example, the role of the focus group as a means to produce an indicator of public opinion. To reiterate, the survey data is being given a prominence in the thesis because it is being used as a comparator against which the data on public opinion which has been collected by the Independent Regulatory Agencies (IRAs) is compared.

This chapter consists of three sections: the first offers an overview of the theoretical understandings of what constitutes public opinion, the second examines how public opinion is measured, and the third explores whether there is a public opinion of genomics. In the first part there is recognition of the fact that the concept of public opinion is fluid and inherently dependant upon context. Additionally, it is important to delimit my line of study, because an analysis of public opinion could include references across disciplines and draw from inter alia, sociology, psychology and political science. Discussions of public opinion are found in many disciplines and it is unfortunate that intellectual travel between the disciplines is limited as there is much to be gained by the cross-over. I refer primarily to the socio-legal and political science literature to maintain the focus of the chapter.

As stated in Chapter 1, it is argued that, when faced with novel regulatory objects, there is an absence of categorical precedence which leaves regulators unable to draw upon policy learning as they do not have any experience in managing these technologies as

they have done in the past or in relation to a similar issue.²⁵ This argument is found in the policy rhetoric, and the concept of regulatory novelty and lack of categorical precedence is often cited as a major justification for the high levels of political attention devoted to genomics, and is often used as a reason for turning to the public opinion data. The idea is that the technological developments pose unique problems about which regulators cannot draw upon the rule learning of earlier decisions. Combined with the lack of rule learning is the fact that the technology is creating very critical social and ethical dilemmas and there are no frames of reference to be drawn upon. It is thus argued by regulators and policy makers that genomics needs novel and special regulatory handling as it is testing the cognitive limits of the existing regulatory structures. The powerful and emotive push for enhanced reference to public opinion in the regulation of genomics necessitates a study of the understandings of public opinion being utilised in the regulatory process.

In this thesis I contend that enhanced reference is given to the public opinion of genomics relative to other regulatory spheres, and that one of the driving forces for this is as a response to the absence of categorical precedence in this sphere. Lezaun and Soneryd discuss a 'new centrality of the public to science and technology policy' and argue that it has almost become a 'new orthodoxy'.²⁶ Indeed Lezaun et al extend this point by arguing that it is in the areas of science and technology policy in which innovative instruments of consultation are being developed while in other policy domains 'citizen engagement is waning'. In fact it is almost as if the call for increased public participation and recourse to public opinion data in genomics has taken on its own momentum.

²⁵ Felstiner, Abel & Sarat refer to the concept of the absence of categorical precedence as a generic term and not in connection with genomics. They are cited in Cobb & Ross 1997: TR doc

²⁶ Lezaun, Javier & Soneryd, Linda, 'Government by Elicitation: Engaging Stakeholders or Listening to the Idiots?' CARR Discussion Paper No: 34, May 2006 at p.1&2.

2.1 Understandings & Definitions of Public Opinion

This first section offers an overview of the most commonly held understandings of public opinion. The five definitions of public opinion outlined by Glynn, Herbst, O’Keefe and Shapiro²⁷ are utilised here as reference points in the mapping of the many interwoven and overlapping concepts of ‘public opinion’. The five understandings of public opinion are:

- (i) Public opinion is the aggregation of individual opinions
- (ii) Public opinion is the majority view
- (iii) Public opinion is the result of the channelling of the public voice by interest groups
- (iv) Public opinion is a construction created by elite groups and the media
- (v) Public opinion is a fiction as it is simply a construct.

The first definition is the classic and most commonly held view of public opinion: that it is the aggregation of individual opinions. It is due to such a view of public opinion that specific forms of public opinion apparatus, such as the survey, have arisen. Related and in many ways overlapping with this is the second view of public opinion which is that it is the reflection of majority beliefs. This interpretation is perhaps more a consequence of what occurs in the policy process as opposed to the result of an effort to delimit what public opinion is normatively. An additional element to understandings of majority opinion equating with public opinion stems from the argument that individuals do tend to conform and adhere to the majority opinion. Noelle-Neumann’s research has been influential in this area. Her thesis is that as individuals we will generally keep quiet if we hold a view that is widely divergent from our peers. An individual with an unpopular opinion has the choice to voice their own view with the risk that it will be tempered by the majority opinion or to fall into what Noelle-Neumann calls a ‘spiral of silence’. Noelle-Neumann contests that people do in general temper their views as a means of conformity.

²⁷ Glynn, Carroll J., Herbst, Susan, O’Keefe, Garrett J. & Shapiro, Robert Y. ‘Public Opinion’ Westview Press, 1999.

Noelle-Neumann researched elections and noted the phenomenon in which voters move to back the 'winning team' as the election draws closer. The critical factor at the heart of her theory of the 'spiral of silence' is individuals' perceptions of the distribution of public opinion. Noelle-Neumann contends that:

'.....people sense a climate of opinion without public opinion research, that they virtually have an 'opinion organ', capable of registering the most minute changes.'²⁸

This idea of the opinion organ may indeed be relevant to the regulators themselves in that they may refer to their own opinion organ and assume that this will filter any other public opinion data which crosses their path. There is limited research on the ways that people can sense the public mood, and importantly, what sources they use as a gauge of the majority opinion, whether derived predominantly from the media, peer groups or elite sources. What is evident is that people generally do wish to align their own views with those of their peers and do not wish to isolate themselves with an unpopular or unfashionable view.²⁹ This effect evidently plays a role in reinforcing the adherence of regulators to this understanding of public opinion. Whether this understanding of public opinion has a greater role than the other understandings of public opinion is examined in relation to the case-studies in Chapters 5 and 6.

The third definition of public opinion examines the cultivation of public opinion and the channelling and communication of the public voice by interest groups. It is the political parties, the trade organizations, the consumer groups and the single issue NGOs who lobby for regulatory change and have spokespeople who offer an articulation of the public voice. This articulation is often formulated so that a simplistic view of the issues is portrayed which aids the idea that one can take a particular side on an issue – the battle grounds are clearly defined. From this perspective, public opinion is understood to be more of a procedural issue as a force to be shaped, manipulated and directed with the view to a specific policy outcome which may or may not involve the mobilization of the public. Glynn et al highlight that underlying such a construction of public opinion is the assumption that interest groups are constantly engaged in the struggle to define

²⁸ Noelle-Neumann, Elisabeth, 'Public Opinion and the Classical Tradition: A Re-evaluation', *Public Opinion Quarterly*, 1979, pp.143-156 at p. 148.

²⁹ Noelle-Neumann 1979 *ibid.* at p.148

social problems and to provide solutions to them.³⁰ Tilly argues that evidence of collective action is best viewed as a complement to survey data in order to gain an understanding of the public's views and attitudes.³¹ This understanding of public opinion will be particularly pertinent with reference to the discussion of GM Foods in Chapter 5.

The fourth understanding is that public opinion is not an entity in its own right. It is not distinct from the media and elite projections of what public opinion is. Thus public opinion is viewed as a construct or simply a projection of the views held by journalists, politicians and other elites. Indeed the Liberal Democrat MP, Evan Harris subscribes to this view arguing that 'public consultation is essentially delegation to the views of the Daily Mail'.³² While this comment was made with tongue in cheek, readers of the populist press do make up a large sector of the public and it could be argued that many people make a decision on an issue as a result of something they read in the paper. The extent to which the media lead and define the issue is critical. Lippmann adheres to this idea that public opinion evolves from what we are told is the public opinion and as such may be driven by the media. Lippmann supports this argument by pointing out that it is not feasible for the average citizen to be au courant in relation to every issue in the public domain. Public opinion is thus viewed as a mechanism instituted by policy makers, regulators and politicians to overcome this, it is a 'symbolic phrase used by orators to make their own arguments'. Lippmann does not adhere to the deficit model; the reason he gives for the public's lack of knowledge and information is that they are time-poor.³³ The knowledge deficit model can be understood in terms of the strapline 'to know science is to love science' as it was traditionally believed by many policy makers that a greater knowledge of science and technology correlated with greater public acceptance of a novel technology. There is a difference to be drawn between the discussion pertaining to the factions constructing public opinion to serve their own

³⁰ Glynn et al 1999, pp.19-20.

³¹ Tilly, Charles, 'Speaking Your Mind Without Elections, Surveys or Social Movements', *Public Opinion Quarterly* Vol.47, pp.461-478 passim.

³² Evan Harris MP at Public Meeting – Manchester University BioLawConference, July 2008

³³ Lippmann, Walter, 'The Phantom Public' (New York: Harcourt, Brace and Company, 1925) cited in Glynn et al 1999 *ibid*.

purposes and Lippmann's argument that decision-making by elites will lead to more effective regulatory output. Lippmann strongly held that it was impracticable to place the private citizen in the role of the 'omnicompetent citizen' and he argues that the informing of decisions on social policy should come from specialists and not private citizens.³⁴

The fifth definition of public opinion offered by Glynn et al is that the whole notion of public opinion is a fiction. Advocates of such a view argue that the term 'public opinion' is nothing more than a rhetorical construct which is over-used by journalists and politicians without there being any substantive evidence to support their claims. Advocates of this view purport that political decisions will often be based upon weak survey data. An additional line of argument is that there is little correlation between survey respondents' opinions and their actual behaviour.³⁵ It is held that public opinion can be manufactured through rhetoric, and certainly surveys and polls can be designed in such a way as to draw out a certain response. A further issue is the epistemic divide which exists between politicians, regulators and the lay public. This is greater than differences in terminology and impacts upon the ways in which policy and regulatory processes function. These five understandings of public opinion act as a heuristic tool for analysis of the role of public opinion in relation to the case-studies in Chapters 5 and 6 where it will be seen that there is a great deal of movement between the understandings by the politicians and regulators.

2.2 Public Consultation Mechanisms & Representations of Public Opinion

We move now from theoretical understandings and definitions of public opinion which may offer the most commonly utilised or the most normatively desirable understanding of the term to the methods adopted by government agencies to extract this elusive entity. This section of the chapter provides an overview of the various engagement mechanisms utilised and highlights the specific mechanisms which have been used to gauge public opinion in the case-studies. The majority of data collected on public opinion is collected in accordance with the understanding of public opinion that views it

³⁴ Lippmann, Walter, 1925 *ibid*.

³⁵ On this point and the manipulation of survey design more generally, see further: Bertrand, Marianne & Mullainathan, Sendhil, 'Do People Mean What They Say? Implications for Subjective Survey Data.' Mimeo, University of Chicago, 2000.

as the aggregation of individuals' opinions. As such, it is predominantly survey data and attitude polls which are conducted. As already discussed above, while this thesis examines a number of methods used to collect data on public opinion, survey data is reviewed in greater depth because of the way the BSA survey data is being used here as a benchmark against which the data collected by the IRAs is reviewed. This is not to say that the BSA data is without limitations but that discrepancies which arise are of interest because they enable a review of the means of collecting data per se and of the inconsistencies of the whole premise that public opinion data can be collected by any of the mechanisms discussed here.

The positioning of the public, or rather data purporting to represent the public, in regulatory decision-making is central to this thesis. There are two principal stances in respect to the role of the public voice in regulatory decision making: firstly, there is the idea that increasing a public's familiarity with a technology or the ensuing product will make them more positive towards it; the second view is that since the public will be affected by the introduction of novel technologies then it should be the public who decide whether or not they should be readily available. In conjunction with these two standpoints is the continuum across which the amount of weight the public voice should or does have in regulatory process varies, with decisions being made by the elite at one end of the spectrum and regulation by referenda at the other.³⁶

There are limitations with all areas of data collection and public opinion data is no different. For instance, Zaller argues that 'attitudes' simply do not exist but that people make attitude reports or give 'survey responses'. This view rests upon the premise that individuals present a temporary attitude for the purposes of surveys and participatory processes.³⁷ Connecting Zaller's comments and the view of Lippmann that individuals do not have enough time to hold an informed view on every policy issue are the thoughts of Key. Key states that:

'The voice of the people is but an echo. The output of an echo chamber bears an inevitable and invariable relation to the input. As candidates and parties clamour for

³⁶ Gaskell et al (2010) Eurobarometer Report 73.1, op cit.

³⁷ Zaller, John R. 'The Nature and Origins of Mass Opinion', (Cambridge University Press, 1992), passim.

attention and vie for popular support, the people's verdict can be no more than a selective reflection from the alternatives and outlooks presented to them'.³⁸

Such a view does not negate the value of such data but its value must reflect an accurate understanding of what the data represents. Survey responses do function as indicators of current patterns, predicting trends and attitude changes. The central problem with survey data is the gap which exists between what it actually is and represents and the elevation of its status by policy makers. The argument put forward in this thesis is that rigorously collected survey data does indeed have a value as an input into the regulatory-policy arena, however, it loses its potency when it is held up as being truly representative of public opinion.

2.2.1 The mechanisms used to measure public opinion

Rowe and Frewer conducted a review of public engagement mechanisms and came up with no less than one hundred processes, techniques and tools used to elicit the public voice. The purpose of Rowe and Frewer's review was not to provide an exhaustive list of public engagement mechanisms but to highlight both the volume and the variety of the mechanisms available and as such they comment on the confusion created by the large array of options available.³⁹ This 'confusing plethora' of engagement mechanisms has arisen as a consequence of not only the uncertainty about how best to involve the public but additionally the increased drive for public involvement in the policy process per se.⁴⁰ Lezaun and Soneryd argue that the increased engagement of the public has become 'a veritable extractive industry' which attempts to increase the productivity of government.⁴¹

³⁸ Key Jr., V.O. 'The Responsible Electorate' (Cambridge, Mass.: Harvard University Press, 1966) at p.2 cited in Zaller 1992, *ibid.* at p.310.

³⁹ Rowe, Gene & Frewer, Lynn J. (2005) 'A Typology of Public Engagement Mechanisms' *Science, Technology & Human Values* 30, pp.251 at p.259.

⁴⁰ Rowe, Gene & Frewer, Lynn J. (2005) *supra.* at p.251-258 list of public engagement mechanisms is figure 2 at p.257.

⁴¹ Lezaun, Javier & Soneryd, Linda, 'Government by Elicitation: Engaging Stakeholders or Listening to the Idiots?' CARR Discussion Paper No:34, May 2006 at p2.

Rowe and Frewer introduce a typology of public engagement mechanisms by splitting public engagement into the three sub-groups: public communication; public consultation and public participation. An understanding of the varied public engagement mechanisms is useful here in order to understand the remit of the thesis and to ring-fence the field of study. Rowe and Frewer refer to an expansive definition of public participation which states that it is:

‘...the practice of involving members of the public in the agenda-setting, decision-making, and policy-forming activities of organisations/ institutions responsible for policy development.’⁴²

However, Rowe and Frewer criticise this definition as being too broad and therefore open to different interpretations because the public may be involved in various ways and at various levels. This is thus the motivation for Rowe and Frewer’s division of the mechanisms into three subgroups where the mechanisms are viewed in terms of the flows of information between the sponsor and the public participants. The sponsor is the initiator of the engagement initiative which is in most cases a governmental or regulatory agency. To turn to the three groups in turn: *public communication* refers to initiatives where information flows in a one-way direction from the sponsors of the exercise to the public representatives, and where there is no requirement for information to be fed back to the public. The second classification is *public consultation* where information flows in the opposite direction in that it is from the public representatives to the sponsor as a consequence of an initiative being set up by the sponsor. In these instances, ‘[t]he information elicited from the public is believed to represent currently held opinions on the topic in question’.⁴³ Thirdly, there is *public participation* where information flows both ways between the public representatives and the sponsor. Rowe and Frewer state that in such circumstances, ‘rather than simple, raw opinions being conveyed to the sponsors, the act of dialogue and negotiation serves to transform opinions in the member of both parties (sponsor and public participants).’⁴⁴ The classification system offered by Rowe and Frewer highlights the level of passivity or activity of the public representatives in the process of engagement.

⁴² Rowe and Frewer (2005) supra. at p.253.

⁴³ Rowe and Frewer (2005) ibid at p. 255.

⁴⁴ Rowe and Frewer (2005) ibid. at p.255-256.

Rowe and Frewer stress that the choice of public engagement mechanism necessitates a balance between the aims of the mechanism and the criteria for effectiveness.⁴⁵ A salient point is that despite the vast range of engagement mechanisms, there is no clear theory as to which would be the best mechanism to choose in any given circumstance. Different mechanisms inevitably lead to different types of data findings with varying strengths and limitations. It seems lacking that no substantive study has been undertaken of the application of such mechanisms in order to enhance functionality and simultaneously aid policy makers in their selection.

For the purposes of this thesis, of the three groupings of public engagement mechanisms, the focus will be public consultation as these types reflect the relevant data sources in the case-studies. Rowe and Frewer provide a further breakdown of the engagement types and the relevant sections relating to public consultation can be viewed in figure 1. Against the consultation type I have added the data sources being studied in the thesis case-studies in Chapters 5 and 6.

Figure1: Types of public consultation mechanism and corresponding data sources analysed in the thesis⁴⁶

Example of Consultation type	Characteristic	Description	Specific Data Source relating to the Thesis Case-Studies
Opinion poll Referendum Survey Telepolling/ voting	Controlled selection No facilitated elicitation Closed response mode Non-face-to-face Structured aggregation	These mechanisms are essentially highly controlled ways of acquiring answers to specific questions from large samples. Quantity is more important than quality (there is no facilitation of the elicitation process, responses are closed/limited and there is no FTF interaction).	Eurobarometer Food Standard Agency Consumer Attitude Survey (CAS) British Social Attitude Survey (BSA)
Consultation document	Controlled selection	Aims to attain open responses on a significant issue. The typical mechanism is the	Human Fertilisation and Embryology Authority and Human Genetics

⁴⁵ Rowe and Frewer (2005) *ibid.* at p. 256.

⁴⁶ This table is a copy of the typology by Rowe & Frewer *ibid.* table 3 at p.278-281 with an additional column for the thesis areas of study.

	<p>No facilitated elicitation</p> <p>Open response mode</p> <p>Non-face-to-face</p> <p>Unstructured aggregation</p>	<p>consultation – in which a document is sent to a list of potentially interested people (often representatives of interest groups and other organisations) with limited time available for open commentary. Potentially, non-selected others may contribute but may find it difficult to do so if they are outside of the information loop.</p>	<p>Commission consultations</p>
<p>Electronic consultation (interactive web site)</p>	<p>Uncontrolled selection</p> <p>No facilitated elicitation</p> <p>Open response mode</p> <p>Non-face-to-face</p> <p>Unstructured aggregation</p>	<p>As type 2, but with uncontrolled selection. Some local authorities in the UK have internet sites inviting e-mail messages from citizens on particular local issues or service matters.</p>	<p>Human Fertilisation and Embryology Authority and Human Genetics Commission consultations</p> <p>GM Nation? Debate</p>
<p>Focus Group</p>	<p>Controlled selection</p> <p>Facilitated elicitation</p> <p>Open response mode</p> <p>Face-to-face</p> <p>Unstructured aggregation</p>	<p>This type of consultation emphasises quality of information over quantity, with effort expended to facilitate the information elicited with FTF interaction. It is typified by the focus group, which may involve as many as a dozen people facilitated in discussion of a general issue. Because there is no significant sponsor information, this may be seen as a consultation rather than participation mechanism.</p>	<p>GM Nation? Debate</p> <p>British Social Attitudes Survey (BSA)</p>

The data sources being analysed as gauges of public opinion in the regulatory system in this thesis are: British Social Attitudes Survey (BSA), Eurobarometer, HFEA and HGC consultation exercises, the Food Standards Agency Consumer Attitude Survey (CAS), and the GM Nation? debate. The HFEA and HGC consultations are examined in terms of both the submissions themselves to the consultation, the reported findings and the outcome documents. The stages of the analysis shed light on the empirical bases given

for the statements made in the final document and subsequently its use in the regulation of PGD. For the remaining sources: Eurobarometer, the GM Nation? debate and the FSA's CAS survey, these are analysed from their published results. As such, the British Social Attitude survey data is being used as a type of gauge by which to assess the other sources. It is not claimed that the BSA survey is more representative, rather that discrepancies and alignment of sources will illustrate the role public opinion data has in the regulatory process. Although it should be remembered that Sturgis et al have made the claim that the BSA survey data is more robust than any data collected by an IRA on the same subject area of genomics.⁴⁷

While the GM nation? debate included open meetings, an interactive website and focus groups which by virtue of the open meetings extends beyond public consultation to include an element of public communication, I am focussing on the public consultation relating to GM foods. For the purposes of this study, despite the fact that some of the BSA survey collection is carried out face to face, I have placed it in consultation type 1 as it does not in any other way meet the criteria for participation.

2.2.2 Surveys & Consultation Exercises as Measurements of Public Opinion

'One should carefully distinguish between public opinion and published opinion. The two can be very different from each other'. (Noelle-Neumann 1979)⁴⁸

As the principal source of public opinion data referred to in the thesis, it is pertinent to discuss some of the criticisms and limitations of survey data as a representation of public opinion. Bourdieu highlights a number of the problems with survey data and one of the points he stresses is the ways in which data findings are simplified as absolute statements and then fed into the policy process. This process gives the output of survey data a very black and white feel in reports which state that 'the public like x' or 'the public are anxious about x'. An example of this would be the use of the 1996 Eurobarometer finding that one third of the UK public believe that non-genetically modified tomatoes do not contain genes, a statement which can be found in a report

⁴⁷ Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, 'Genomic Science: Emerging Public Opinion', From Park, A., Curtice, J., Thomson, K., Bromley, C. and Phillips, M. (Eds) (2004), British Social Attitudes – the 21st Report, London: Sage at p. 121.

⁴⁸ Noelle – Neumann, Elisabeth, 'Public Opinion and the Classical Tradition: A Re-evaluation', Public Opinion Quarterly, 1979 pp. 143-157, at p.153

commissioned by the Human Genetics Commission. The summary of the data which includes the infamous tomato statistic states that there has been:

‘Improved knowledge of DNA and genes over the past 10 years, but this is still minimal. The GM food debate seems only to have confused the issue (i.e. possession of genes), although publicity surrounding the Human Genome Project should hopefully have corrected misunderstandings about this. Genes are still seen more as vague inheritable concept than solid physical entities.’⁴⁹

Bourdieu contests that reducing survey data to such a level removes the validity of the findings. He states that:

‘A rigorous interpretation of opinion polls would require an epistemological examination of each of the questions asked, plus, concerning the system of the questions, an analysis of the whole system of answers which together would be the only way to know what questions the people thought they were answering’.⁵⁰

Further, Bourdieu argues that even in cases where enormous care is taken to design and undertake meaningful surveys, the complexity of the results almost negates the effort and that no clear public opinion is discernable from them. I contend in this thesis that while the findings of surveys are not a true representation of public opinion, it remains a representation of something and it retains a level of significance in the regulatory policy process. It is a case of establishing what this is and what value it has in the policy process. This view does not negate my opinion that regulatory bodies should continue to strive to improve their engagement processes. While an alethic representation of public opinion is unrealistic, significant procedural improvements can be achieved.

Blumer stated in 1948 in his seminal paper that public opinion polling does not succeed in isolating public opinion as a generic object of study.⁵¹ Blumer criticises what he describes as the very narrow operationalist view that public opinion consists of what

⁴⁹ Voss, Georgina, ‘Report to the Human Genetics Commission on Public Attitudes to the Uses of Human Genetics Information’ September 2000.

⁵⁰ Bourdieu, Pierre, ‘Public Opinion Does Not Exist’, in Armand Matterlart and Seth Siegerlaub, eds, ‘Communication and Class Struggle’ (New York: International General, 1979) pp.124-130 at p? cited in Glynn et al 1999 *ibid.* at p.24.

⁵¹ Blumer, Herbert, ‘Public Opinion and Public Opinion Polling’, *American Sociological Review*, Vol. 13, No. 5, (Oct. 1948), pp.542-549 *passim*.

public opinion polls measure.⁵² I am in agreement with Blumer on this point and would like to argue that in response there are two options: to delineate what public opinion is and to establish a means of measuring it, or to reclassify this thing that is captured by the subjectifying technologies. 'Subjectifying technologies' is a term employed by Rose to mean the devices which function to enfranchise the public and are the measures of the understandings and opinions of the public.⁵³ Interestingly Rose views deliberative processes such as surveys as providing a reciprocal link between authorities and subjects.⁵⁴ The technologies are certainly, in Blumer's view, part of the cause of the conflation problem, that is, that people infer that the outcome of the collection process constitutes public opinion. Arguably this is the reason why the most commonly used definition of public opinion is the aggregation of individual opinions because it stems from the popularity of election polls. Blumer argues that researchers should start by characterising the object of study and that devices such as surveys and opinion polls can serve a purpose when used as part of the study of public opinion.

Blumer rails strongly against the commonly held view that the aggregation of individual opinions equates to public opinion. He contests that the formation of public opinion occurs in large measure as a consequence of interactions in groups and not through the interaction of disparate individuals. Blumer criticises the representational value of opinion polls in which all responses are recorded equally because, as he highlights, in society citizens are not equal.⁵⁵ It is on the grounds of equality that Blumer thus states that polls do offer a representation of the vox populi. How do we tease out the value of survey data from this? In terms of equality and seeking to gauge what individuals think about genomics, there is a measure of validity only if we disagree with Zaller's thoughts that individuals are not giving their honest opinion but providing 'survey responses on the basis of momentarily salient considerations'.⁵⁶

⁵² Blumer, 1948, *ibid.* at p.543.

⁵³ Rose 1996, cited by Hill & Michael 1998 *op cit.*

⁵⁴ Rose, 1996 at p.165 cited by Hill & Michael 1998 *ibid.* at p.204.

⁵⁵ Blumer 1948 *op cit.* at p.548.

⁵⁶ Zaller, John R. 'The Nature and Origins of Mass Opinion', (Cambridge University Press, 1992), p.118.

To clarify, this is a two stage process: there are the limitations surrounding what is actually being recorded, collected and collated by the survey and secondly, there is the manipulation of this data by the regulatory or policy agencies in order for it to become 'functional'. With regards to the manipulation of the data, all the regulators interviewed for this thesis were very keen to improve the robust nature of the data they use. Thus this process is not one where overt or conscious distortion is taking place by regulators, it is rather that the data has a purpose which requires that it is digested into a policy document or part of a regulatory decision-making process, and since data is often contradictory and untidy in its outcomes, it is not always easy for this to be achieved. It should be stressed here that the business of survey data analysis has a long history and this thesis is not an attempt to unduly criticise regulatory agencies who do employ the most sophisticated techniques available, however I contest that something is going wrong in the conveyance of this data both within the regulatory process and back to the public per se. The question of whether the publication of opinion data has an impact on the public is disputed by Noelle-Neumann who instead argues that individuals are perceptive and sensitive to the climate of opinion.⁵⁷

The process of analysis of survey data involves looking at four variables: the direction, intensity, stability and the information content of the opinion.⁵⁸ The resulting findings of these four measures are critical factors in the robustness of the findings and output. To take the first of these, the direction of the opinion, whether people are for or against or indeed ambivalent about something produces many of the statements that Bourdieu would have decried. To make a claim more substantive one needs to entwine these four measures so, for example, a measure of the intensity of feeling for or against an issue will make a statistic more reliable. The power inherent in this is sometimes quite startling, for it is argued that when there is no particularly intense public mood on an issue this can be taken as permissive of the regulators' or policy-makers' actions.⁵⁹ This idea is explored in relation to the two case-studies. Intensity of opinion is very interesting in cases where a very vocal minority has greater political weight than an

⁵⁷ Noelle-Neumann 1979 op cit. at p.147-148.

⁵⁸ Glynn et al 1999 op. cit. at p.26-7

⁵⁹ Reference to Glynn et al op cit. at p. 26-27 and Hood, Christopher, Rothstein, Henry & Baldwin, Robert, 'The Government of Risk: Understanding Risk Regulation Regimes', Oxford University Press, 2001.

apathetic or ambivalent majority. It is difficult to see how this would be reflected or indeed picked up in a survey as the minority view may be identified but the level of influence would require a different method to track. While random selection may appear a better means to achieve an overview it may be that the sample of respondents fall into one or two overriding social classes or age-groups. Systematic selection may be more appropriate, but this can be hampered by a lack of response from certain sections of society and is no guarantee that people will participate. Blumer calls for a model which could 'allow the development of a realistic method of sampling in place of what seems...to be the highly artificial method of sampling used in current public opinion polling'.⁶⁰

In the case-study chapters cases will be shown where the public are invited to respond electronically. These initiatives are not generally successful either due to a lack of interest from the general public in responding or because it appears that it is only the views of stakeholders which are being sought. More generally, such sampling issues relate to representative democratic principles and to the balancing of interests within a democracy. This raises the question as to whether much effort is made by policy makers and regulators in the identification of a silent, passive majority. Indeed it seems likely that, as has already been established, this silence causes regulators no problems and thus they are left to interpret it as meets their own political ends. In contrast to this Lezaun and Soneryd argue that in some instances the reticent publics and 'hard to hear' constituencies are the very ones who are being targeted for their opinions in an attempt to broaden participation.⁶¹ Indeed Lezaun and Soneryd ascertain that another way to refer to the general public is as the silent majority and they present an image of a much divided terrain where on the one hand there are the stakeholders and on the other are the general public.⁶² A quick aside here relates to the application of problems such as silent majorities and stakeholder hijack and asks whether their existence is less likely in relation to survey data collection. These issues will be addressed in the case-study

⁶⁰ Blumer 1948 op cit. at pp.548-9.

⁶¹ Lezaun, Javier & Soneryd, Linda, 'Government by Elicitation: Engaging Stakeholders or Listening to the Idiots?' CARR Discussion Paper No:34, May 2006 at p3.

⁶² Lezaun & Soneryd 2006, op cit. at p. 8.

chapters because it is clear that what is portrayed as the ‘public opinion’ in regulatory-policy documents is in many cases a reflection of stakeholder views.

The third variable is stability which relates to the consistency of measures of public opinion over time. Evidently, one must classify the time period considered appropriate in order to argue that a mood is stable or consistent. Stability is deemed important to policy making as it is widely held that a stable mood is more representative of public feeling on the grounds that it is a reflection of a more measured attitude and not of a ‘capricious’ survey response. However, Glynn et al highlight that just because a mood is fickle or dynamic does not mean that policy makers do not respond to it. The example Glynn et al raise relates to the death penalty in the USA where over a period of time corresponding to public opinion, the death penalty was abolished and then reinstated.⁶³

The final variable of public opinion is information content, which refers to how well informed members of the public are, and this is a thorny issue for regulators. It is an area which has been neglected and it is generally the case that the very sparse results of surveys are published with no mention of the underlying knowledge or understanding of the survey respondents. Furthermore the level of informed response is extremely pertinent in relation to public attitude to genomics because it raises the question of how realistic is it to expect the public to keep up with the rapidly moving technological developments in genomics. A number of studies have attempted to link knowledge levels and attitudes to genomics and these are discussed further in the second section of this chapter. This issue will be examined in relation to the case-studies in Chapters 5 and 6.

Normatively one would assume that survey responses from an informed public would be more valuable than those from individuals who do not grasp the issues at question. However if there are high levels of non responses or ‘don’t knows’ then these should be valued as important indicators of public opinion. As already highlighted, it is my belief that there are cases where the data shows that the public is uninformed, yet the findings have persisted in shaping regulatory output. Glynn et al conclude, however, that an informed public opinion is likely to have a greater influence over policy than an

⁶³ Glynn et al 1999 op cit. at p.27 cite Corbett, Michael on this point from ‘American Public Opinion Trends’ (New York: International General, 1979) pp.14-130.

uninformed one.⁶⁴ Does this however simply reflect the involvement of the concerned public or stakeholders, those with a vested interest in the policy direction of a particular issue, who ensure that their views are heard? Information content is an issue which has been explored in the interviews with the regulators and their comments are discussed in subsequent chapters.

In summary then this thesis has to wrestle with two issues: the definition of public opinion and the value of the various measurement devices or subjectifying technologies available, principally in the case of survey data. The operationalist definition that public opinion is simply whatever public opinion surveys measure has been discussed. This seems to be coming at the problem the wrong way in that we should perhaps rename the findings of the subjectifying technologies and attempt to draw some analyses about the perceived gap that exists between the results from these mechanisms and what can be delimited as public opinion.

Glynn et al conclude critically that ‘the meaning of public opinion is always in flux, depending upon the context in which the term is used’.⁶⁵ This is in line with Habermas who contends that the meaning of public opinion shifts over time. The evolutionary and fluid nature of public opinion is due to it being tied to broader political and social arena that Habermas terms the ‘public sphere’. To give an illustration of this, the idea of public opinion in nineteenth century Britain would be that of a group of men, since women were entirely excluded from such. With the changing public sphere, the voices of women were added to the mix.

In terms of adopting a single understanding of ‘public opinion’, not only are there different views on what constitutes public opinion, but also the understandings change according to context. The question raised is whether it is possible to weave a way through the tangle of these overlapping and competing conceptions of what public opinion means. While it is difficult to ring-fence and unpick the public opinion data pertaining to the case-studies here, it is evidently a useful exercise if it can enlighten us as to the representativeness of such data. Further to this, whatever the level of representativeness of public opinion, the analysis of the role the data has played in the

⁶⁴ Glynn et al 1999 op cit. at p,27

⁶⁵ Glynn et al 1999 op cit. at p.33.

regulatory process is paramount. Gaskell et al point out that ‘Survey results do not have a single, obvious and unequivocal meaning. Whether the glass is half full or half empty is a matter of personal preference.’⁶⁶ This is a salient point in terms of the interpretation, potential for bias and presentation of public opinion data by regulators.

2.3 Public Opinion of Genomics

The first part of this chapter outlined the definitions of public opinion, ranging from the most commonly utilised understanding to discussion of the normative parameters of such a concept. The chapter subsequently explored the variety of ways that public opinion data is gathered, with a focus on the role of the survey. In this final section of the chapter an examination is undertaken of whether there is a measurable public opinion of genomics. The response to this question is not straightforward because although it is argued that public opinion data is not representative, public opinion data collection continues in spite of this. This position leads us to ask: what does this mean in terms of the data and its processing in the context of genomics? Underlying the debate will be a study of whether there are idiosyncrasies in the measurement of opinions of genomics, either resulting from the inherent nature of the subject of genomics per se or as a consequence of special measurement techniques being applied to this case (techniques which are looked at in the next section). Following this, some of the principal sources of public opinion data on genomics are examined, giving an insight into the machinations of the data collection process. It is also necessary to examine the motivations behind the collection of such a vast quantity of data and to critique the lack of coherence in the collection. Running through this chapter and the thesis as a whole are thoughts relating to the different publics referred to in the data collection process and how these are married to the concept of public opinion.

⁶⁶ Eurobarometer Report by Gaskell, George, Stares, Sally, Allansdottir, Agnes, Allum, Nick, Castro, Paula, Esmer, Yilmaz, Fischler, Claude, Jackson, Jonathan, Kronberger, Nicole, Hampel, Jurgen, Mejlgaard, Niels, Quitanilha, Alex, Rammer, Andu, Reveulta, Gemma, Stoneman, Paul, Torgersen, Helge, Wagner, Wolfgang, ‘Europeans and Biotechnology 2010: Winds of Change’, European Commission, DGR 2010 at p.12.

2.3.1 Different Publics

‘From the public’s perspective, scientific research might make products available that could have important impacts on society. It is not surprising, therefore, that all parties involved – including scientists, legislators, physicians and ethicists – are quick to make assertions of what the public believes about genetics.’(Condit 2001⁶⁷)

Condit’s comment highlights the problem of multiple parties wishing to use public opinion data in ways which suit their own personal needs and wants. There is clearly a strong motivation for some parties to hail public opinion as supportive of the introduction of new products; be it a genetically modified tomato or a new prenatal test for a genetic condition. Evidently this use of public opinion is one of the drivers for the collection of data on public views in the first instance. However, this then raises the question of whether the commissioners of this process are expecting the results they need. It would be inaccurate to argue that regulators are uniformly dismissive of the public and, as will be shown in the interviews I carried out and equally in the investment of resources in data collection, there is clear evidence of the pursuit of robust data. This does not, however, negate the point that regulatory agencies have a remit and in genomics, their remit is generally permissive or supportive of the novel products and not prohibitive. IRAs need to retain and sometimes work to enlarge their remit of mandate in order to remain viable. Consequently they will want public opinion data which shows support of or at least reduced anxiety surrounding a product. There is an added procedural element to this in that IRAs are requested to act in conjunction with the Government’s guidelines set out in the code of practice on consultation.⁶⁸ While this is not a legally binding document a number of government agencies have signed up to the code; these include the Food Standards Agency (FSA), the Department of Health and the Department of Food and Rural Affairs (Defra). In addition to the code of practice on consultation there are requirements under some laws for the Government to consult certain groups on particular issues.

Hill and Michael contend that ‘the tacit recognition of the public entails a slippage between two facets of the public (qua consumer or qua citizen) which enables a

⁶⁷ Condit, Celeste, ‘What is ‘public opinion’ about genetics? *Nature Reviews, Genetics*, vol.2, Oct. 2001, pp.811-815 at p.811.

⁶⁸ HM Government Code of Practice on Consultation has been in place since 2000 and sets out seven consultation criteria.

particular, relatively positive, vision of biotechnology'.⁶⁹ Hill and Michael argue further that data on attitudes to biotechnology from Eurobarometer highlights a particular construction of the public by EU regulators which conflates the 'citizen' with the 'consumer'. The construction of the public as a consumer by regulators runs through both case-studies in this paper and its role in setting and closing issue attention cycles is critical. Hill and Michael advocate that the specific construction of the public through data manipulation by the EU produces a measure of public attitude which is very pro-biotechnology. When examining surveys, Hill and Michael have looked at the 'target' of the survey with an eye on the manipulation of survey questions to engender a specific response in the participant. Thus Hill and Michael argue the survey participant will be encouraged by the survey design to think as either a consumer or a citizen and each self-representation will bring about a different response.⁷⁰

Over the course of the thesis the idea of a public opinion will be opened up and in doing so the various roles an individual plays as a member of the public are explored, from consumer to patient to service-user, to the 'man on the street'. These are seen as separate to the idea that an individual who is a scientist or clinician is equally a member of the public. The relationship between and value given to the expert and layperson is looked at in more detail later in the chapter and throughout the thesis as I attempt to identify which party holds more sway in regulatory-policy decision making.

2.3.2 An overview of the features of public opinion in relation to genomics

This part of the chapter opens with a further look at the four variables commonly used in the analysis public opinion data: direction, intensity, stability and information content.⁷¹ These four factors will be discussed in relation to the measurement of public opinion of genomics to help draw out the specific features and limitations of the gauging of a public opinion of genomics.

⁶⁹ Hill, Alison & Michael, Mike, 'Engineering Acceptance: Representations of 'The Public' in Debates on Biotechnology', Chpt. 12 in Wheale, von Schomberg & Glasner (Editors), 'The Social Management of Genetic Engineering' (Ashgate Publishing Ltd. 1998) p.201.

⁷⁰ See further: Hill & Michael 1998 *ibid*.

⁷¹ Glynn et al, *op cit*. at p.26-7.

Sturgis and Allum's review of the surveys carried out between 1980 and 2006 on the public opinion of biomedical science provides a very clear impression of the huge volume of survey data being collected. Within the parameters of their meta-analysis which dictated that only national or international sample surveys that included measures of knowledge, interest and attitudes about biomedical science were considered, they managed to amass a cache of 136 surveys.⁷² It would be impossible to accurately measure the number of additional surveys that have proliferated over the past few decades in this field as the number has been astronomical. Linked to this has been the rise in the commercial side of data collection, and it is common for regulatory agencies to outsource and to commission a survey from specialist public opinion data collection companies.

(i) Direction

As regards the direction of public opinion towards genomics it is first important to ask whether the public hold a uniform opinion of all applications of genomics. Most people respond differently to the different applications of genomic science and technology. There is a divergence between the public's opinion of the biomedical and the agricultural applications of genomics. In simplistic and generalised terms, there is cautious support for the medical applications of genetics such as genetic testing of adults; by contrast there is very strong opposition to human cloning, gene therapy and xenotransplantation. As regards public opinion towards GM foods, it will be shown in Chapter 5 that while there have been times of extreme opposition, public opinion is less polarised in recent times. This distinction runs deeper, meaning that people will be more favourable, for example, towards prenatal testing and a selective abortion in the case of a serious genetic condition such as Tay-Sachs disease but disapprove of this for sex selection.⁷³

It is necessary to break down the data findings and a fascinating result can be found in the Eurobarometer 2010. In this survey questions were introduced relating to cisgenic and transgenic apples. These techniques were introduced to the respondent in the

⁷² Sturgis, Patrick and Allum, Nick, 'A Literature Review of Research Conducted on Public Interest, Knowledge and Attitudes to Biomedical Science', August 2006, The Wellcome Trust.

⁷³ Condit 2001, op cit. at p.812. In support of her argument, Condit cites 'Singer, Corning & Lamias, 'The Polls – trends; Genetic Testing, Engineering and Therapy. Publ. Opin. Quart. Vol. 62, 633-664 (1998).

survey as a similar process to that of genetic modification. The following introductions were used, the first for GM and the second for the transgenic, cisgenic questions:

‘Let’s speak now about genetically modified (GM) food made from plants or micro-organisms that have been changed by altering their genes. For example a plant might have its genes modified to make it resistant to a particular plant disease, to improve its food quality or to help it grow faster’.

‘Some European researchers think there are new ways of controlling common diseases in apples - things like scab and mildew. There are two new ways of doing this. Both mean that the apples could be grown with limited use of pesticides, and so pesticide residues on the apples would be minimal. The first way is to artificially introduce a resistance gene from another species such as a bacterium or animal into an apple tree to make it resistant to mildew and scab.....The second way is to artificially introduce a gene that exists naturally in wild/crab apples which provides resistance to mildew and scab.’⁷⁴

This apparent anomaly will be looked at in greater detail in Chapter 6, however it is interesting to note that in the Eurobarometer survey, 27% of respondents held GM food to be safe while the corresponding results were 37% for transgenic (the first example) and 53% for cisgenic (the second example). Also worthy of note are the responses for whether the practices were deemed ‘unnatural’, which 76% deemed GM foods to be and 78% for transgenic apples and 57% for cisgenic apples. This last result highlights how crude survey data output is, in that such survey style statements report that 33% of the European public support transgenic apples yet the data has been published with the ‘don’t know’ responses excluded.⁷⁵ While the report is transparent about this, it is common for such blunt statements to be reproduced in the media and in regulatory-policy documents without attention drawn to this fact. Clearly this example shows that survey respondents can be led by the phrasing and framing of survey questions.

In order to assess the direction of public opinion of genomics, it is necessary to compare relevant opinion data with that relating to other modern technological developments. In doing so one can assess whether the public are simply anxious about novelty. The Eurobarometer 2010 report states that 53% of the public think that biotechnology will

⁷⁴ Eurobarometer 2010 Report by Gaskell et al, op cit. at pages 36 and 47.

⁷⁵ Eurobarometer 2010 Report by Gaskell et al, op cit. at p.50.

have a 'positive effect' on our way of life in the next 20 years; 7% responded 'no effect', 20% think it will have a 'negative effect' and a further 20% answered 'don't know'. The report compares the results for seven technologies: solar energy with extremely positive responses: 87% responding that it will have a positive effect and the least popular being nuclear energy with a corresponding 39%. Biotechnology ranked fourth of the seven technologies listed but the responses to biotechnology are almost evenly balanced between the positive effect responses and the combined no effect, negative effect and 'don't know'.⁷⁶ Condit points out that there is not a uniform negativity to new technologies but that genetic technologies do receive less support from the public than other technologies and that the responses are more polarised.⁷⁷

Gaskell et al discuss the concept of a habituation effect in relation to public perceptions of biotechnology whereby the 'novel of the past becomes the taken-for-granted of the present'.⁷⁸ As an aside however, it is evident that this type of effect is not relevant to the case of nuclear energy which has equal numbers of people for it as against in the 2010 Eurobarometer Report.⁷⁹ In terms of any habituation effect in relation to biotechnology, the same report shows that the trend for optimism towards biotechnology in the UK from 1991 to 2010 has been quite unpredictable and irregular. In order to show the irregularities I have analysed the relevant data from the Eurobarometer report 2010 below.

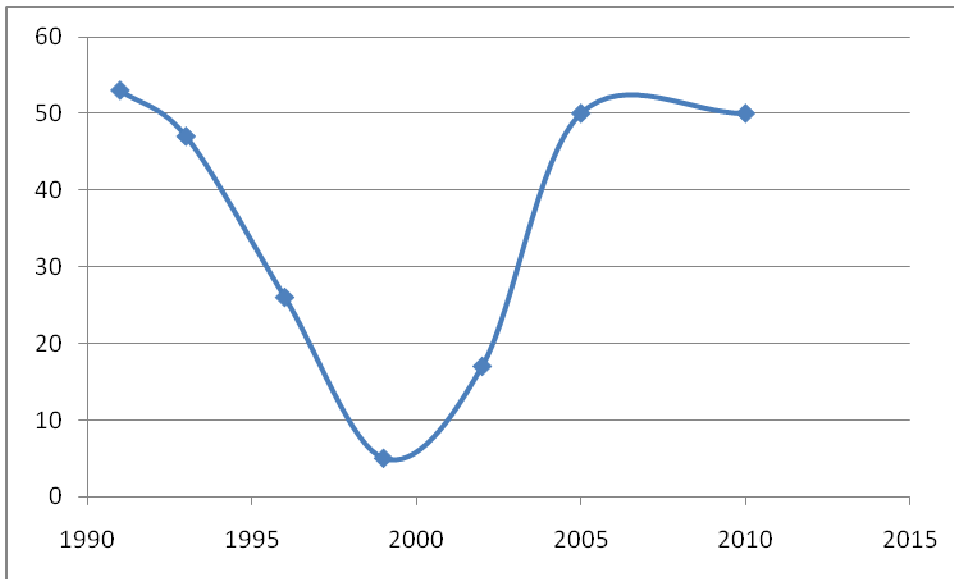
⁷⁶ Eurobarometer Report by Gaskell et al (2010) at p. 16.

⁷⁷ Condit, Celeste, 'What is 'public opinion' about genetics?' Nature Reviews Genetics Vol.2, October 2001, pp.811-815 at p. 812.

⁷⁸ Eurobarometer Report by Gaskell et al (2010) at p.13.

⁷⁹ Eurobarometer Report by Gaskell et al (2010) at p.16.

Figure 2: Trends in optimism for biotechnology in the UK



While the lowest point for public optimism in biotechnology is consistent across the European states, the UK is not in line with the rest of the European states in the period since 2005 where there has been a marked decrease in the levels of optimism.

(ii) Intensity

Examples of an intense public mood would be public protests and the boycotting of products and companies. However, in terms of measuring the intensity of public opinion through survey data, indicators are more subtle and will range from the numbers of ‘don’t knows’ expressed and the polarisation of opinion. The ‘don’t know’ responses may be high as a result of public apathy, lack of interest in either the subject and/or the survey per se, confusion, or lack of knowledge about the subject of the survey. In terms of interest in genomics, the 2003 BSA highlights that half of all people surveyed in Britain described themselves as being ‘not very’ or ‘not at all’ interested in modern genetic science’.⁸⁰ In the chapter on GM food, a discussion will be had surrounding the levels of polarisation of views relating to GM and it will be asked whether increased polarisation correlates with contentious issues; has the confusion over the scientific arguments led people to more readily take sides on the issue?

In the case of genomics, the public referred to in regulatory debate are often patients or consumers. Thus should we only consider the public attitude at the point of a choice

⁸⁰ Sturgis and Allum 2006 op cit. at p.12.

regarding whether to take up the outputs of genomics? I believe that there exists a pragmatic or utilitarian attitude to the embracing of knowledge on a 'need to know' basis because, as Lippmann argues, we cannot as individuals have extensive knowledge on all areas of policy. There is a distinction to be made between the public and the individuals utilising the technology. There is a strong difference between the abstract situation where an individual is asked in a survey whether there should be strict laws to regulate xenotransplantation and the reality when an individual is seriously unwell and the use of this application may save their life. This distinction is related to the gap which is often commented on between what people say in surveys and their actual behaviour.

(iii) Stability

Regulators respond more easily to survey data which shows stability over time. Volatility however may also be useful if there is an obvious trigger for the changes such as a regulatory change, heightened media coverage, a food or health scare relevant to the survey subject. In the case-study chapters I will ask whether regulators are taking account of stability or changeability of public opinion over time. It makes sense to presuppose that for regulation to successfully respond to public opinion a stable public opinion is important.

At the heart of the drive to collect data pertaining to the public's views on genomics is a critical lack of coherence both across and within organisations. This leads, for example, to the limitations in analysis resulting from a lack of data which would enable a researcher to conduct a longitudinal study from one consistent data source. For example in the cache of questions devoted to genomics in the BSA survey those on prenatal testing were only asked in 1998, 2000 and 2003 and those relating to GM foods in 1999 and 2003. Additionally the questions posed were not always duplicated.

Sturgis and Allum comment on this thus:

'While it is likely that the current mix of ad hoc initiatives and recurrent Eurobarometer modules will continue to provide an insight into public opinion toward biomedical science for the foreseeable future, by its very nature this form of evidence is partial. Lacking core funding and a clear a priori research agenda in the medium to long term, the content and timing of initiatives is likely to remain sporadic and irregular'.⁸¹

⁸¹ Sturgis and Allum 2006, op cit. at p.3.

(iv) Information Content

The questions I wish to address in this section and across the thesis as a whole are:

Does informed opinion carry more weight in the regulatory-policy arena?

Does greater knowledge of a technology lead to a more positive view?

The idea of ‘public understanding’ of science and technology gives the impression that a person either has a level of knowledge about science and technology or not. From the outset, it is critical to move away from this mode of thinking. As Sturgis et al highlight, there is no arbitrary threshold which signals understanding.⁸² Any such demarcations are the constructs of the social scientist or regulator. As a general rule, levels of scientific literacy amongst the public are often considered by researchers and policy makers alike as being surprisingly low.

Surveys can show inter alia how well a respondent fares in a quiz on genetics or whether the respondent has a degree in science and this data is useful relative to the representativeness of the sample. However, the point where survey respondents are deemed knowledgeable is subjective: be that as a crude measure such as whether respondents attain a certain number of correct answers in a quiz or a more sophisticated measure. Durant et al have been trying to ascertain knowledge levels not only on a factual level but additionally the underlying ‘processes of scientific inquiry’. From their research they conclude that there is a positive correlation between the level of scientific understanding and the self-reported interest in science.⁸³

The example of Durant et al is but one example of the attempts by survey practitioners to strive for increasingly sophisticated techniques in the drive for that ever more representative sample of public opinion and the public’s understanding of science (PUS). The collection of public opinion data is not only big business, it is highly evolved. The question of whether respondents are knowledgeable about science continues to be strongly contested and while survey techniques are elaborated to include more sophisticated measures and variables there is an additional argument; that there is a strong value to lay opinion. Wynne’s research on Cumbrian sheep farmers after the

⁸² Sturgis et al 2005, op cit. at p.32.

⁸³ Durant et la 1992 cited in Sturgis et al 2005, op cit. at p.32.

Chernobyl incident illustrates this latter point. Wynne highlights the way that a lay person's valuable knowledge is denigrated in contrast with the 'expert' opinion. The sheep farmers drew on their understanding of their terrain and cattle which Wynne describes as 'specialist knowledge'. If this knowledge had been acknowledged and added to the knowledge of the scientists studying the impact of Chernobyl in Cumbria it would have led to a more representative picture. In the case of one experiment (where sheep were being penned off in order to test the effects of the chemical absorption of minerals in the soil as a means to prevent recontamination of the sheep) the farmers claimed that hill sheep do not respond well to being penned up and would 'waste', which is what happened and this experiment was ultimately abandoned.⁸⁴

Information content is a key variable in any discussion of the features or potential sui generis nature of public attitudes to genomics. Sturgis & Allum state:

'A key issue in measuring public opinion to new and emerging technologies relates to how the researcher should go about measuring opinion towards areas of science and technology about which most members of the public are only dimly aware'.⁸⁵

It has long been known that there are inherent problems in the establishment of knowledge levels of individuals. Interestingly, findings on the knowledge-attitude relationship differ in relation to whether an individual has self-certificated their level of knowledge or whether it has been assessed by a third party. (The question of self-perception of knowledge is outside the scope of this thesis.)

Rates of genetic literacy are rising over time in response to increased familiarity with the technologies, and the clearest indicators of this increase are education and age. For instance, there is evidence that the younger age groups have greater knowledge of what DNA, gene and chromosome are.⁸⁶ Interestingly, Wolpert picks up on some examples in the 2005 Eurobarometer where even the question setters have displayed a lack of understanding of the science in the wording of the questions! For instance: 'the cloning

⁸⁴ Wynne, Brian, Chapter 1 of Irwin, Alan & Wynne, Brian (Editors) 'Misunderstanding Science?: The Public Reconstruction of Science and Technology', Cambridge University Press 1996.

⁸⁵ Sturgis, Patrick and Allum, Nick, 'A Literature Review of Research Conducted on Public Interest, Knowledge and Attitudes to Biomedical Science', (Wellcome Trust 2006) at p.2.

⁸⁶ Study from Finland shows this, cf: Jallinoja, Piia, Aro, Arja, 'Knowledge about Genes and Heredity among Finns' *New Genetics and Society*, Vol.18, No.1, 1999.

of human beings results in perfectly identical descendents'.⁸⁷ Sturgis et al comment that 'empirical research [...] finds that public 'scientific literacy' is generally low, falling well short of what normative criteria would consider 'acceptable'.⁸⁸ The study conducted by Sturgis et al in 2005 carried out a regression-based modelling technique to investigate whether attitude correlated with knowledge level in relation to biotechnology using data from the 2000 BSA and the 1999 Wellcome Consultative Panel on Gene Therapy. The paper concludes that while scientific knowledge does appear to have an impact on attitude, in that increased knowledge is more likely to lead to a positive attitude, these results do not apply across the board because both the biotechnology product and the social location of the individual have an influence.⁸⁹ The relationship is too complex to be interpreted as simply supporting the deficit model. It is argued by many academics and politicians that a knowledgeable public is a vital element of a vibrant democracy and as a consequence there has been an outpouring of data collection concentrated on the measurement of the public's knowledge of science – or 'civic scientific literacy' (Miller⁹⁰) levels. While it is laudable to strive for a knowledgeable public, one must consider a number of points: firstly: how realistic is this? The previous discussion of how an individual cannot maintain knowledge on every conceivable subject sheds light on this question. Secondly, it is the case that science-communication funding has been pumped into this area but this will always only affect a small proportion of the public. Finally, over time and as a technology becomes more familiar, data shows that genetic literacy levels increase. In line with the deficit model it is often assumed that increased familiarity with a technology leads to increased engagement and subsequently a more positive view of the said product. However, studies including Sturgis et al 2005, and the MORI poll of 2001 on genetic information commissioned by the Human Genetics Commission found that the respondents with a

⁸⁷ Wolpert, L. 'The Public's Belief about Biology', *Biochemical Society Transactions* (2007) 35, pp.37-40. Wolpert cites the following statements which are stated to be true in the Eurobarometer 2005: 'Embryonic stem cells have the potential to develop into normal humans'.

⁸⁸ Sturgis, Patrick, Cooper, Helen & Fife-Shaw, Chris, 'Attitudes to biotechnology: estimating the opinions of a better informed public', *New Genetics & Society*, Vol. 24, No.1, April 2005 pp.31- 56 at p.31

⁸⁹ Sturgis et al 2005, op cit. at p.31.

⁹⁰ Miller, J.D., (1983) 'Scientific Literacy: a conceptual and empirical review', *Daedalus*, 112, pp.29-48.

higher level of knowledge were the most likely to be critical and less optimistic about genetic technologies.⁹¹

2.3.3 The sources and gauges of public opinion

For the purposes of the thesis, the principal survey data referred to is drawn from the British Social Attitude Survey and Eurobarometer. Sturgis and Allum argue that the BSA survey series has been the most consistent (outside Eurobarometer) site of survey investigations of public opinion toward science and technology. It included a cache of questions on biomedicine in the years: 1993, 1996, 1998, 2000 and 2003.⁹²

Eurobarometer have conducted a series of seven surveys which specifically examine biotechnology with the most recent conducted in 2010. Sturgis et al argue that with reference to biotechnology: ‘public knowledge is low and opposition high in most contexts in which it has been studied’.⁹³ The critical point relates to the context of study but equally if a large number of reliably collected surveys show similar results these can be given a stronger standing and resonance in regulatory decision-making. This raises the question as to whether such meta-reviews of surveys on the same subject are being seen by regulators or whether regulators rely on the latest survey or consultation exercise commissioned by their own institution.

As already discussed, Sturgis and Allum criticise the lack of co-ordination of data collection in this realm and describe the survey collection as sporadic. They argue that surveys are generally conducted in a reactive manner, for example as a response to heightened media attention, but due to the varied funding bodies and different teams leading the survey collections the results are difficult to analyse in conjunction with each other.⁹⁴

The high levels of funding and resources on data pertaining to genomics is evidenced in the enormous volume of survey data are indicators of the political and commercial import given to such an undertaking. Lezaun and Soneryd state that:

⁹¹ Sturgis et al 2005, op cit. and the Human Genetics Commission (HGC) 2001 ‘Public Attitudes to Human Genetic Information. People’s Panel Quantitative Study (London: HGC)

⁹² Sturgis and Allum (2006) op cit. at p.10.

⁹³ Sturigs et al 2005 op cit. at p.49.

⁹⁴ Sturgis & Allum 2006 op cit. at p.58.

‘In many countries, the need to seek lay views that could inform complex technical and scientific decisions has become almost a new orthodoxy, and it is to increase public participation in science and technology policies that the most innovative instruments of consultation are being devised today, at a time when citizen engagement in other spheres of policy-making is waning’.⁹⁵

In the next chapter this enhanced reference by the IRAs to public opinion in the domain of genomics is addressed in terms of whether it arises from a need for the IRAs to appear to be more responsive to the public as a result of the controversial issues raised by the novel technologies. An alternative perspective is that this enhanced reference to the public voice results from the drive to placate public anxiety over novel technologies. Regulators may feel that their best way of proceeding in the introduction of novel products is to move ‘softly softly’ in line with increased familiarity.

2.4 Conclusions

Public opinion measurement has serious limitations and the resulting data can never be called an accurate representation of public opinion. However, the data which is collected is a measurement of something, even if to call it representative of the public is inaccurate, this data retains significance in the regulatory system. The question then turns on how one marries these two inconsistencies. Is it simply a case of renaming public opinion ‘public opinion data’? Would it be better if policy makers and regulators become more open and transparent in the discussion of this data and highlight its inconsistencies and limitations? Is it feasible to ask for data results to be communicated in a more accurate manner in that a result such as ‘x% of the public believe y’, has greater punch than ‘we have consulted 300 people and x% of these believe y’. It is pertinent to return to Blumer’s argument here in which he highlights the discrepancy between the ordinary use and interpretation of public opinion in everyday life and the narrow operationalist view that public opinion is what surveys survey.⁹⁶ The latter perspective ties in with the argument that public opinion only exists where it serves a purpose.

Does this line of argument turn the quest for an answer to the question ‘is there a public opinion of genomics?’ into a moot point? Undoubtedly, there has been a high level of

⁹⁵ Lezaun & Soneryd 2006 op cit. at p.2

⁹⁶ Blumer, Herbert, ‘Public Opinion and Public Opinion Polling’, *American Sociological Review*, Vol. 13, No. 5, (Oct. 1948), at p. 543.

funding and manpower applied to the measurement of public opinion in this sector and as such some of the data collected will be deemed to be robust relative to the limitations of all survey data. The data findings are that the public are generally supportive of health genomics and fairly split in relation to agricultural genomics. Such data will be explored in greater depth in the case-study chapters and in doing so the specific idiosyncrasies of the data pertaining to genomics such as the information content will be highlighted. The findings resulting from an instrument are often regarded as constituting the object of study instead of being some contributory addition to knowledge of the object of study.⁹⁷ Although this conflation can be criticised on the grounds that it is not representative, the conflation enhances the role of public opinion data in the regulatory-policy process. An alternative route would be to move away from this conflation approach to the operationalist view mentioned at the start of the chapter and maintain that the survey data retains a value and role but should be presented in a more transparent way. This gap between the data per se and the representativeness value attributed to it in the regulatory-policy documents is analysed in depth in the case-study chapters.

⁹⁷ Blumer 1948 op cit. at p,543

Chapter 3

An Exploration of the Definitions of Regulation and the Regulation of Genomics

3.0 Introduction

The aim of this chapter is to explore the meaning of the term 'regulation' and then to locate a definition which is workable for the thesis when applied to the regulation of genomics. It is important to recognise that not only are there many definitions of the term regulation but additionally that it is acceptable for these meanings to work alongside each other and co-exist. Further to this, Baldwin, Scott and Hood state that such multiple usages of the term regulation are not 'reducible to some platonic essence or single concept'.⁹⁸ While this suggests that arriving at a definition of regulation may be problematic, definitions are necessary prerequisites for both academics and practitioners in order to frame analysis and implementation. Within the multiple uses of regulation, a working definition of regulation is established for the purposes of situating and delimiting the field of research in the thesis. It is the case therefore that the definition of regulation given here will be utilitarian and act as a framing or boundary-setting tool. Additionally, the understandings of regulation outlined in this chapter act as a platform for the discussion of the regulation that has developed in response to the products, devices and techniques which have emerged from the techno-science of genomics.

A common portrayal of genetic and genomic technologies is that they need to be controlled and if left unleashed have the potential to wreak social havoc. As Black states:

'Regulation of genetic technology some would claim is an oxymoron. Genetic technology is simply out of control.'⁹⁹

⁹⁸ Baldwin at al 1998 op cit at p.2.

⁹⁹ Black, Julia, 'Regulation as Facilitation: Negotiating the Genetic Revolution' in Brownsword, Roger, Cornish, William R. and Llewelyn, Margaret, 'Law and Human Genetics: Regulating a Revolution'. (Hart 1998) at p.29. Black cites Beck as one of the principal proponents of this view, cf.: Beck, U. 'Risk Society: Towards a New Modernity' (London: Sage 1992 trans. M. Ritter).

This idea has dominated the regulatory ethos and can be seen to be part of the framing of the technology as far back as the influential Asilomar conference of 1973, which focussed on the recent reports of successful recombination of DNA molecules. The Asilomar conference is generally viewed as one of the principal triggers of the regulatory system and helped to set the course of the regulatory agenda in genomics. The *raison d'être* for Asilomar was to find a balance between scientific autonomy and the protection of the public from any potential risks. There was some concern at the time relating to the risk of the release of pathogens into the environment and a particular concern relating to a strain of *E. coli* bacteria, K-12, and whether it could colonise in the human gut. At this conference letters from leading scientists were published calling for a moratorium on research relating to recombinant DNA.¹⁰⁰ It is argued in this thesis therefore that there has been a strong push for regulation as a means to oversee the development of genomics, although there are cases where the genomics revolution has run its course unchecked and these specifically relate to cases where the science has outstripped the regulation. Additionally, there is not a consensus across the stakeholders (the scientists, the medical professionals, the interest groups, the food suppliers) as to the substance of the regulation. When reviewing the regulatory field of genomics however, the regulators and scientists alike are in favour of regulation as a means to protect the public while also acting to facilitate and validate scientific endeavours. There arises a regulatory dialectic with which the regulation of genomics wrestles: to exert control over the technology in order to protect the public and the environment from potential harm while at the same time to facilitate the development of genomics in order to maximise the benefits for humankind and to maintain industrial and commercial advantage.

This chapter is divided into two parts: in the first part, understandings of regulation and the rationale for regulation are outlined and the principal theoretical perspectives are described. In the second part of the chapter, the regulation of genomics is examined in terms of whether it is correct to describe it as a discrete area of regulation, and the differences between the terms genetics, genomics and biotechnology are explored. The question is posed as to whether the regulation of genomics is special relative to other fields of regulation and in addressing this, the regulatory set-up is examined. The

¹⁰⁰ Greif, Karen Faye and Merz, Jon Frederik, 'Current Controversies in the Biological Sciences: Case Studies of Policy Challenges from New Technologies (2007, MIT) at p.111.

regulation of genomics is reviewed to see whether it can be classed as being *sui generis* or as having regulatory features which are idiosyncratic. These discussions set up the theoretical frames with which the role played by public opinion can be analysed in the ensuing empirical chapters.

The principal goal of the second part of the chapter is to define and describe what is meant in this thesis by the regulation of genomics. In justifying the study of the regulation of genomics in the thesis as opposed to the regulation of biotechnology or genetics, the trajectory of the gene and its transformation from a scientific to a legal entity is discussed. The chapter poses the argument that there are cognitive gaps between law, regulatory policy making and the scientific community and that there is evidence that the concepts of genomics and the gene have carved out legitimate ontological spaces in both camps, but that when the epistemological communities meet it can lead to problems of cognitive dissonance.

In this chapter, I hope to extend the current literature on the regulation of genomics which is currently, according to Scott, 'concerned with the construction of only one element of a regulatory regime – the normative structure of principles, standards and rules'.¹⁰¹ I aim to address this limited approach in the literature and set out to do so by bringing together the normative debate with an overview of the substantive regulation. In the following section of the chapter, I set out an overview of the principal normative justifications given to support the case that the regulation of genomics merits special regulatory handling. The regulatory response to these normative drivers is then outlined in an attempt to draw out whether the regulation has been handled differently relative to other policy domains.

The regulation of genomics offers up a multitude of ways that the *problématique* can be formulated and this in itself may lead us to question whether it constitutes a discrete area. As Black notes, the problematisation can be framed in terms of risk to human health or the environment, it can be a question of consumer or patient choice, a matter of property rights relating to patents or to an individual's DNA, an issue of confidentiality related to employers, insurance companies or family members, and

¹⁰¹ Scott, Colin, 'Rethinking regulatory governance for the age of biotechnology' chpt. 2 in Somsen, Han (Ed) 'The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents'(Edward Elgar 2007) at p. 19.

finally the regulation of genomics may be framed in terms of the inherent ethical issues.¹⁰² There is no doubt therefore that this creates difficulties in terms of streamlining the ethos of the regulation and legal rationality. Thus Scott argues that:

‘Biotechnology regulation, as a field of public policy, has not yet matured to the point where other elements of regulatory regimes – notably processes for monitoring and mechanisms of behavioural modification – are routinely considered or problematised.’¹⁰³

3.1 Understanding Regulation

3.1.1 Definitions of Regulation

The Oxford English Dictionary offers the following definition of regulation which has etymological roots in the latin *régula*, a rule:

‘A rule prescribed for the management of some matter, or for the regulating of conduct; a governing precept or direction; a standing rule.’

Traditional definitions of regulation generally refer solely to a command and control (CAC) form of regulation whereby regulation is introduced by the state through the use of legal rules and is backed up by criminal sanctions.¹⁰⁴ While command and control is a *style* of regulating it is often conflated with an *understanding* of regulation. It is characterised by being highly prescriptive and positivist in its application and receives heavy criticism for its rigidity. CAC is a linear and unilateral form of regulation, in that it functions by governments dictating the behaviour of the people. As such it is often criticised for being an unsophisticated form of regulation and subject to information and knowledge failures which lead to both motivation failure and potentially to regulatory capture. Regulatory capture is when the regulators who have been commissioned to act in the public interest develop an overly close relationship with those they are regulating

¹⁰² Black, Julia, ‘Regulation as Facilitation: Negotiating the Genetic Revolution’ in Brownsword, Roger, Cornish, W.R., Llewelyn, Margaret, ‘Law and Human Genetics: Regulating a Revolution’ (Hart Publishing Ltd. 1998) at p.29.

¹⁰³ Scott, Colin, ‘Rethinking regulatory governance for the age of biotechnology’ chpt. 2 in Somsen, Han (Ed) ‘The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents’(Edward Elgar 2007) at p. 19.

¹⁰⁴ Black (2002) *ibid.* at p.2

which has an impact on their independence as a regulatory agency.¹⁰⁵ Additional criticism comes from socio-legal academics, for instance, Griffiths has written extensively on the subject of the relationship of regulation and simple cause-effect relations between the state and the public.¹⁰⁶ Black points out however that CAC is a straw man in many senses and becomes an easy target for all criticism levelled at regulation as a policy tool.¹⁰⁷ Currently, the ‘rules backed by sanctions’ interpretation still holds ground but it is more common for regulators and academics to talk beyond this form and conceptualisation.

Baldwin et al offer three meanings of regulation which are a natural starting point for a discussion of definitions of regulation. The first of these three definitions is essentially the classic command and control view of regulation. In describing this Baldwin states that:

‘at its simplest, regulation refers to the promulgation of an authoritative set of rules, accompanied by some mechanism, typically a public agency, for monitoring and promoting compliance with these rules’.¹⁰⁸

The second meaning put forward by Baldwin expands the concept of regulation to include all modes of state intervention or influence which act to steer society, industry and/or the economy. Importantly, this conceptualisation still maintains that state autonomy is a prerequisite for regulation. The third understanding of regulation is yet more expansive and refers to all forms of social control or influence including those which are beyond state-led intervention, for example, the influence of the financial market.¹⁰⁹ These three meanings of regulation evolve and as they do so there is a softening of the use of control as a regulatory mechanism to one of influence. The three definitions may be viewed as points along a continuum and as such are a useful heuristic in deliberation of regulatory styles and definitions of regulation. In terms of

¹⁰⁵ See further: Helm, Dieter, ‘Regulatory Reform, Capture and the Regulatory Burden’, *Oxford Review of Economic Policy*, 2006, Vol. 22, No.2.

¹⁰⁶ Griffiths, John (Graciela’s book) – causal complexity

¹⁰⁷ Black (2002) op cit. at p.4.

¹⁰⁸ Baldwin, Robert, Scott, Colin & Hood, Christopher, ‘A Reader on Regulation’, (Oxford University Press, 1998), p.3

¹⁰⁹ Baldwin et al (1998) *ibid.* at p2-4.

causal relationships between the regulator and the regulated it is significant that the third meaning given here includes incidental causality.¹¹⁰ This is significant in terms of intentionality (which is often classified as a prerequisite of regulation in a conventionalist sense) and is unavoidable in terms of describing state-derived regulation, and yet arguably absent in relation to market influence upon behaviour.

It is generally argued that lawyers and economists adhere to the understandings of regulation given in the first two of Baldwin's definitions, whereas the third definition is a less commonly held interpretation and is more likely to appeal to socio-legal scholars and academics in that it refers to concepts such as the discovery of regulation in 'unsuspected places'.¹¹¹ Black criticises the use of the three meanings identified by Baldwin and contends that even to identify these is to 'gloss over the multiplicity of meanings given to regulation'. Black also highlights the way that academics, and she includes herself, are very utilitarian when it comes to selecting an interpretation of regulation in their writing, and it is common for them to switch between definitions.¹¹² Black argues that regulation should be viewed as an ever expanding concept and produces a table to illustrate this point.¹¹³ However, as a social scientist it is important to make an attempt to clearly define the object of study, and in this thesis it is necessary to put forward a definition of regulation to be used as a means to define the remit of the study. Black's table explores the competing conceptualisations of regulation as a type of legal instrument, as an action, as a process, as an outcome and as a property. Brownsword prefers to view regulation as any type of controlling or channelling strategy.¹¹⁴ As such it is conceptualised as an activity, which is also the way regulation is talked of in autopoietic analyses of regulation where regulation is controlling, governing or directing.¹¹⁵

¹¹⁰ Baldwin et al (1998) at p.3.

¹¹¹ Black, Julia (2002) 'Critical Reflections on Regulation', LSE Paper, CARR, at p.1.

¹¹² Black, (2002), *ibid.* at p.9.

¹¹³ Black (2002) *op cit.* at p.11-12.

¹¹⁴ Brownsword (2005) *op cit.* at p.4-5.

¹¹⁵ Black (2002) *op cit.* at p.13. To do: definition of autopoiesis

Black highlights that in decentred analyses of regulation, the ‘regulation is not so much an activity as a product of activity’.¹¹⁶ From this perspective, the focus of the regulation moves from the centre to a more decentred conceptualisation in which regulation is diffused throughout society. Such a conceptualisation of regulation draws heavily on systems theory. The third definition of regulation offered by Baldwin, as noted above, relates to a decentred perspective. It is however problematic as a definition of regulation which can be utilised for an area of study because, as Black notes, it;

‘provides no boundaries as to where regulation might end and some other influencing factor take effect and so provides very little analytical purchase.’¹¹⁷

Decentrism works from the assumption that there is an ‘inherent ungovernability of social actors, systems and networks’.¹¹⁸ To assume such a stance would not be appropriate for the examination of this thesis’ research questions which are focussed on the relationship between regulation and public opinion. However in relation to the thesis, whether social actors may be deemed ungovernable or not is a moot point, as the influence of regulation on public opinion is not a question of governability.

A further commonly held interpretation of regulation is that it is a form of institutionalised norm control. From this perspective questions arise, such as: Can we distil the essence of regulation down to a set of processes by which norms are established? How are such norms promulgated and perpetuated? Regulation may be viewed as either an activity or a process that has the capacity to facilitate and prohibit specific activities. Foucault describes regulation along these lines as ‘the conduct of conduct’.¹¹⁹

¹¹⁶ Black (2002) op cit. at p.6.

¹¹⁷ Black (2002) op cit. at p.8.

¹¹⁸ Black, J. (2002) op cit. at p,6.

¹¹⁹ Foucault M. (1991) ‘Governmentality’ in Faubion, James D. (Ed), ‘Power: The Essential Works 3’

3.1.2 The Rationale given for Regulation

‘Regulation has existed forever, but regulation for defensible reasons of economic or social policy is more recent’. (McLean 2004¹²⁰)

Baldwin and Cave make a distinction between the technical justifications for regulation and ‘motives for regulating’ by which they include, inter alia, the influence upon governments of a powerful economic argument, an industrial lobby or a particular regulatory stance which may benefit their chances of re-election.¹²¹ The overriding rationale for regulation is that of market failure. This is the argument that the market alone will not account for certain areas of public interest, and that externalities such as environmental pollution will arise. Additional reasons why the uncontrolled market would fail include the emergence of monopolies, windfall profits, and anti-competitive behaviour. Regulation is deemed a corrective solution to such problems. A further potential problem would be the emergence of information inadequacies. This is pertinent to the case of genomics, since regulation can provide information to give a consumer the knowledge to make a choice over products (as in the labelling of GM foods) and regulation can ensure that new health techniques are researched and attain quality standards (as in the case of prenatal testing and PGD). It is important to acknowledge the point made by Baldwin and Cave that:

‘Any analysis of the need to regulate will be skewed if it is assumed that regulatory techniques will operate perfectly’.¹²²

The market failure understanding of regulation derives from the function that regulation performs in the name of public interest, which is to restore equity following the vagaries of the market; i.e. to iron out market failures in the interests of the public. This theory is dominant as a justification given for the necessity of regulation. However, the traditional definition of this theory has shifted slightly, and it is common now to hear reference to additional factors which stand alongside the identification of market failure as the sole rationale for regulation. Thus market failure alone may not be enough as a

¹²⁰ McLean, Iain, ‘The History of Regulation in United Kingdom: Three Case Studies in Search of a Theory’, Chpt. 3 in Jordana & Levi-Faur 2004 op cit. at p.46.

¹²¹ Baldwin, Robert and Cave, Martin, ‘Understanding Regulation: Theory, Strategy and Practice’, Oxford University Press 1999 at p.9.

¹²² Baldwin Robert and Cave, Martin, ‘Understanding Regulation: Theory, Strategy and Practice’, Oxford University Press 1999, p.16.

justification for intervention, and subsequent economic or social reasons may also be required.¹²³ Additionally, questions arise about whether it is the public that is calling for regulatory intervention in order to remedy the inequity of the market and, if not, who is driving this strongly normative mandate.

Classically, regulation has been viewed as a mechanism which can plug the gap caused by market failures and thus provide a safety net for the protection of the public. Market failures traditionally arise as the result of inter alia: externalities, information asymmetries and inadequate competition, or as a combination of these.¹²⁴ To take these in turn: externalities or spillovers are usually taken to be the costs or benefits which result from an activity but do not accrue to the people undertaking that activity. The classic example of this is pollution. Without regulation it would in many cases be cheaper for a firm to pollute and for society to suffer the social costs. Regulatory intervention acts to internalise the cost of the externalities and to protect society. Information asymmetries or deficits will occur without regulation and the majority of these relate to a lack of consumer protection. For example, a lack of product information may mean that consumers are unable to compare competing products, or the situation could arise where producers failed to inform consumers of possible side-effects or associated harm.¹²⁵ Interestingly, some commentators would now argue that access to information has led to a form of ‘regulation by information’ which links to the proceduralist¹²⁶ mandate and as such the justification for regulation includes more than a market failure justification, since it engulfs democratic principles such as the advancement of an active and engaged citizenship. Majone states:

‘It is a truism that public policy is increasingly dependent on relevant, timely and especially, credible information. Nowhere is such dependence stronger than in the area

¹²³ Prosser, Tony, ‘Regulation and Social Solidarity’, *Journal of Law & Society*, Vol. 33, No.3, September 2006, pp. 364-387 at p.366.

¹²⁴ This is not an exhaustive list, further examples of market failures are given in Baldwin, Robert, and Cave, Martin 1999, ‘Understanding Regulation: Theory, Strategy and Practice’, (Oxford University Press) Chpt. 2.

¹²⁵ Baldwin & Cave 1999 op cit. at p.12.

¹²⁶ Proceduralisation has been a regulatory trend in developed nations and the two principal features of it are firstly, information generation and a learning approach in decision-making and secondly, an enhanced system of communication across the social spheres. Thus proceduralisation is the provision of procedures which enable these goals to be met.

of social regulation – environmental and consumer protection, risk regulation, occupational health – where the policy-maker often faces problems at the frontier of scientific and technological knowledge.’¹²⁷

The third rationale for intervention is the assumption that the self-regulating or unregulated market will engender the development of monopolies. From a public interest perspective, this may lead to the monopoly powers maximising their profits and restricting their output which may result in consumers paying prices which are set in excess of the marginal cost.¹²⁸ The corollary of this has been the development of competition (anti-trust) law, although it should be noted that not all monopolies work against the public interest. Baldwin and Cave highlight the case of ‘natural monopolies’ where it may be less costly to society and more efficient to exempt certain cases from competition law. An example of this given by Baldwin and Cave is the building and maintenance of railway lines, where the economies of scale are so large that it is more efficient to allow a single firm to dominate.¹²⁹

The failure of the market is examined to see whether it justifies regulatory intervention. Importantly, regulation is not the only mechanism which can remedy such a failure: market failure may be remedied through the introduction of certain market transactions. Ogus adds that the civil law system also remedies such failings and as such he argues that civil law falls outside his conception of regulation.¹³⁰ Thus the identification of market failure alone is not an adequate justification for regulatory intervention. As already noted, market failure is not the only theory given to justify the introduction of regulation, and Prosser identifies other reasons for regulatory intervention which are the protection of rights and the maintenance of social solidarity.¹³¹

The motives for regulation are reviewed in this next part of the thesis through the theoretical framework outlined by Baldwin and Cave, and these are: public interest

¹²⁷ Majone, Giandomenico, ‘The New European Agencies: Regulation by Information’, *Journal of European Public Policy* 4:2 June 1997, pp.262-275 at p.264.

¹²⁸ Baldwin, Robert, and Cave, Martin 1999, ‘Understanding Regulation: Theory, Strategy and Practice’, (Oxford University Press) Chpt. 1.

¹²⁹ Baldwin & Cave 1999, *ibid.* at p.10

¹³⁰ Ogus (2004) *op cit.* passim.

¹³¹ Prosser (2006) *op cit.* passim.

theories, private interest theories, interest group theories, force of ideas theory and institutional theories.¹³² These perspectives are neither mutually exclusive nor without overlap and thus to some extent the differentiation between them masks the multiplicity of theories and sub-theories between and across them. The purpose of giving these explanations for regulation is to provide an introduction to discussion of the role that regulation plays in genomics which is discussed in section 3.2. In the overview of these four perspectives it is clear that disciplinary divisions on the theory of regulation have played a consequential role and are more than merely post-facto tools of intra-academic analysis. The theoretical underpinnings help to define regulation in that they may push a specific ideological agenda which influences the regulatory form and style and as such the meanings of regulation over time.

Understandings or definitions of regulation may be viewed from a number of standpoints, for instance one may take a functional, essentialist or conventionalist perspective. Black gives an overview of these three stances. The functionalist viewpoint is that regulation performs a function and so a functionalist would want to know how regulation performs as a contribution to society and would discuss regulation in terms of 'regulation does...' The second perspective is that of the essentialist which involves the identification of the principal components of regulation. Once these have been identified, the essentialist will assess whether these components are all present and if they are then they attribute to this concept the term regulation. Thus an essentialist would question what it is that regulation achieves or does in practice. Finally, the conventionalist examines the ways that the term regulation is used in practice and where the community being considered identifies something as regulation and as such talks in terms such as 'regulation is conventionally taken to mean.....'.¹³³ The conventionalist perspective allows multiple definitions of regulation to co-exist.

Baldwin et al attribute the multitude of definitions of the term 'regulation' to the rush of professionals and academics 'to colonise a new or newly important field of activity'.¹³⁴ This may be something which is recognisable in the area of novel technologies.

¹³² Baldwin, Robert and Cave, Martin, 'Understanding Regulation: Theory, Strategy and Practice', Oxford University Press 1999, Chapter 3.

¹³³ Black (2002) op cit. at p,17.

¹³⁴ Baldwin et al, op cit. at p.2-3.

However, this argument is surely weakened by the fact that regulation has a rather vague and sometimes amorphous character in order to encompass and accommodate the wide number of applications that are attributed to it. In this sense the meaning is often determined by application, for example, in the choice of command and control over self-regulation. However, it is common in the literature for either regulatory form (legislation, tradeable permits and codes of conduct) or regulatory strategy to be conflated with the definition of regulation.

(i) The Public Interest Theory

The public interest theory overlaps with the market failure model outlined above in that it relates to the idea that regulation is drafted with the public interest in mind and regulators are thus viewed as agents acting in the public interest. Such regulators are deemed to be trustworthy, disinterested and public-spirited.¹³⁵ The rationale for the regulation has been given above in that in cases where the public interest is not being protected, regulation can act to resolve this. Criticism of this theory arises in relation to the fact that regulation often has to deal with competing interests which represent the public interest, meaning that the public interest is not such a clear objective in many cases. For instance in the case of genomics, many of the applications of genomics correspond to the needs of the public but equally they are entangled in a myriad of ethical issues.

(ii) Interest Group Theory

The interest group theory views regulation as a product of relationships between groups and relationships between these groups and the state. Rather than seeing public interest as the main driver for regulation, this theory is premised upon competition for power. As such it focuses on power struggles, the politics of negotiation and issues such as political compromise. From this perspective regulation happens as a response to the most powerful and strategic political lobbying and bargaining. Within this theory stand two predominant theoretical strands: the pluralists and the corporatists. While pluralists analyse the role played by parties within power struggles, coalitions and factions, corporatists examine the ways and reasons why partnerships are formed between certain

¹³⁵ Baldwin and Cave, op cit. at p.20.

factions and the state, and how subsequent regulation serves to restrict further political access by competing parties to the regulatory arena.¹³⁶

(iii) Private Interest Theories

Private interest theories take the view that regulation is driven and developed by private interests and these theories include inter alia: the economic theories, the Chicago theory, private interest, public choice, regulatory capture theory, special interest, economic, and rent-seeking theory.¹³⁷ It is worthwhile to look at the economic theories. Posner highlights two pervasive assumptions within economic theory which are limitations to this theory; firstly that economic markets are extremely fragile and will act inefficiently or inequitably, and secondly that government regulation is costless. Ogus argues that the economic theory has had a profound impact on the way that regulation has been both analysed by academics and implemented as policy.¹³⁸ The theory was developed in the 1960s and 1970s and according to Ogus is part of the reason for the rationale for and failure of the regulation of this period. The theory fell out of favour in the period of deregulation of the 1980s and 1990s and according to Ogus was of little explanatory value in this period. The focus of the economic theory of regulation is on individual policy actors who behave according to their own private self-interest and act in a rational manner to this end. There is thus a deviation from the pursuit of regulatory goals, and individual motives are acknowledged behind the collective rationale, such as the rationale for regulation as given by a state. This theory denies a role for public interest regulation and as Baldwin et al state:

‘Stress is placed on the propensity of such individual actors to circumvent official regulatory goals by substituting objectives that are self-serving and to act in pursuit of such ends as job retention or aggrandisement, re-election or the accumulation of personal wealth’.¹³⁹

¹³⁶ Baldwin, Hood & Scott (1998) op cit. at p.10

¹³⁷ Baldwin, Hood & Scott 1998 op cit. at p.10.

¹³⁸ Ogus, Anthony, ‘W(h)ither the economic theory of regulation? What economic theory of regulation? Chpt.2 in Jordana, Jacinct & Levi-Faur, David (Eds), ‘The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance’(Edward Elgar Publishing Limited, 2004). Ogus stresses that economic theory is not to be confused with economic analysis.

¹³⁹ Baldwin, Hood & Scott 1998, op cit. at p.10.

Within this theory, individuals behave as agents in a market where regulation is viewed as a commodity to be purchased by the most powerful player.¹⁴⁰ According to this theory, regulators as political actors act no differently when it comes to regulation than they would in their private lives. Policies are therefore implemented in order to increase the wealth or utility positions of the most powerful actor or actors.¹⁴¹

The ‘Chicago theory’ was developed by Stigler, 1971 and Peltzman, 1989, and functions when there is a failure of competition law to prevent monopoly dominance. From this perspective regulation becomes a market commodity and its substantive content and quantification are dependent upon the forces of demand and supply. The principal political demands come from producer groups such as firms, trade unions and consumer groups, and the supply emanates from the authority of politicians who always have re-election in mind. The demands from industry carry the most political weight and the regulation is thus captured by industry. As such, the regulation is synonymous with industry’s wishes. Criticisms of the Chicago theory are that there is the assumption that all parties are income maximisers, that they all are as well informed as possible and learn from experience, and that regulation carries no costs.¹⁴²

(iv) The Force of Ideas Theory

The force of ideas theory came about in response to the Reagan and Thatcher deregulation programmes. Baldwin and Cave explain that:

‘[deregulation] was driven not by interest group pressures but by an intellectually guided process of economic rationalism that managed to benefit dispersed consumer groups at the expense of concentrated producers’ interests’.¹⁴³

This citation is premised upon the theory of the force of ideas, and attempts to offer an insight into the process of regulatory change. Force of ideas explanations are generally discussed in tandem with the economic theory of regulation as a rationale for the

¹⁴⁰ Baldwin, Hood & Scott (1998) op cit. at p.10

¹⁴¹ Baldwin, Hood & Scott 1998 cite Downs 1957 and Olson 1965 on this point.

¹⁴² Baldwin, Robert & Cave, Martin, ‘Understanding Regulation: Theory, Strategy and Practice’ (Oxford University Press, 1999)

¹⁴³ Baldwin & Cave 1999 op cit. at p.26, they cite Derthick, M. & Quirk, P. for this comment.

government regulation of business. However, the force of ideas theories carry some merit beyond the economic account in that ideas or intellectual conceptions can be separated from private interests

(v) **Institutional Theories**

The final theoretical standpoint posited here centres on the role of institutions in shaping regulation and offer an explanation of regulatory change. There is scepticism that individuals act solely as rational maximisers, instead, institutional theories hold that there is more going on in the push for regulatory development than merely the pursuit of individual goals. Wider factors are at play such as institutional structure and the social setting of regulation. Individuals are deemed to be subject to the influences of institutional procedures. Within this theoretical shift away from atomistic accounts of regulatory development is the ‘new institutionalist’ account.¹⁴⁴ This derives from socio-legal literature and includes analysis of the problems of bureaucratic and legislative drift and the potentiality of corrective administrative processes.¹⁴⁵ A further important strand of institutional theories is the principal agent theories. These examine the workings of institutions through the power relationships between the principals and agents and supporters of these theories would hold that this type of analysis enables a quantification of optimum levels of regulation.¹⁴⁶

3.1.3 Thesis Definition of Regulation

Having reviewed the principal theoretical perspectives on regulation, it is evident that regulation involves an assertion of control or influence on the part of the regulators over another party. This control or influence may be achieved through the use of sanctions or incentives in order to achieve compliance. Regulation additionally may occur outside of state activity and apply to all areas of society. The definition of regulation to be used in this thesis comes from Hood’s cybernetic analysis of regulation which Black draws upon. She proposes the following definition of regulation:

¹⁴⁴ Baldwin and Cave 1999 op cit. at p. 27-31.

¹⁴⁵ Bureaucratic and legislative drift refers to the deviations of bureaucracies from their legislative mandate and thus the wishes of the politicians. See further: McCubbins, Noll and Weingast cited in Baldwin and Cave 1999, op cit. at p.28.

¹⁴⁶ See further: Laffront & Tirole 1993 cited in Ogus, p.39

‘regulation is the sustained and focussed attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes which may involve mechanisms of standard-setting, information-gathering and behaviour-modification’.¹⁴⁷

The forms of regulation studied in the thesis cross the three tiers of regulation as set out by Baldwin. These include rules which emanate from Government and rules which are produced by the departments of state and government agencies. The decision to focus on governmental rather than parliamentary rules stems not merely from a concern to impose limits on this study but from a special interest in the problems of legitimising governmental rules which differ from parliamentary rules. The thesis examines the ways that public opinion as an input into the regulatory process can help IRAs to legitimise their regulatory position and the regulation they produce. In relation to the layers of regulation, primary legislation is analysed as it is central to the regulation of GM foods in the shape of European Directives and for the PGD and prenatal testing in the form of the Human Fertilisation and Embryology Act. However, secondary rules are also included. These are rules which have legal force and are conferred by an Act of Parliament and are often called delegated law or ‘the regulations’. Further to this tertiary rules are included in the regulation examined here. These relate to guidance notes, codes of practice, professional codes and voluntary codes and as such are rules which do not create rights that are directly enforceable through criminal or civil proceedings, although they may have the capacity to produce indirect legal effects.¹⁴⁸ I adopt the boundary set by Baldwin on the matter of tertiary rules in that they will only fall within the scope of this study if they are in written form. This therefore excludes social convention and informal understanding.¹⁴⁹ I wish to remain within the decentrist school of thought and look for regulation in unexpected places and additionally to highlight areas which escape regulation and the reasons for such lacunae. Self regulation may be an example of this, and this form of regulation is commented upon in the case of GM foods where the role of the retailers in response to the public mood led to a very clear self regulatory stance. This is described in more detail in chapter 5.

¹⁴⁷ Black (2002) op cit. at p.20

¹⁴⁸ Baldwin, Robert, ‘Rules and Government’, (Oxford University Press, 1995) at p.60.

¹⁴⁹ Baldwin., Robert (1995) ibid. at p.4.

In reviewing the role played by the IRAs, one approach taken in the thesis is to analyse the ‘discretionary zone’ which is a concept developed by Heritier to examine the area between the mandate set for the IRAs and their powers of discretion to move beyond this mandate. In the thesis the discretionary zone is examined in terms of the IRAs’ mandate and powers of discretion relating to the measurement of and responsiveness to public opinion. The IRAs which regulate GM foods and PGD and prenatal testing are outlined in the next section of the chapter. It is interesting to reflect upon Horkheimer’s commentary on the preoccupation of modern thought with means, where the ends are taken as given. This stands in stark contrast to classical thought which views regulation as instrumental in understanding and determining the ends.¹⁵⁰ In the course of this thesis, it will be interesting to ask whether in the case of the regulation of genomics the regulators are driven by means or ends based decision-making.

3.2 The Regulation of Genomics

The purpose of this section of the chapter is to define what is meant by regulation of genomics in this thesis. Firstly, a précis is given of the history of the gene and an overview of the principal definitions of genomics. Following this, the differences between genetics, genomics and biotechnology are given as a means to support my chosen interpretation of genomics. A discussion follows relating to whether the regulation of genomics is special and is subject to special regulatory handling, which leads into an examination of whether this sector can be deemed a discrete area of regulation.

3.2.1 The role of the gene in science and definitions of genomics

It is argued that the gene is a ‘fuzzy object’ and that ‘a gene is anything a competent biologist chooses to call a gene’.¹⁵¹ However fuzzy, the trajectory of the term ‘gene’ in the twentieth century has been unprecedented and, as Moss argues, it is viewed as a central organising theme of twentieth century biology.¹⁵² In this thesis I will only briefly touch upon the fascinating debate of how biology has been transformed by the

¹⁵⁰ Horkheimer, *Eclipse of Reason*: 1947: 2004:7 in ‘Tailoring Biotechnologies’, vol.3(1) p.1

¹⁵¹ Kitcher, Phillip, cited in Fox Keller & Lloyd, E.A. (Eds) 1992 ‘Keywords in Evolutionary Biology’, (Cambridge MA: Harvard University Press) pp.128-131

¹⁵² Moss, Lenny, 2003 ‘What Genes Can’t Do’. (Cambridge, MA: Bradford Books/MIT Press) p. xiii

concept of the gene and to some extent re-organised itself around it. What is important in the context of this thesis is to gain a measure of how the level of significance given to the gene in biology has rubbed off on the public, in terms of public opinion of those products resulting from genetic science as well as levels of genetic literacy. As a very crude heuristic device, I will outline ideas of genes as functional and molecular; from here I will describe the movement from genetics to genomics which involves a spatial dimension.

An interesting framing of any discussion of the gene, is Moss' theory of gene P and gene D and how these become conflated by the general public. Gene P is described by Moss as preformationist¹⁵³ and in crude terms it equates to a Mendelian type of genetics which is concerned with the relationship between gene function and phenotype. Thus in classical genetics this interpretation aided the development of agricultural practices related to inherited traits in plants. In such an interpretation the gene is functional as a carrier of DNA information which when expressed produces a specific trait. Moss adds that 'the preformationist gene predicts phenotypes only on an instrumental basis where immediate medical and/or economic benefits can be had'.¹⁵⁴ This is described here as the functional conceptualisation of the gene and is commonly referred to in the media in terms such as 'the gene for x', where x may be a disease such as breast cancer, Down's syndrome, or a phenotypic feature such as having brown eyes. Moss argues that this conceptualisation is overly simplistic and is misleading to the public.

In contrast, Moss' Gene-D accords to an epigenesist understanding and relates to a molecular understanding. Interestingly, Gene-D is not a gene at all but is a molecular sequence of DNA along the chromosome, a developmental resource.¹⁵⁵ Moss argues that the public and media often conflate these understandings of Gene-P and Gene-D. He states that:

'Genes are not at once both molecular sequences and pieces of the phenotype, and yet it is precisely this conflationary confusion which has buoyed up the notion of the genetic code and a blueprint that regulates its own execution'.¹⁵⁶

¹⁵³ Moss, Lenny, 2003 'What Genes Can't Do'. (Cambridge, MA: Bradford Books/MIT Press).

¹⁵⁴ Moss 2003 *ibid.* at p.xiv.

¹⁵⁵ Moss 2003, *ibid.* at p.44-50.

¹⁵⁶ Moss 2003 *op cit.* at p.50.

Keller comments that the conceptualisation of the gene has a great deal to do with its construction as an entity which enables scientific investigation.¹⁵⁷ To this end therefore, the gene is socially constructed and fulfils a performative role. When the term is taken up into legal regulation it can be manipulated, so it is additionally dynamic and evolving. Regulatory science in this area is fascinating in terms of opening up novel insights into the meeting of the different epistemic cultures of law and science. Additionally, it allows us to understand how the legal system enables norms to become facts. The performative role of the gene is widely held in the philosophy of biology literature and is reflected neatly in Moss' statement that:

'Unlike proteins, lipids and carbohydrates, the gene did not come onto the scene as a physical entity at all but rather as a kind of placeholder in a biological theory'.¹⁵⁸

The conceptualisation of the gene in this fluid manner enabled the science to progress and has additionally led to both a greater recognition of the preformatism of the term and a narrowing down of the definition of the term. This performative role of the gene is the background for any definition of the genome and genomics.

The term 'genomics' was publicly launched by McKusick and Ruddle in 1987 when they used the term to name a journal.¹⁵⁹ Hearsay claims that the term was coined by Roderick in 1986 at a party where a group of scientists were playing with the term 'genome'. It is argued that the distinction made between genome, a term attributed to Winkler in the 1920s, and the gene signifies the shift from a thing to an activity.¹⁶⁰ Part of the move from genetics to genomics is evidence of an acceptance of the complexity of the science in this field. Genomics covers the mapping and sequencing of genomes but there is the promise of much more. As such the genome can be conceived in spatial terms as a place where things happen which involve the entire genetic complement of an

¹⁵⁷ Keller, Evelyn Fox, 'The Century of the Gene' (2002, First Harvard University Press) passim.

¹⁵⁸ Moss, Lenny, 'What Genes Can't Do', (MIT Press, 2003) at p.2.

¹⁵⁹ McKusick, Victor & Ruddle, Frank established the journal 'Genomics' in 1987 and with it launched a new discipline. As cited in Powell, A., O'Malley, M., Müller-Wille, S., Calvert, J.& Dupre, J., 'Disciplinary Baptisms', (February 2007) as yet unpublished.

¹⁶⁰ Attributed to Linderberg, Joseph but cited here from Powell et al, 2007.

organism.¹⁶¹ It is argued that the term ‘genomics’ results from sheer pragmatism, as a consequence of the human genome being mapped and the development of the technology, which was so consequential that it almost demanded a renaming in order to highlight how enormous the developments were.¹⁶² The importance of giving this background is twofold in that understandings of the terms ‘genetics’ and ‘genomics’ will both aid the understanding of the gap between the science and the regulation and shed light on whether the applications emerging from genomics denote that they should be regulated in similar ways under the umbrella ‘the regulation of genomics’. The next section discusses applications relating to the science a product or technique emerged from, and the utilisation of the products. Regulators then make a decision about where to locate the product in terms of related products and devices.

3.2.2 What is the regulation of genomics as opposed to the regulation of biotechnology?

Following on from the last section where the shift from the gene and genetics to genomics was discussed, there is now the question of the term ‘biotechnology’. We have established that there are a variety of titles applied to this field which include inter alia: genetics, the new genetics, genomics, post genomics and biotechnology. Let’s turn firstly to the term ‘biotechnology’ which is defined in the Convention on Biological Diversity as:

‘Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.’¹⁶³

The distinction between biotechnology and genomics lies in the question of application and specific use. Genomics as a term conjures up images which rest closer to the laboratory and is not end-goal orientated. In my choice of the term, I view genomics as a technoscience that encompasses all the stages from the laboratory to product. Thus the use of the term genomics allows me to extend the analysis beyond the products, which the term biotechnology would not allow. This I believe is an important exception as it will enable me to refer to the various stages of development from the laboratory to the

¹⁶¹ Attribute to Steve Hughes – from discussion and the NIH definition of ‘genome’.

¹⁶² This idea is attributed to Jane Calvert.

¹⁶³ Article 2, Convention on Biological Diversity, United Nations 1992.

clinic or shop floor. As such, I argue that a more in-depth analysis of the nature and use of rhetorical function in the evolution of the regulatory science will be achieved. It is acknowledged that in the thesis the terms ‘genetics’ and ‘biotechnology’ will be used as they appear in the literature, however the central focus will remain ‘genomics’.

Regulatory science is simply the science which has been adopted to form the basis for policy making and regulation. It is generally perceived that the use and application of regulatory science in relation to genomic technologies is more controversial than relative to other areas of technology. Indeed in the later chapter on GM foods, it is evident that the contested nature of the science is central to the regulatory response. Calvert highlights the issue of ‘policy folklore’ which refers to the acknowledgement by policy makers of the results of studies which are supportive of the policy status quo while being unable to cite the sources or references. As Calvert sums up: ‘it is not necessary for policy makers to know the details of the justification for the outcome of a paper, they only have to be aware of the conclusions of the argument’.¹⁶⁴ In this way therefore policy makers have the capacity to pick and chose research which supports the direction they have outlined for the policy as a means to legitimise and crystallise their policy stance.¹⁶⁵ What must be a part of this process is the shoehorning of science into a package which is readily digestible by the regulatory policy arena. It is without doubt that scientists take into account the regulatory framework in addition to the profitability (in terms of further funding or practical applicability) when designing and undertaking their research. As Calvert comments, policy makers want ‘hard and fast answers’ and ‘quantitative ways of setting priorities and choosing different scientific fields’.¹⁶⁶ It is profitable for scientists to attempt to meet such requirements and as such regulation becomes a factor in the shaping of the science.

¹⁶⁴ Calvert, Jane, ‘Goodbye Blue Skies? The Concept of ‘Basic Research’ and its Role in a Changing Funding Environment’ DPhil, 2002 at p.246.
<http://www.centres.ex.ac.uk/egenis/staff/calvert/Calvertthesis.pdf>

¹⁶⁵ Calvert 2002 *ibid.* at p.246

¹⁶⁶ Calvert, Jane, 2002 *op cit.* at p.188

3.2.3 Historical Evolution of the Regulation

Whether to direct, regulate and exploit are issues which mirror the central tension at the heart of the Asilomar conference of 1975. Many feel that the Asilomar conference carries some kind of legacy and this relates to the fact that the issues dominating the conference discussion have not been resolved in the thirty plus years since. Resolution has not been brought about by virtue of the dichotomous nature of the regulatory position. The International Congress on Recombinant DNA Molecules at Asilomar, California (Asilomar) brought together 140 people. The majority were biologists together with some lawyers, physicians and there were additionally, sixteen members of the press. The aim of the conference was to discuss the safety of recombinant DNA research and to discuss a voluntary moratorium on research into r-DNA until the risks or hazards posed were understood.¹⁶⁷ This followed the results of Cohen and Boyer's research in 1973 which is hailed as the 'invention' of recombinant DNA (rDNA) which involved the splicing together of genes from different species and their transfer into bacteria.¹⁶⁸ It appears that the majority of the scientists at Asilomar were in favour of self-governance. So the conference was called amid the voluntary moratorium which had been directed by the US bioresearch community in 1974 as a result of the heated controversy surrounding Berg's work. Paul Berg, a US biochemist, had the idea of inserting the tumour producing virus SV40 into *Escherichia coli* (*E coli*) which is a bacterium found in the human gut. As is a common theme, this is probably the first case in genomics where the science has arisen and the regulatory bodies are pushed to respond due to societal pressures or perhaps pressure from within the scientific community. The problem of the science outstripping the regulation had only just begun. The account given is that scientists believed that they could divine what socially responsible behaviour was and argued in favour of self-regulation.

¹⁶⁷ Hindmarsh & Gottweis: 300

¹⁶⁸ Cohen, Stanley and Boyer, Herbert published their findings in November 1973 in "Construction of Biologically Functional Bacterial Plasmids *in vitro*", which described a technique to isolate and amplify genes, or DNA segments, and insert them into another cell with precision creating transgenic bacteria. Recombinant DNA technology was made possible by the discovery of restriction endonucleases by Arber, Nathans and Smith.

3.2.4 Should genomics be given special regulatory handling?

In the course of time it became clear that self-regulation by scientists would not be adequate as a means of overseeing the introduction of the novel products and techniques emerging from genomics. The regulation relating to the case-studies will be described in chapters 5 and 6 and it is apparent that there is evidence of special regulatory handling. This section provides an overview of the principal arguments given in support of special regulation for genomics relative to other novel foods and novel medical devices. I have synthesised the principal arguments which have repeatedly arisen in the literature and these are:

- a) genomics touches upon the very meaning of life;
- b) the ethical issues are singularly significant and complex;
- c) genomics is without any frames of reference and demands novel regulatory handling;
- d) the issues are controversial and there is a lack of consensus on how to regulate;
- e) it is difficult to marry the promotion of biotechnology with the protection of the public and the environment from risks;
- f) there are risks associated with genomics, not all of which we are aware;
- g) there is a very large imbalance of knowledge between the scientific community and regulators;
- h) there is a breakdown of public trust in this area;
- i) it is an area of highly contested science;
- j) the speed of scientific developments often outstrips the regulatory response.

It is difficult to distinguish these arguments from features of the regulation of genomics and as such they endow this field of regulation with particular idiosyncrasies. An additional characteristic has been the hype and promise surrounding the development of the technology in this area, since genomics is rich in technological promise. For example, GM crops are often heralded as a means to alleviate world hunger. The justifications for a special handling of the regulation of genomics are commonly framed

alongside technologically determinist arguments, which hold that new technologies are autonomous or out of control. Martin notes that this perception of technology is shared by both policy makers and the public.¹⁶⁹ Wheale et al contend that the direction, regulation and exploitation of scientific revolutions need to be managed in social terms.¹⁷⁰ Each of the arguments given for special regulatory handling will be discussed. Following this, I review the regulatory response in terms of whether it can be demonstrated that the regulation is special. In matching the arguments given for special regulatory handling with any demonstrable substantive regulatory response an analysis is undertaken as to whether a gap exists between this normative rhetoric and what happens in practice.

To delve deeper into the arguments raised above, the first argument posed is that genomics touches on the very meaning of life. Fukuyama writes of a posthuman future and proposes one visualisation of a world where there no longer exists any notion of a shared humanity because we have mixed human genes with those of so many other species that we no longer have a clear idea of what a human being is.¹⁷¹ This links in with Huxley's 'Brave New World' where biotechnology has developed to ensure that everyone is happy and healthy but the payoff is that in achieving this something intrinsic to being a human being has been sacrificed. I think it is important to stress the fictional bases which do hold sway as cultural reference points in the determination of public opinion. Fukuyama argues that the 'most significant threat posed by contemporary biotechnology is the possibility that it will alter human nature and thereby move us into a 'posthuman' stage of history'.¹⁷² The central root of Fukuyama's concerns over biotechnology is that it 'in contrast to many other scientific advances [it] mixes obvious benefits with subtle harms in one seamless package'.¹⁷³

¹⁶⁹ Martin, Paul, 'From Eugenics to Therapeutics: The Impact of Opposition on the development of Gene Therapy in the USA', Chpt. 8 in Wheale, Peter, von Schomberg, René & Glasner, Peter (Eds), 'The Social Management of Genetic Engineering' (Ashgate Publishing Ltd., 1998) at p.139.

¹⁷⁰ Wheale et al 1998 in Webster & Nelis 1999; 301

¹⁷¹ Fukuyama, Frances, 'Our Posthuman Future: Consequences of the Biotechnology Revolution', (check page ref – my e-version has at p.20). (Profile Books Ltd. 2002).

¹⁷² Fukuyama 2002 ibid at p.7.

¹⁷³ Fukuyama 2002 op cit. at p. 7

Developments in genetics and genomics such as the mapping of the human genome and the potential of stem cell science to advance medicine have been widely hailed as revolutionary. This characterisation results from the potential of genomics to reshape the relationship between scientific disciplines, and to recreate the boundaries between species and organisms and additionally to offer us information about human identification.¹⁷⁴ If we accept that the advent of this techno-science is revolutionary then the next logical step is to decide whether it needs to be managed or whether it can progress under its own direction without causing harm. This connects with the additional argument that the ethical issues raised by genomics are singularly significant and complex. Genomics raises a wide array of ethical issues which relate to the use of genetic information, the ownership of genetic material, the use of embryos for research purposes, animal welfare, and issues relating to human identity. There is overlap with this argument and the one above, because if genomics deals with issues pertaining to our very understandings of what it is to be human then it is not surprising that we have witnessed a rise in the number of bioethicists entering the regulatory-policy arena. One area of particular ethical concern is that relating to reprogenetics and genetic screening of the foetus. MacKenzie states that:

‘Eugenic underpinnings of current medico-legal practices may be discerned by disability activists and their supporters who contend that the lack of social assistance provided for the handicapped renders increasingly possible a free choice over whether to abort a foetus under s.1(1)(d) of the Abortion Act 1967’.¹⁷⁵

The interpretation of statute is open to controversy in relation to the use of the Abortion Act 1967 as the means to permit abortions in relation to the increase and ever-growing array of pre-natal testing and screening. Section 1(1)(d) of the Abortion Act 1967 permits a legal abortion of a foetus at any stage of the pregnancy where there is a substantial risk that if the child were born s/he would suffer from such physical or mental abnormalities as to render him/her ‘seriously handicapped’. What genomics has done is raised the profile of the status of the embryo and brought novel legal and ethical issues which test the legal status quo. Thus society’s duty towards the foetus is re-evaluated. Genomics is a harbinger of increased regulatory debate. In many ways it is

¹⁷⁴ Webster and Nelis 1999, at p.301

¹⁷⁵ Cunningham-Burley 1998 cited by MacKenzie, Robin ‘From Sanctity to Screening: Genetic Disabilities, Risk and Rhetorical Strategies in Wrongful Birth and Wrongful Conception Cases’, *Feminist Legal Studies* 7, 1999, pp.175-191.

viewed as an onslaught on the legal status quo because developments are moving at such a rapid pace that the regulatory system is finding it impossible to adjust and adapt. In the course of the case-studies it is clear that the role of the regulatory institutions as interpreters of the regulation is enhanced. This is but one issue that raises ethical discussion and there are many more, from admixed embryos and cloning to genetically modified cattle.

The novelty of genomics means that there are no pre-existing frames of reference and as a result, there is evidence of greater regulatory variation across policy regimes.

Appleyard refers to the absence of a stable set of expectations or discourses through which the language of acceptable and legitimate genetics might be constructed.¹⁷⁶

Added to this is the controversy arising from the ethical issues posed and the ensuing lack of consensus on regulatory direction. It is argued that the regulation of genomics has no clear policy objectives. This is unusual compared to other areas of regulation where there are broad policy objectives expressing some consensus. Gunningham states of this area that even the protagonists are diametrically opposed on fundamental issues.¹⁷⁷ This is often a case of diametrically opposed interests. For instance, regulators are faced with having to marry and balance the commercial interests of the biotechnology companies with the protection of the public, be that protection from actual or perceived risks. Such a regulatory dialectic is not unique in regulation but perhaps the polarisation of public opinion when linked with the contested science adds some weight to the argument that there are sui generis features within the regulation of genomics. It is argued by Beck that there is a substantial imbalance of knowledge and power between the scientific community and the state. Beck talks of this phenomenon, not strictly with reference to genomics per se but science as a whole, and argues that science is defining the regulatory agenda. Beck argues that the debate about the course of science occurs as an obituary for activities begun long ago.¹⁷⁸

¹⁷⁶ Appleyard in Webster & Nelis 1999, 'Regulating the gene: from genetic consumption to regulatory trust', *Health, Risk and Society*, Vol.1, No.3, at p.302.

¹⁷⁷ Gunningham 2007:8

¹⁷⁸ Black 1998 at p.29 citing Beck, Ulrich 'Ecological Politics in an Age of Risk' (London: Polity Press 1992, trans. A.Weisz).

The argument that there has been a breakdown of public trust springs from the case of GM crops and food. It is debateable whether this was a short-term issue in the late 1990s or whether it persists today both in relation to GM products and across the whole of genomics. The link between public opinion and public trust is inevitably very significant, especially in areas where the science and risks posed are highly contested, as in some areas of genomics. However it can be argued that the science is no more contested than in other novel technologies, but it is the role of NGOs that has made more evident this internal conflict.

One very clear feature of the regulation of genomics has been the speed of scientific development in outstripping regulatory mechanisms. There is no doubt that this is taking place and it has led to concerns from the scientific community that the UK will lose its competitive position in, for example, the consternation amongst scientists over the accreditation of stem cell storage¹⁷⁹. In such circumstances, the scientists need the regulation in order to legitimise their activities. As such, many of these justifications for special regulatory handling have been triggers for regulation.

In relation to these arguments or justifications for the special regulatory handling of genomics, I am of the belief that when questioning where these normative arguments have come from, it is important to examine our own role as social scientists in perpetuating them. Yet, I argue that the corollary to the dominance of the normative discussion in the literature is necessary, and that is to assess whether there is evidence in the regulation of anything *sui generis*. One must also acknowledge the enhanced role of the social scientist in this sector as being an additional feature and possible indicator of specialness. However in the endeavour of the social scientist to carve a space for themselves has this resulted in an overly privileged set of arguments?

¹⁷⁹ A recent example in the case of stem cell therapies where the Government has received criticism for not coming to a decision over the institution responsible for the accreditation of 'clean laboratories' to store stem cells. There has been institutional ping-pong between the HTA and the MHRA as both claim it is not within their remit to accredit the labs. Scientists are criticizing the Government and threaten a brain drain. [ref: letter to Gordon Brown, Jan 2007 from inter alia Whittaker, Newcastle Uni – viz: Guardian 19.04.07].

3.2.5 Is there evidence that the regulation of genomics is special?

This section of the chapter will outline the principal regulatory approach to genomics by examining the substantive regulation and the institutional organisation. Scott argues that the focus of the regulation of genomics has been upon ‘the normative structures of principles, standards and rules’ and this has led to the ‘neglect of the machinery for implementation of regulatory policy’. Scott contends that ‘processes for monitoring and mechanisms of behavioural modification are not routinely considered or problematised’.¹⁸⁰ Thus it may be argued that the current regulatory regime is in the process of maturation and is currently preoccupied with establishing the norms and appropriate regulatory mechanisms to achieve them. This regime is described in detail later in the chapter. Scott makes a second pertinent distinction between the focus of the regulatory scholarship and that of the people working in biotechnology policy per se. The former, argues Scott, ‘take policy objectives as given and focus on the means by which they may be delivered’. In doing so they may question the types of rules and regulatory institutions needed and the best means to monitor compliance. In contrast, those who work within biotechnology policy are preoccupied with the development of normative guiding principles.¹⁸¹ This idea is developed in this next section whereby the normative drivers pushing for special regulation are outlined and the response made to them by the regulators. A further point made by Scott is that the scope of the regulation analysed should be extended beyond governmental powers to legislate, to include biotechnology firms, retailers and NGOs.¹⁸² This is indeed done in this thesis where, as already stated, an extensive definition of regulation is being applied which includes a wider net of influences on the regulation.

In the table below the normative arguments for special regulatory handling of genomics are listed with the corresponding substantive regulatory response. From these responses it can be divined that the regulation in this area does demonstrate certain features which

¹⁸⁰ Scott, Colin, ‘Rethinking regulatory governance for the age of biotechnology’, Chpt. 2 in Somsen 2007 op cit. at p.19.

¹⁸¹ Scott in Somsen 2007 at p.20. Scott cites Baldwin & Cave 1999 regarding the ‘what types of rules’ etc. approach; Baldwin, Robert & Cave, Martin, ‘Understanding Regulation’, (Oxford: Oxford University Press: 1999)

¹⁸² Scott in Somsen 2007, op cit. at p.20.

are sui generis. It is as a result of these idiosyncracies, which thus become common to most areas of genomics, that the regulation of genomics is often talked of as discrete area of regulation. However, I argue that in many ways although each product or process is being treated differently (or as a special case) relative to other novel products or processes, they are not being grouped as a regulatory regime by the regulators. The products and techniques emerging from genomics are part of many overlapping regulatory spheres both nationally, at EU level and internationally. And while GM products are regulated by a body that oversees food safety and prenatal testing by the Department of Health, PGD is covered by an IRA which deals specifically with genomics regulation. These variations are not as central in identifying what is common across the regulation of genomics. I contend that there is evidence of specific features in the regulation of genomics which are related to the normative arguments and justifications which underpin its regulation and the responses made by the regulatory organisations to these arguments.

Figure 3: Normative arguments given for the special regulatory handling of genomics and the substantive regulatory responses

Normative	Substantive
Genomics touches upon the fundamental meaning of life	Enhanced reference to public opinion and a greater use of the rhetoric that regulation is responsive to public opinion Shifting responsibility from central Government to IRAs
Ethical issues	Enhanced role for bioethicists (Salter ¹⁸³) and of the public voice in deliberative governance
Ontological novelty There are no established frames of reference to draw upon	Institutional structures Proliferation of soft law responses
Controversy and lack of consensus	Regulatory science Public engagement Institutional structures The politics of negotiation (Beck)
Regulatory dialectic to promote biotechnology and protect the public/environment	Institutional set-up Regulatory pluralism: civil engagement, NGOs and industry
Perceived and actual risks to human health and the environment	Again an enhanced use of the rhetoric that regulators are responding to public opinion Higher levels of prescriptivism –stricter regulation
Imbalance of knowledge between scientific community and regulators (science outstripping regulation)	Institutional structures Science communication programmes Raised levels of funding to social scientists to bridge the gap
Breakdown of public trust	Enhanced role given to public consultation
The contested nature of the science & the role of regulatory science	Novel ways of handling expert opinion & regulatory science

From figure 3, the principal and most evident regulatory responses which demonstrate that the regulation of genomics is being handled as a special case are:

¹⁸³ Salter, Brian and Jones, Mavis, 'Human genetic technologies, European governance and the politics of bioethics', *Nature Reviews Genetics* 3, pp.808-814 (October 2002)

- An enhanced reference to public opinion and a greater use of the rhetoric that regulation is responsive to public opinion by the regulators
- Features of the institutional structure which include the particularly high numbers of advisory bodies and morass of regulatory institutions
- The enhanced ethical dimension in regulatory decision making including the increased autonomy given to bioethicists
- A proliferation of soft law mechanisms
- The stricter regulatory approach relative to similar non-genomics products and devices (for instance, GM foods in contrast to other novel foods)

While each of the responses by the regulators to the sui generis features is of note, it is the response in the form of enhanced deliberation in the formulation of regulatory policy which is most pertinent to the thesis.

The time which elapses between basic research and product approval in the sector of genomics influences the nature of the public's relationship to the regulation. It is argued by Norton-Wise that increasingly research which is carried out for profit is not actually in the public interest and that the commercialisation of research is skewing 'its direction away from what would most benefit society'.¹⁸⁴ This is in line with Krimsky who believes that science is increasingly conducted in the private interest and that the 'entire system of biomedical research no longer serves the public'.¹⁸⁵ The speed of approval systems for novel genomic products or techniques is a critical issue to biotech companies in terms of maintaining market competition.

¹⁸⁴ Norton Wise, M. 'Thoughts on the Politicisation of Science through Commercialisation', *Social Research* vol. 73: No.4, Winter 2006 at p. 1257

¹⁸⁵ Krimsky, Sheldon, 'Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?' Lanham, Md: Rowman & Littlefield, 2003. Cited in Norton Wise 2006 op cit. at p.1259.

3.2.6 The Regulatory Regime of Genomics

The responses to the normative drivers for the special regulatory handling have in many ways become self-prophesying as they have meant that this area of regulation has some very distinctive features which were outlined above. With regard to the institutional set up, there are a large number of new authorities of which the HFEA is the most prominent. However in other areas of genomics, there has been a mapping onto current IRAs, for instance the regulation of GM foods is overseen in the UK by the Food Standards Agency (FSA). However genetic modification is not so novel a product these days and when it was a novel technology there were a vast number of advisory organisations overseeing its development. The institutional structure has been a response to the regulatory focus upon epistemological issues, such as what we know about these technologies and how we know this.¹⁸⁶ The table below outlines the principal regulators overseeing the regulation of the cases under study in the thesis.

Figure 4: Regulatory activity

Regulatory Activity	GM Foods	Prenatal testing, screening & diagnosis
Public Regulation of the Public Sector		
European	European Food Safety Authority (EFSA) The European Commission, DG Health & Consumer Protection (SANCO)	
Central Government	Department for the Environment, Food and Rural Affairs (Defra)	Department of Health (DoH)
Statutory Bodies, Independent Regulatory Agencies	Food Standards Authority (FSA)	Human Fertilisation & Embryology Authority (HFEA)
Non-statutory advisory organisations/committees	Advisory Committee on Novel Foods and Processes (ACNFP)	Human Genetics Commission (HGC) UK National Screening Committee (NSC)

¹⁸⁶ Black, Julia 'Regulation as Facilitation: Negotiating the Genetic Revolution', *Modern Law Review*, 61(5), 621-60 [check page ref]

Private Regulation of the Public Sector		
Industry	Producers, Manufacturers & Retailers	Scientists, Pharmaceutical industry
Self-regulation	Retailers	Clinicians
Oversight by interest groups ¹⁸⁷	Greenpeace, Friends of the Earth (FoE) Consumer Organisations	Committee on Reproductive Ethics (CORE) Patient Groups – such as the Genetics Interest Group (GiG)

Beyond the principal regulators which are under review in this thesis, there have been a huge number of additional advisory groups, committees, government departmental directorates and agencies. In terms of mapping the institutions which play a critical role in the regulation of genomics, Black's comment is revelatory. She states in 1998 that;

'If you turn to ask what structures exist to regulate genetic technology.....then you find a mass of legal regulations, non-legal rules, codes, circulars, practice notes, international conventions, and ethical codes. There exists an enormously complex set of advisory bodies, regulatory bodies, committees, professional bodies, and industry associations, operating at international, national, and sub-national level. In the UK, at national level alone there are over eleven different bodies involved in the regulation of some aspect of genetic technology. Surely in this morass of regulation someone, somewhere, must be exerting some sort of control?'¹⁸⁸

It is the case that the response to the controversy and ethical dimensions posed by these novel technologies has been to establish a large number of bodies to oversee every potential aspect of the object of regulation.

A number of political trends regarding regulation generally by necessity impact upon the regulation of genomics. These include the increased role of the private sector in matters which may be described as public. Beck describes a 'reinvention of politics'

¹⁸⁷ Scott, Colin 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance' *Journal of Law and Society*, Volume 29, Number 1, March 2002, pp.56-76, at p.66. (public interest litigation or the threat of as a means to enforce standards) – use information strategies in addition to interest litigation (Scott at p.69)

¹⁸⁸ Black, Julia, 'Regulation as Facilitation: Negotiating the Genetic Revolution', in Brownsword, Roger, Cornish, W.R. & Llewelyn, Margaret (Editors), 'Law and Human Genetics: Regulating a Revolution' (Hart Publishing Limited: 1998) at p.

which he relates to the growth of regulatory agencies, advisory bodies, quangos and advocacy groups which he terms 'subpolitics'.¹⁸⁹ Beck contends that newer modes of governance have arisen as a result of this and that there has been a subsequent shift from 'the authoritarian decision and action state ...to the negotiation state.'¹⁹⁰ This idea that the regulation is more negotiable and less authoritarian will be examined in relation to the discretion given to independent regulatory agencies (IRAs) in the following chapter.

Gunningham and Grabosky outline a number of regulatory instruments utilised in environmental law and these include: information, education, voluntarism, self and co-regulation, market-based and direct regulation. Gunningham makes a case that the majority of these instruments do not translate easily from environmental to biotechnology regulation. To summarise Gunningham's argument, he highlights the limited range of instruments which are applicable. Information and education, for example, are not likely to influence the regulatees (the biotechnology companies). He questions whether self-regulation is feasible 'given the gap between the self-interest of those companies in rapid commercialisation and the public interest in minimizing the unanticipated consequences of biotechnology'.¹⁹¹ Similarly, market-based instruments are dismissed as being unable to bring about any change in regulatee activity, although Gunningham accepts that these may have some use in relation to consumer behaviour. Thus, concludes Gunningham, we are left with a limited selection of instruments and those selected in the regulation of biotechnology are principally direct government regulation. This relates primarily to biotechnology products being regulated through systems of mandatory pre-market risk assessment and approval. Safety standards are imposed and regulatory agencies established to monitor and enforce them. Liability rules are set out and these are capable of sending powerful economic signals about the consequence of failure to meet the legal standard. Additionally, informational regulation is implemented, for instance, in relation to GM foods as product labelling.¹⁹²

¹⁸⁹ Beck, Ulrich 1997 cited in Webster & Nelis 1999, op cit. at p. 303.

¹⁹⁰ Beck 1997 *ibid.* at p.303.

¹⁹¹ Gunningham in Somsen 2007 op cit. at p.6. Gunningham supports this argument with reference to the StarLink episode in the USA. cf. Bratspies, R. (2003) 'Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco', *William & Mary Law & Policy Review*, Vol.27, 2003, p.593.

¹⁹² Gunningham in Somsen 2007 op cit. at p.6.

In the mapping of the interactions between public opinion and regulation, it is apparent that both the levels of control exerted by the regulation and the regulatory instrument can have critical consequences. Gunningham states that:

‘[O]nce the biotechnology genie is out of the bottle (or the genetically modified crop has escaped into adjoining fields) it is very difficult to get it back, and the consequences if the initial policy instrument fails are unacceptable’.¹⁹³

There is an argument posed in the next chapter which posits that stricter regulation helps to alleviate public concerns in the case of novel technologies. It is interesting throughout the thesis to see how this corresponds with the attempts by regulators to facilitate the development of genomics. Genomics is one of the enabling technologies and as such the opportunities arising from it are viewed by regulators as generally positive.

As stated in the earlier part of the chapter, the regulation has principally taken the form of administrative oversight which is bound in a facilitating and enabling ethos combined with procedural safeguards, product standards, product authorisations, codes, and pre and post-market approval systems. It is therefore rich in softer regulation, however, there is very clear statute in relation to the authorisation processes surrounding GM foods and the newly revised Human Fertilisation and Embryology Act oversees PGD. There has been a strong trend towards a precautionary approach in relation to GM foods which is not seen in relation to health genomics. The contrasting regulatory approaches are analysed in depth in chapters 5 and 6.

3.2.7 Does the Regulation of Genomics Constitute a Discrete Area?

A very wide range of products, devices and processes fall under the umbrella of genomics. These are regulated in two ways: the establishment of novel regulatory institutions or regulation in existing institutions. The critical divide is the bifurcation between human/medical genomics and food/agricultural genomics. This study acknowledges this by selecting case-studies from each side of the bifurcation: one red and one green biotechnology. As is shown in the later chapters, these technologies have had very different public receptions and regulatory frameworks. There has been a high level of opposition and resistance to the introduction of GM crops and foods.

¹⁹³ Gunningham in Somsen 2007, op cit. at p.7.

Prenatal testing and PGD on the other hand, have received more support from the public, and it is argued that such technologies have become ingrained in our society through normalization.¹⁹⁴ There will be some rich comparisons to be found in examining these two technologies. The choice of GM foods is of great value in that it carries a historical legacy deriving from the debates over the regulation of genetic engineering in the 1970s and 1980s. It therefore invites us to pose questions relating to the initial regulatory rationality about whether there have been any shifts in the rationality resulting from technological developments or whether the central premises of the genetic engineering regulation are evident in more recent regulation. The regulation is reviewed in the thesis to show whether it is a case of regulating by product or process or whether the regulation is distinctive enough to be called a discrete area in its own right.

While there is a consensus that genomics involves the manipulation of the genome or genomic information then there is potentially a case to say that these technologies should all be regulated as one discrete area along the same criteria. It is immediately evident however that the wide range of products and techniques emerging from genomics necessitate very different regulatory responses. For instance, an unregulated escape of GMOs may pose a risk to the environment whereas the provision of an unregulated new genetic test poses concerns for human health. The application of genomics is far-reaching and by necessity therefore touches upon a wide range of regulatory areas such as intellectual property, international trade law, consumer protection, health law, medical ethics, environmental law, human rights, security, and insurance law.

Scott defines the principal regulatory issues which may be viewed as the central problematisations as:

1. the safety of new technological applications (in particular with respect to food)
2. the protection of the environment from irreparable change (in particular with respect to crops)

¹⁹⁴ Habermas, Jürgen 'The Future of Human Nature' (Polity Press, 2003) *passim*.

3. the protection of consumers' economic interests (largely focussed on issues of disclosure and labelling)
4. the protection of intellectual property rights
5. the complex ethical issues concerned with such issues as genetic testing, cloning and therapeutic applications of recombinant DNA.¹⁹⁵

The central theme of this section is the question of whether genomics can be classed as a discrete area, or whether the techno-science enters so many areas of regulation that it is unhelpful to classify it in this manner. All of the regulatory areas discussed have in common the normative issues raised in the above sections, that is, they are controversial and pose novel ethical questions. The crux is therefore whether they are subject to special regulation or whether there has been an adoption or adaptation of existing regulation to encompass them.

An important point is how the novel products and techniques emerging from genomics are defined. The regulation which they map onto is critical to both the public perception and the levels of permissiveness given to facilitate development. A common strategy of new technologies which is often adopted in order to avoid any controversy which may be attached to them, is to associate their 'products' with already legitimated practices. This relates to the lack of categorical precedence. One example of such a pragmatic approach which enabled the development of gene therapy was that a demarcation was made between germ-line and somatic therapy. Germ-line therapy alters the sperm and egg and thus passes on any alterations to future generations, whereas somatic limits the alterations to the non-reproductive cells. This distinction allowed the technology of somatic gene therapy for people suffering from life-threatening diseases to develop and become viable, whilst moving away from concerns that it was eugenic. Martin has argued that the impact of this has been a shift in perceptions of gene-therapy from what was viewed by some as a controversial neo-eugenic treatment to a promising new technology.¹⁹⁶

¹⁹⁵ Scott in Somsen 2007 op cit. at p.21.

¹⁹⁶ Martin 1998 in Wheale et al, op cit. at p.153.

3.3 Conclusion

In the first part of this chapter the understanding of regulation as applied to the thesis was made clear. An extensive definition of regulation is applied which is in keeping with cybernetic regulatory theory. The role of IRAs in terms of the discretionary zone will be introduced in greater depth in the next chapter and examined in relation to the case-studies later in the thesis. It has been established that the regulation of genomics is the study of the regulation relating to the development of products from laboratory to clinic and from the clinic to the consumer. Genomics is defined for the purposes of this thesis as the place where things happen which involve the entire genetic complement of an organism.¹⁹⁷ The second issue addressed in this chapter was whether the regulation of genomics is a discrete area and how the normative cries for regulatory specialness have been responded to. This thesis is concerned with one regulatory response in particular: the idea of increased reference to the public. This chapter has outlined the regulatory form and institutions in genomics. The overriding impression of this area of regulation is that the Government's response to the potential harm or risks posed by genomics has been the creation of a vast morass of regulatory and advisory oversight bodies which in turn produce a huge volume of predominantly soft law, codes and quality standards, and authorisation procedures.

It is presented here that the regulation of genomics should be deemed a discrete area of regulation. It is the case that the regulation encompasses a wide range of products and techniques and there is a lack of commonality with regard to the regulation whereby some products are regulated by mapping on to existing structures while others are overseen by IRAs specifically tasked with regulating genomics. However, the products and techniques have inherent *sui generis* features which have been clearly defined in this chapter. It is argued therefore that while the genomics does not correspond neatly to the definition of a regulatory regime as set out by Doern and Wilks, there are a number of common features which hold the products and techniques together. In this sense therefore genomics does respond to the contention of Doern and Wilks state that 'the first test of the existence of a regime is the presence of some inner core of shared norms, features, or characteristics that warrant such a designation for analytical or

¹⁹⁷ Attributed to Steve Hughes – from discussion and the NIH definition of 'genome'.

practical purposes'.¹⁹⁸ It is contended here that the debate over whether genomics should be regulated in response to the process from which the products and techniques originated from or in terms of the products produced is too basic. For instance, GM foods are regulated with an IRA responsible for food products and not genomics, yet GM foods receive very special regulatory handling relative to the other novel foods regulated by that institution. These issues are analysed in more depth in the case-study chapters.

¹⁹⁸ Doern, G. Bruce and Wilks, Stephen (Eds) (1998) 'Changing Regulatory Institutions in Britain and North America' University of Toronto Press, chapter 2.

Chapter 4

The Interaction between Public Opinion and Regulation

4.0 Introduction

New technological developments bring with them novel challenges to the regulation and policy systems and to society at large. As outlined in the previous chapter, the technology of genomics is having an enormous impact upon agriculture, food and medicine and has produced a vast number of novel products and techniques in these sectors. It is vital to explore the interactions between public opinion and regulation in order to determine whether regulation has the capacity to offer some level of resolution to anxieties or problems in the minds of the public. The aim of this chapter is to explore the different theoretical angles and arguments pertaining to the relationship between public opinion and regulation as a means to introduce the focus of the analysis of this relationship in relation to the case-studies examined in the next two chapters. This chapter explores how public opinion is valorised as an input into the regulatory-policy process; how public opinion triggers and shapes regulation; and the role played by regulation in affecting public opinion. The speed of technological developments outstripping the regulation has been discussed already, however the focus shifts in this and subsequent chapters to how and if the regulation closes up the then created lacunae and can achieve a level of resolution. One measure of successful resolution may be measured by a reduction in public anxieties surrounding the product.

This chapter opens with an overview of the central justifications given for the inclusion of public opinion in regulatory decision-making. Extricating the role of public opinion from the very strong normative drivers surrounding the role of public opinion is necessary as a means to delimit this thesis. While it is interesting to question the role we want public opinion to play in the regulatory process and to ask whether there is an optimal level, these issues are not being addressed in the thesis. These questions lead into the following section of the chapter which examines the distinction between regulation which responds to public opinion, responsive regulation, and regulation produced in the public interest. The chapter outlines the principal models of opinion-responsiveness from the political science literature: the public thermostat (Wlezien 1995 and 1996) and Attention Cycles model (Jones 2001, Jones and Baumgartner 2005), and

Bernstein's life cycle model of regulation. The purpose of describing these models is to gain a view of the central theories surrounding interactions between regulation and public opinion and as such provide a framework for the conceptualisation of public opinion and regulation. The regulatory output may serve a dual purpose: to aid the resolution of the attention cycle so that it helps establish equilibrium, and to alleviate public concern and by doing so result in reduced political attention. The latter will mean that the issue is removed from the attention cycle entirely or shifts it down the agenda, in other words, issue decay occurs. This raises two questions in relation to genomics: firstly whether regulation has the capacity to alleviate public concern in this sector, and secondly whether genomics as a policy subsystem responds according to the model of Punctuated Equilibrium.

In the final section of the chapter, the influence of public opinion on regulation is explored, and the capacity of public opinion to trigger and shape the regulatory direction is discussed. Evidently, inputs additional to public opinion are at play in the development and production of regulation. On the subject of additional factors or variables which influence the interaction between regulation and public opinion, Page and Shapiro state:

'To cast doubt on the likelihood of spuriousness is by no means to deny that third factors affect opinion and policy, which they surely do. We only argue that public opinion is a real influence – often an intervening one – upon policy, in many (probably more than half) of our cases of congruent change. When some third factor affects both opinion and policy, it tends to affect policy through opinion; policy changes only because opinion changes.'¹⁹⁹

This is a very forceful and resounding statement that public opinion has a marked impact on policy. Additional variables at play are mentioned throughout the thesis and include references to the media output, NGO lobbying, commercial activity and clinician and expert opinions.

¹⁹⁹ Page & Shapiro 1983, *ibid.* at p.186.

4.1 The rationale for public opinion as an input into the regulatory process

Many reasons are given for the justification of the inclusion of public opinion in regulatory decision-making. I have identified the four most commonly cited and discuss them below. They come with a couple of caveats, which are that the reasons given are not exhaustive and that they are overlapping and not mutually exclusive. The principal reasons given for the inclusion of public opinion in the regulatory process are:

- (i) It is in keeping with the central tenets of liberal democracy
- (ii) It legitimates IRA activity and is a measure of accountability for a regulatory stance
- (iii) Regulation which is responsive to public opinion leads to more effective output
- (iv) It raises levels of public trust in the regulatory body and the regulatory output

The sources of evidence to support or detract from these arguments for inclusion are analysed in this thesis in terms of both the rhetorical use of public opinion and the public opinion input in practice. These four issues are now addressed in turn as a means to tease out the underlying arguments.

4.1.1 The inclusion of public opinion in the regulatory process is in keeping with the central tenets of liberal democracy

The first of the reasons given for the incorporation of public opinion in regulation is that it is in keeping with the central tenets of liberal democracy, that is, it is a critical part of a representative democracy. It is democratically laudable to invite the public to participate in decision making. Indeed, the literal meaning of ‘democracy’ is rule by the people (from the Greek ‘demos’, people and kratos, rule). Classical thinking on democracy held that for a democracy to function there had to be direct citizen participation. Rousseau argued that for citizens to be truly sovereign they should gather in a sovereign assembly. However, it is evident that it is not feasible for each citizen of a nation to have his or her opinion heard on every issue. Dahl refers to this as the problem of the ‘arithmetic of participation.’²⁰⁰ The solution created to solve this problem is representative democracy which is defined by Birch as:

²⁰⁰ Dahl, Robert A. ‘Democracy and its Critics’, (Yale University Press, 1989) passim.

‘.....one in which representatives of the people share, to a significant degree, in the making of political decisions.’²⁰¹

Representation by the elected elite still requires that a balance is struck to ensure that the citizens of the democracy feel like participants in the decision making process and not alienated from it. Interestingly, it is often questioned whether public consultation is necessary as a means to enhance democratic and accountable process. There is the view that once an election takes place, the elected are the public’s representatives and as such there is no requirement to consult further. In support of this view, an MP at a public meeting I attended stated that:

‘If Parliament decides that something should be lawful and subject to regulation then it ought to be done. Certain decisions if well debated in Parliament shouldn’t be subject to veto by public consultation.’²⁰²

However the push for increased participation and public involvement in regulation is showing no signs of slowing down. Indeed the recently updated Code of Practice on Consultation constantly reiterates the Government’s commitment to effective consultation and it states therein that the code ‘should help improve the transparency, responsiveness and accessibility of consultations.’²⁰³ On the practicalities of attempting to listen to the public, Dahl states that:

‘To propose that all persons significantly affected by these decisions should be included in the process would seem fanciful: that they should be included as political equals, democratic citizens if you like, seems an even more utopian claim.’²⁰⁴

The issue of delimitation of those consulted thus becomes central to the regulators; in later chapters, the questions of who those consulted are, and to what extent they are representative of public opinion, are analysed.

Underlying these questions of democracy is the value of the public opinion input, and one criticism often levelled against the process, which was highlighted in chapter 2, is

²⁰¹ Birch, A. H., ‘Representative and Responsible Government: An Essay on the British Constitution’, (Unwin Brothers Limited 1964) at p.13.

²⁰² An MP at Public Meeting – Manchester University Biolaw Conference, July 2008 – he asked not to be named in this quote.

²⁰³ HM Government, BERR, ‘Code of Practice on Consultation’, (3rd version) July 2008.

²⁰⁴ Dahl, Robert A., ‘A Democratic Dilemma: System Effectiveness versus Citizen Participation’, Political Science Quarterly, Vol. 109, No.1, (Spring 1994), pp.23-34 at p.32.

that the public have low levels of knowledge of the issues under deliberation (such as genomics), and therefore the public input would not be worthwhile. In this thesis, data was collected from interviews with regulators suggesting that they do not generally question whether the public opinion data they use is based on informed opinions. Fishkin argues that ‘an ordinary opinion poll models what the public thinks, given how little it knows.’²⁰⁵ It is argued in some quarters that some citizens are more qualified than others to make decisions, thus leading to expert-lead consultation. Public consultation and deliberation are important for maintaining the tenets of democracy where all citizens are equal in the decision-making process. However if the resulting public opinion data identifies an uninformed public then the participation process may be deemed futile. Whether findings of this nature are then utilised by the regulators in their decision-making, regardless of their limitations, is addressed in the case-study chapters. It should be noted however that to some degree the consultation process, the survey, is bound and delimited from the outset by the IRA, since it is argued that only responses which are intelligible and digestible by the regulatory system are valid. The level that this is deemed manipulation is arguable. Dahl argues processes should be put in place to enable the citizens to educate themselves in order to be able to participate fruitfully.²⁰⁶ It is not only the issue of whether the public are adequately educated to respond to a particular question on a topic, a further issue is whether they are actually interested and wish to be involved in the decision-making process. Finally, it is worthwhile noting that the process of deliberation itself may enhance public awareness of issues such as genomics.

²⁰⁵ Fishkin, James S. ‘Democracy and Deliberation: New Directions for Democratic Reform’, (Yale University Press, 1991) at p.1.

²⁰⁶ Dahl comments on this matter in ‘A Democracy and its Critics’, (1989 Yale University Press) at p.112.

4.1.2 The inclusion of public opinion in the regulatory decision-making legitimates the Independent Regulatory Agency's activity

The purpose of this section is to give an overview of the capacity of public opinion to enhance the performance of regulatory bodies in terms of credibility, accountability and legitimacy. As already discussed, in the last chapter, an IRA functions because a level of discretionary control has been passed to it from central government. This discretionary control may come in the form of a legislative mandate or it may be a looser relationship. Even with the existence of a legislative mandate, this discretion is necessary because, as Fessler and Kettl state: 'no legislature could ever specify all the factors that administrators must weigh in making decisions'.²⁰⁷ The discretionary zone mentioned in chapter 4 is relevant here as regulations and guidance exist on when and how an IRA should undertake consultation, yet such regulations cannot dictate the level at which an IRA must respond to the public opinion data. Secondly, discretion within the system gives an IRA the opportunity to use public opinion as a tool and to manipulate the findings. It is very difficult to undertake a post-facto examination of how public opinion data was utilised by regulators because a large proportion of decision making happens in committees and is successfully hidden between the lines of the minutes of such meetings. Meeting reports examined in this thesis may offer insights but it should be borne in mind that they can often be misleading.

IRAs are also termed non-majoritarian agencies due to the fact that the regulators are neither elected nor directly supervised by the government. This facet combined with the levels of discretion pertaining to decision-making which these agencies can assume imbues them with a level of power. Critics argue however that IRAs lack accountability and create a democratic deficit in the regulatory process. It is argued that IRAs attempt to carve out a credible position in an attempt to gain legitimacy. Scott pertains that the most usual means of achieving legitimacy is through a level of demonstrable accountability.²⁰⁸ Thus the enhancing of public opinion as an input into the regulatory process is a mechanism which imbues both this level of demonstrable accountability

²⁰⁷ Fessler, James W. & Kettl, Donald F. 'The Politics of the Administrative Process' (2nd Edition) Chatham House Publishers, Inc. 1996 at p.372.

²⁰⁸ Scott, Colin 2000 cited by Morgan, Bronwen & Yeung, Karen, 'An Introduction to Law and to Regulation: Text and Materials' (Cambridge University Press 2007) at p. 228-9.

and in doing so can aid an IRA's legitimacy. One argument is that legitimacy occurs at the point of public acceptance of the activities and decisions made by an IRA. It is useful however, to examine this in terms of Baldwin's five potential claims for legitimacy:

- (i) The legislative mandate claim;
- (ii) The accountability or control claim;
- (iii) The due process claim;
- (iv) The expertise claim;
- (v) The efficiency claim.²⁰⁹

Baldwin argues that government processes may be regarded as legitimate if they can fulfil one or more of these claims. In practice there are high levels of interaction between the claims and variations in the weighting devoted to each. The regulatory agencies analysed in the case-study chapters have a legislative mandate, yet there is always the problem of an IRA moving beyond this mandate by stretching their discretionary powers so that in some cases there is a blurring of the lines of control between central Government and the IRA. Indeed, the HFEA has been taken to judicial review for just such a claim that it was behaving *ultra vires* with regard to PGD for tissue-typing in the 'saviour siblings' cases. This case is discussed further in chapter 6 and it must be stressed that the HFEA were not found to be acting beyond their legal mandate.²¹⁰

The accountability or control claim is pertinent here because it is invoked when an IRA claims that they are basing their decisions on public opinion or 'more narrowly-defined groupings as conduits for the democratic voice'.²¹¹ This concept of responding to 'more narrowly-defined groupings' is comparable to the understanding of public opinion as the channelling of the public voice by interest groups. While on the one hand the IRA could argue that they are behaving in a responsive and representative manner in that they have consulted stakeholders and are enacting transparent decision-making structures, Baldwin notes that regulation by IRAs is open to the criticism of being

²⁰⁹ Baldwin, Robert, 'Rules and Government', (Oxford University Press, 1995) at pp.41-46.

²¹⁰ Legal reference to JR -

²¹¹ Baldwin 1995 op cit. at p. 43.

unrepresentative because the system is not controlled by an elected body.²¹² The due process claim relates to the ideas of procedurally just activities which uphold individual rights and interests. However, it does not always follow that the corollary of a system of just or democratic processes is a set of efficient and morally just outcomes. The fourth claim which may be held by an IRA is that the decision-making is credible and legitimate because it is based on expert opinion. Within the regulation of genomics it is indeed the case that the role of scientists and clinicians is sought, often in conjunction with public participation or consultation exercises, and the weighting given to each is explored further in the next two chapters. However, a heavy reliance on expert judgement as the basis for regulatory output may not be deemed representative and can lead to the public not understanding the bases for decisions. Furthermore, as Baldwin highlights, where there is conflict between the experts, as is the case in GM foods, this can lead to a further weakening of the IRA policy position or regulatory output.²¹³

The final claim an IRA may make is that it is behaving in an efficient manner. Baldwin discusses two ways that this can be claimed: that stated objectives are achieved in an effective manner; and that economically efficient actions are being taken.²¹⁴ Baldwin contends that these claims are the most contentious, and it seems apparent that they are indeed a difficult means of inculcating public acceptance or engendering credibility to a regulatory agency, partly due to the problems of measurement of, for example, an IRA's objectives.

It is thus apparent that in addition to the concept of the inclusion of public opinion in the making of regulation, there are other mechanisms and processes which an IRA may utilise as a means to enhance its legitimacy. The central question is: does the public per se prefer a system of responsiveness to their desires, however that is divined, to one based on reference to elite or stakeholder opinion? What is evident is that IRAs such as the HFEA and FSA publish the findings of consultations and public meetings in conjunction with their policy or regulatory documents as a means to show that they are responding to the public voice. In relation to the weighting given to the five claims for

²¹² Baldwin 1995 op cit. at p.44.

²¹³ Baldwin 1995, op cit. at p.46.

²¹⁴ Baldwin 1995, op cit. at p,46.

legitimacy posited by Baldwin, it is argued here that in the sphere of genomics the second claim, the accountability or control claim, is privileged. By this it is argued in this thesis that public opinion is utilised more heavily as a mechanism to denote legitimacy and credibility to the IRAs dealing with issues relating to genetic technologies. However, it is additionally the case that in areas of contested and complex science and technology there is a greater resort by the IRA to expert opinion, and that this is a feature of policy making in the field of genomics. The capacity of an IRA to argue that the decision-making was deferred to public opinion allows arms-length bodies to mitigate their responsibility or to shift blame for the regulatory stance, and this is a common feature of IRAs. Hood talks of blame management and blame avoidance in relation to this phenomenon.²¹⁵

The final point to make here in relation to the strength of the argument that the role of public opinion is a valuable input in the regulatory process is that while regulators themselves may back up this contention on the grounds of democratic principles, they would not argue openly in favour of it being used to enhance the role of their own regulatory body. However, while raising the latter argument may be viewed as politically damaging, the impact of enhanced legitimacy of an IRA's activities may not be. For instance, the legitimisation of the regulatory position may result in reduced anxiety over novel technologies.

4.1.3 The inclusion of public opinion in the regulatory process leads to more effective regulatory output

The third argument given in support of feeding public opinion into the regulatory decision-making is that it leads to more effective regulatory output. Proponents of this would argue that the consulted public provide 'the creative reservoir' which introduces novel solutions and new approaches to regulatory problems which would have not been envisaged by the regulators and administrators alone. However, we can ask how realistic the 'creative reservoir' idea is. It may be more the case that this is the result of consulting stakeholders, that is, people who know the object and area of regulation, and not the public who may have low awareness and knowledge of the subject. It is purported that solutions resultant from public consultations are not conducive with the

²¹⁵ Hood, Christopher, 'The Blame Game: Spin, Bureaucracy and Self-preservation in Government', (2011) Princeton University Press, *passim*.

regulatory process. Keynes writes that one of the problems faced by regulators is that of coping with the mass of information made available to them; public opinion is sometimes a knotty issue which adds to this mass. Keynes states that:

‘there is nothing a Government hates more than being well informed: for it makes the process of arriving at decisions much more complicated and difficult’.²¹⁶

4.1.4 The inclusion of public opinion in regulatory decision-making increases public trust in the IRA and the regulation

‘A system – economic, legal or political – requires trust as an input condition. Without trust it cannot stimulate supportive activities in situations of uncertainty or risk’.
(Luhmann)²¹⁷

The final argument posited here for the inclusion of public opinion in regulation is that it enhances public trust in the IRA and the regulation per se. While this issue evidently overlaps and falls under the issues of legitimacy and accountability of regulatory agencies, it has been listed separately in order to highlight its importance in the process. A further element to this argument would be that the public needs to know that public participation processes are taking place in order to place trust in the regulatory system. The public may therefore have a level of expectation that such would occur and a regulatory body would be found lacking if it was discovered that regulation was being produced and enacted without recourse to public opinion on the matter.

With reference to regulation per se, a level of trust in the regulation is usually taken to be a prerequisite to the idea that a causal link can be made between public attitude and regulation. Regulation will only offer some level of reassurance if the public trust its capacity to remedy some problem. Public trust in regulation has been widely discussed in academic circles and it is useful to take Weber’s comments on ‘intellectualised rationalisation’ as a starting point.²¹⁸ Intellectualised rationalisation arises as a result of

²¹⁶ Keynes, John Maynard quoted in Skidelsky, Robert (1992) ‘John Maynard Keynes: A Biography: The Economist as Savoir 1920-1930’ Macmillan: London p.630.

²¹⁷ Luhmann, N. ‘Familiarity, Confidence, Trust: Problems and Alternatives’ in ‘Trust: Making and Breaking Cooperative Relations’, Gambetta, D., (Ed), 2000 at www.sociology.ox.ac.uk/papers/luhmann94-107.doc

²¹⁸ Poortinga, Wouter and Pigeon, Nick F. ‘Trust in Risk Regulation: Cause or consequence of the Acceptability of GM Food?’ Risk Analysis, Vol.25, No.1, 2005. Poortinga & Pigeon offer a wide list of sources including; Renn & Levine, 1991; Kasperson et al, 1992, Freudenburg, 1993; Slovic, 1993.

the increasing complexity, differentiation and specialisation of society and refers to the process by which we can make use of a technology without needing to know explicitly how it functions. We place this kind of trust in people and technologies on a daily basis in order to function in modern society. Figure 5 which I have produced using the BSA survey data (2003), shows attitudes to four public trust statements. The concept of intellectualised rationalisation can be linked to a trust statement from the BSA survey of 2003 in which fifty per cent of people stated that they strongly agreed or agreed that *'modern genetic science is so complex that public involvement in policy decisions is not realistic'*.²¹⁹ I contend however that the gap between the layperson and the scientist is not greater in this realm than in relation to, for example, nuclear power, an area where there is no doubt that the public feel themselves to be important in the creation of policy.

Figure 5: UK Public Trust (2003)

(n=3,272, the 'don't know' answers have not been included)

Trust Statement	Agree strongly	Agree	Neither Agree nor Disagree	Disagree	Disagree Strongly
Those in favour of new developments in genetic science cannot be trusted to act in society's interest	7%	27%	35%	23%	2%
Rules set by Government will keep us safe from any risks linked to modern genetic science	2%	21%	27%	36%	8%
Modern genetic science is so complex that public involvement in policy decisions is not realistic	7%	43%	18%	22%	4%
Genetic scientists only tend to tell us what the people paying their wages want us to hear	10%	34%	15%	10%	0.5%

It is evident from the table above that mistrust is more prevalent than trust.

Unfortunately, these trust measures were not included again in the BSA survey so no measure of change over time can be analysed. However, there is one question which

²¹⁹ Question 810 of British Social Attitude Survey, 2003.

was repeated in the BSA survey in 1999 that was repeated in 2003 which relates to levels of public confidence in the government's regulation of biotechnology. This showed a negative score of -4 in 1999, which represents a confidence deficit. By 2003 this figure had risen to 8, indicating a small confidence surplus.²²⁰

Eurobarometer use the same statement relating to trust in government regulation of biotechnology, which Gaskell et al have analysed in a different way but which also shows a rise in trust from 1999 to 2005. Eurobarometer includes two additional statements relating to trust in scientists carrying out research in biotechnology and trust in industry developing new products with biotechnology. Both of these also show significant increases in trust, but especially the latter which rises from -12 in 1999 to 20 in 2002 and to 41 in 2005.²²¹ Freudenburg argues that 'recreancy and trustworthiness have been shown by systematic research to be key factors behind the increasingly toxic social chemistry that has been associated with an ever-increasing range of technologies'.²²² Bier warns that in cases of distrust, it is important to listen to the concerns of the public prior to giving out any new information. Bier adds that giving information in order to allay public concerns often backfires, as it is viewed as not taking those concerns seriously. Hence this kind of policy is more likely to increase distrust than to engender trust.²²³ This view is pertinent in relation to GM foods where labelling regulation is the focus in recent years which would constitute an increase in information to the public and evidently is in opposition to Bier's advice. The impact of labelling regulation on public opinion is examined in the next chapter.

Lofstedt contests that there is a direct correlation between levels of public trust in a regulator and the perception of that regulator as a tough or weak player. He continues

²²⁰ Gaskell, George, Allum, Nick, Bauer, Martin, Jackson, Jonathan, Howard, Susan, Lindsey, Nicola (2003) 'Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002', Life Sciences in European Society Report: London School of Economics and Political Science.

²²¹ Gaskell et al 2006, op cit. at p.46.

²²² Recreancy refers to the failure of experts or institutions to carry out a duty which they have been explicitly entrusted to do. See further; Freudenburg, William R. 'Institutional Failure and the Organisational Amplification of Risks: The Need for a Closer Look' Chpt.4 in Pidgeon, Nick, Kasperson, Roger E. and Slovic, Paul, (Eds), 'The Social Amplification of Risk, (Cambridge University Press, 2003) at p.107.

²²³ Bier, V.M. 'On the State of the Art: Risk Communication to the Public', Reliability Engineering and System Safety, 71, 2001 pp.139-150.

that new regulatory agencies may improve their public perception by the introduction of strict, prohibitive regulation which shows that they are not industry lapdogs and likely to be the subject of regulatory capture.²²⁴ This argument is reviewed in terms of its relevance in relation to the two case-studies. Lofstedt adheres strongly to the view that public involvement in the policy process helps in the process of public acceptance, and he contends that this has been a fashionable view since the late 1980s, following academic research in the UK and US.²²⁵ From this research Lofstedt notes two reasons why public involvement increases public trust: firstly, it gives the public or stakeholders ownership of the process, and secondly, if the consultees feel that they were listened to then they are more likely to accept the regulatory position.²²⁶ This latter reason is not without problems as there is a great difference between listening to comments from the participants of a public engagement exercise and incorporating such views into the regulatory policy position.

4.2 Responsive Regulation versus Regulating in the Public Interest

Skilful manipulation of the concepts of a public voice, the ‘public attitude’ and competing constructions of such occur on a number of political levels. Often, the regulators’ normative directions underpin regulatory development which they may equate with acting in the public interest. Paternalism is not, however, the same thing as the production of regulation which reflects public attitude. Regulators may struggle to reconcile their own interests with their perceptions of what would produce ‘good law’ in a moral sense. George Gallop argued that democracy entailed responding to the voters and not to ‘organised interests, elite opinion, experts or simply those who shout loudest’.²²⁷ In contrast, Warnock argues that:

²²⁴ Lofstedt, Ragnar E. 2007 ‘The Impact of the Cox-2 Inhibitor Issue on Perceptions of the Pharmaceutical Industry: Content Analysis and Communication Implications’, *Journal of Health Communication* vol. 12, pp.471-491 at p. 480-482.

²²⁵ Lofstedt 2007, *ibid.* cites Fischhoff 1989, 1995; Morgan, Fischhoff, Bostrom & Atman 2002; National Research Council (NRC) 1989.

²²⁶ Lofstedt 2007 *op cit.* at p.482.

²²⁷ Gallop & Rae 1940 cited here from Hood, Christopher, Rothstein, Henry & Baldwin, Robert, ‘The Government of Risk: Understanding Risk Regulation Regimes’ (Oxford university Press, 2001) at p. 90.

‘The law must not outrage the feelings of too many people; but it cannot reflect the feelings of them all. It must therefore be drawn with a view to the common good’²²⁸

Although the strong normative push that an IRA should incorporate public participation into its decision-making processes has been established, the IRA has a choice to respond to this public voice or alternatively to regulate in accordance with their own views which they may justify as being in the public interest.

It is argued by Hood et al that there is no correlation between responsive systems and public satisfaction with regulation. Hood et al note that that the public may not even be positive about regulation which they were initially calling for once it is imposed upon them. Such a scenario, it is purported, arises when the regulation called for produces unexpected side-effects, so that the novelty of the regulation wears off, the public become aware of these side-effects and their initial support for such a policy direction fades.²²⁹ The form and substantive content of regulation is therefore critical if it is the objective of policy makers and regulators to act in a truly responsive manner which moves beyond a notional half-hearted attempt to appease the public. The marrying of public attitudes to suitable regulatory output is not a straightforward process and Dicey goes so far as to argue that in certain instances there may not be a mechanism that can meet the change in regulation demanded by public opinion.²³⁰

Rousseau presents an idea that the ‘true’ public opinion is that opinion which is best for the public as a whole. This introduces an idea of paternalistic stewardship of the regulators, the Executive over the Demos. The idea is that regulation is determined by regulators who are acting in the public interest as opposed to responding to the wishes of the public. As Glynn et al argue:

‘Since the quality of public opinion is so central to reaching such normative conclusions about the opinion-policy relationship, we should not dismiss policymakers’ failures to respond to public opinion as undemocratic. There can be cases in which policymakers feel they must make policy decisions which do not have public support because they feel that the public has been misled or manipulated or has not yet become fully informed about a policy at issue.’²³¹

²²⁸ Baroness Warnock, 1990

²²⁹ Hood et al (2001) op cit. at p.96.

²³⁰ Dicey, (1905) op cit. at p.72.

²³¹ Glynn et al at p.239

Further to this Feintuck, comments that ‘public interest will often appear to be an empty vessel, to be filled at different times with differing values’ yet in spite of the lack of a consistent definition, public interest continues to be discussed in debate and regulatory matters.²³² Indeed, to invoke the public interest in a debate adds an enormous sense of power and force to an argument even though it is evident that there may be little behind its use beyond a strategic rhetorical device. A regulator may argue that the public interest is a compromise between various competing interests, and this is described by Pal and Maxwell as the utilitarian approach.²³³ Pal and Maxwell state further that ‘the nature of regulatory decision-making imposes an obligation to be guided by a concept [the public interest] that by its very nature is nebulous and shifts case by case’.²³⁴ They continue by arguing further in relation to Canadian regulation that ‘a concept of the public interest that floats disconnected from what Canadians actually think will not be helpful’.²³⁵ Lee contends that ‘the point is not that public opinion should be followed (even if public opinion were ever so monolithic that it realistically could be), but that it should be heard and addressed.’²³⁶

On responsiveness, Hood et al state that:

‘opinion-responsiveness is little if any more definite or reliable as a predictor of the content of regulatory regimes than the market failure hypothesis.....’²³⁷

Hood et al cite two reasons for this: there is no single way of listening to the public voice and secondly, they argue that in relation to the research they have conducted in risk regulation regimes, regulation is only partially opinion-responsive both in process and outcome. The first reason therefore relates to the various methods of gauging and analysing public opinion. In relation to the first of these points, this ties in with the debate over informed publics and the commonly made argument that surveys and opinion polls only record split second judgements often based on limited information.

²³² Feintuck, Mike, ‘The ‘Public Interest’ in Regulation’, (Oxford University Press, 2004) at p. 3.

²³³ Pal, Leslie A. & Maxwell, Judith, ‘Assessing the Public Interest in the 21st Century: A Framework’, Paper prepared for the External Advisory Group on Smart Regulation, (2003) at p.8.

²³⁴ Pal & Maxwell 2003, op cit. at p.4

²³⁵ Pal and Maxwell (2003) op cit.

²³⁶ Lee, Maria, ‘EU Environmental Law’ (Hart, 2005), pp.270.

²³⁷ Hood et al 2001, *ibid.* at page 91.

Hood et al suggest therefore that the opinion-responsiveness relates to how the opinion is sought, which I suggest is the wrong way to look at this.²³⁸ There are better and worse ways of gauging opinions but this is only one stage in the process. The second critical stage is whether the regulator chooses to respond to the data collected. This begs the question of how consistent regulators and policy-makers are across regulatory regimes in requesting and commissioning public opinion data to be collected. As already stated, this stage is significantly removed from the process of analysing and taking into account the findings of public opinion data.

4.3 Models of Opinion-Responsiveness

One may analyse the level of political attention devoted to a specific issue or sector in terms of the attention received from inter alia: the public, interest groups, industry, the politicians, regulators and the media. Studies often attempt to link these different agents in an effort to show the complexity of drawing casual relationships between them.

While it is evident that these agents do interact across attention cycles to varied issues, there are sometimes idiosyncrasies which highlight pronounced activity in one area which may be attributable to, for example, an abnormal level of public discontent with policy or a level of industry lobbying which cannot be easily ignored by policy makers. Technological developments have been marginalised in the attention cycles literature as triggers for a policy attention cycle. The study of attention cycles relating to specific sectors over time is valuable when combined with the role of the public in that it gives some indication of whether regulatory policy is having an impact. Political attention can be measured in terms of budgetary spend, resource allocation and legislative output.

One method of analysing attention cycles is according to the theory of punctuated equilibrium. While Baumgartner and Jones were not the first to adapt the concept of punctuated equilibrium from palaeontology to the field of political science, they did break ground in their application of the metaphor to policy cycles. Baumgartner and Jones refined the term to mean that punctuations in policy outcomes are the result of interactions between changes in the environment and activity from within the political system.²³⁹ Thus policy change may be the result of both endogenous and exogenous

²³⁸ Hood et al 2001, *ibid.* at p.91.

²³⁹ Jones, Bryan D. & Baumgartner, Frank R. 'The Politics of Attention: How Government Prioritizes Problems' (University of Chicago Press, 2005) at p. 5

events. Baumgartner and Jones argue that when issues first merit political attention there is often a growth of institutional structures. This structural set up will often remain in place for decades and as such tightly dictates participatory mechanisms. It is this process which succeeds in giving 'the illusion of equilibrium'.²⁴⁰ The theory of punctuated equilibrium attempts to give an explanation for the observed pattern of longer periods of policy equilibrium within sectors which are sometimes disturbed by punctuations. The punctuations to the equilibrium are shorter periods of volatility, change and instability.²⁴¹

In conjunction with their work on the punctuated equilibrium model, Baumgartner and Jones advocate that a policy subsystem should be conceived as dynamic and fluid, whereas the traditional and more static model of a policy subsystem consisted of interest groups, committees, and regulatory agencies which worked together to establish an equilibrium of interests. The element which Jones et al argue provides dynamism to the process is that of the disfavoured side in the policy subsystem and additionally includes parliament, political leaders and parties and public opinion.²⁴²

Jones and Baumgartner introduce the idea of 'catch up' whereby once an idea has succeeded in being given attention by the primary policymaking institutions, it is necessary for punctuations to occur in order to 'catch up with changing reality'.²⁴³ This is a primary feature of the attention cycle of genomics. To develop the idea further, Jones et al argue that the focus of policy attention cycles should be upon information processing and the means by which 'institutional procedures constrain policy reactions to the flow of information'. It is imperfections in the information flows through the policy process that lead to punctuations.²⁴⁴ Jones and Baumgartner's concept of disproportionate information processing is combined with the idea that political systems respond to 'signals' and this is the basis for variation in attention cycles. All such

²⁴⁰ Baumgartner, Frank R. & Jones, Bryan D. 'Agendas and Instability in American Politics', (University of Chicago Press 1993)

²⁴¹ Baumgartner & Jones 1993, op cit. at p.4.

²⁴² Jones et al 2005 op cit. p. 5

²⁴³ Jones et al 2005, ibid. at p.6.

²⁴⁴ Jones et al 2005 ibid. p.4-6.

signals are characterised by uncertainty and ambiguity and are information flows. Critically, as Jones et al note, governments will often overact to signals because of these characteristics of uncertainty and ambiguity.²⁴⁵ The issues raised by genomics are rich in uncertainty and ambiguity so this plays in to the sector analysed here. Critically, the seriousness or potential harm raised by an issue is no determinant of its uptake by the policy system. Issues are promoted by political agents and mobilised by public opinion or interest groups resulting in certain issues receiving political attention which may arguably be undeserved, or conversely issues of significance may be blocked from the agenda.

A second model of opinion-responsiveness is the public thermostat model. Following empirical research in the USA, Soroka and Wlezien highlight a correspondence between public opinion and policy-making, showing that there is a two-way relationship between policy makers and public attitudes. They argue that:

‘A responsive public behaves much like a thermostat. That is, the public adjusts its preferences for more or less policy in response to what policy makers do’.²⁴⁶

Interestingly, they suggest that the British public are notable and idiosyncratic in their responsiveness.²⁴⁷ As such, a new variable is at play here influencing the workings of the regulation and public attitudes. Evidently, without such a level of public responsiveness, there would be little incentive for policy makers to act in accordance with public attitudes. Soroka et al advocate that effective democracy depends upon a responsive public and that policy budget changes are symbolic of shifts in public attitudes.²⁴⁸

Kingdon presents the idea that an issue has its own specific attributes which are influential in its treatment and have an effect on the level of political attention received and the type of policy response given. Kingdon outlines some attributes which will help

²⁴⁵ Jones et al 2005 at p.8.

²⁴⁶ Soroka & Wlezien, 2005 *ibid.* at p.667

²⁴⁷ Soroka et al, *ibid.* at p.666.

²⁴⁸ Soroka, Stuart N. & Wlezien, Christopher, ‘Opinion-Policy Dynamics: Public Preferences and Public Expenditure in the United Kingdom’ *B.J.Pol.S.* 35, pp.665-689 at p.666-667. Soroka and Wlezien measure the interaction between measures of budget allocation to policy and public preferences for spending in certain policy areas. These variables are analysed longitudinally.

an issue gain political attention. These are: the attractiveness of an issue to politicians in terms of vote drawing capacity; the potential of an issue to be defined as cause for public concern; issues resulting from dramatic innovations which have an impact upon humans; and issues which relate to enormous promise in areas of food and health²⁴⁹. It is evident that genomics ticks all of these boxes and this, combined with the features it exhibits of uncertainty and the framing of the issues within the sector in terms of public risk, have promulgated the sector to a high level of recent sustained political attention.

Felstiner et al advocate a three stage process in the transformation of a private grievance to a public concern and then a political issue. The stages are: naming, blaming and claiming.²⁵⁰ The first stage is naming the problem and thus involves constructive framing of the issue. I argue here in relation to genomics that such framing does not need to be constructed by the public but that a problem may be framed and defined prior to the presentation to the public, by for example, interest groups or the industry per se. Industry may wish to promote regulatory activity in a bid to legitimise its activities and perhaps to see off competitors. The second stage in the transformation of an issue into a political grievance is to isolate a target of blame. In relation to genomics, the subject of blame has often been industry, for example, in the case of GM food and crops Monsanto was widely blamed as a harbinger of potential harm to human health and the environment.

Felstiner's third stage is that of claiming and is broken down further into five components for success: ambiguity, social significance, temporal relevance, non-technical issue definition and the absence of categorical precedence. All of these factors are central to the framing of genomics as a political issue, but it is to the issue of categorical precedence that I now turn. As discussed in chapter 3, if there is an absence of categorical precedence then policy makers are unable to draw upon policy learning and to manage it as they have done in the past or in relation to a similar issue. The argument that there is no categorical precedence is critical as a major justification for the high levels of political attention given to genomics. The idea is that the issues raised are singularly unique and that the technological developments pose unique problems about which regulators cannot draw upon the rule learning of earlier decisions.

²⁴⁹ Kingdon, John W. 'Agendas, Alternatives, and Public Policies' (Second Edition) (Longman 1995).

²⁵⁰ Felstiner, Abel & Sarat cited in Cobb & Ross 1997: TR doc.

Combined with the lack of rule learning is the fact that the technology is creating very critical social and ethical dilemmas and there are no frames of reference to be drawn upon. It is thus concluded and argued by the regulators that genomics needs novel and special regulatory handling as it is testing the cognitive limits of the existing structures, something which has been illustrated in the last chapter. One solution advocated by regulators is to give an enhanced role to the public in the policy deliberation of genomics. This policy position has been accepted as a *fait accompli*, yet surely it is open to debate. If each of the areas of genomics relates and falls under the areas of health, food or agriculture then why is the issue of categorical precedence being pushed so hard and who is doing the pushing? It is, I argue, this attribute above all others which is responsible for the sustained political attention to the technological developments of genomics. Indicators of attention come from a number of sources including structural measures, the institutional set up, the budget and the enormous policy and regulatory output.

4.4 The role of public opinion in triggering, shaping and gaining regulatory attention

‘As force is always on the side of the governed, the governors have nothing to support them but opinion’ (Hume²⁵¹)

While the ‘governors’ may have nothing to support them but opinion, it is the interpretation and construction of this opinion that is pertinent here. There is no doubt that public opinion is critical to the production of regulation and is often cited as both a trigger for regulatory attention and the rationale for regulatory change. Indeed, one justification given by regulators for the disproportionate attention devoted to genomics relates to the alleviation of public concern in terms of the appropriate ethical line to be taken. In these terms, policy makers make reference to the public in connection with the potential implications of technologies and public concern relating to, for instance, stem cell research and gene therapy. In this case, genomics is not ranked according to the priorities of the public’s ‘most important problems’ alongside issues such as

²⁵¹ Hume, *Essays*, vol.1, Essay 4 cited in Dicey, A.V. (1905) ‘Law and Public Opinion in England’, chpt.7 in Aubert, Vilhelm (Ed), ‘Sociology of Law; Selected Readings’, (1969, Penguin Books Ltd.) at p. 71.

housing, employment and crime.²⁵² However, the application of genomics may fall within the sectors of food and health which are valence issues and therefore carry some substantive political purchase. The manipulation of public opinion data is not, however, a recent phenomenon. There are many cases where policy ‘problems’ are not deemed resolvable by the regulators and in order for the problem to be removed from the political agenda there may be resort to a management of the indicators so that the problem no longer exists.²⁵³ As one of the principal indicators is a measure of public opinion then this is particularly pertinent.

Yet, we need to ask whether public opinion as it is generally constructed and interpreted is effective in policy making or whether the political manipulation of public participation and engagement exercises negates its force. I do not wish to critique and outline the inherent flaws of deliberative processes here; it is sufficient to note that when a measure of public opinion is cited it is open to debate on a number of levels. As discussed in chapter 2, not least, the belief that individuals present a temporary attitude for the purposes of surveys and participatory processes.²⁵⁴ In this sense it is postulated that ‘attitudes’ don’t exist, people make attitude reports or ‘survey responses’.²⁵⁵

Cobb & Ross differentiate between the public agenda and the formal agenda. The formal agenda is said to have three characteristics: firstly, there must be some form of objective evidence that a problem exists. This is usually in the form of survey data, a governmental study or statistics related to the problem, for instance, crime or housing. The second characteristic of the formal agenda is that it must have made the public agenda, thus the public believes that there is a problem which requires action. Finally, the third feature has a comparative element in that the government will question

²⁵² For an explanation of the ‘Most Important Problem’ cf: Wlezien, Christopher, ‘On the Saliency of Political Issues: The Problem with ‘Most Important Problem’ Electoral Studies, Vol.24, Issue 4, December 2005, pp.555-579.

²⁵³ Stringer, Joan K. & Richardson, J.J. ‘Managing the Political Agenda: Problem Definition and Policy Making in Britain’ Parliamentary Affairs vol.23, 1980 pp.23-39 at p.29.

²⁵⁴ See further: Wilson & Hodges 1991 cited in Zaller, John R. ‘The Nature and Origins of Mass Opinion’ (Cambridge University Press, 1992)

²⁵⁵ Zaller 1992 *ibid.* at p.118.

whether such an issue is already on the formal agendas of those nations with similar social systems.²⁵⁶

In relation to agenda setting and attention cycles, we need to break down the public into different components, thus we have the 'attentive public' and the 'mass public'.²⁵⁷ In the case of genomics, the public referred to in regulatory debate are often the patients or consumers. Thus, should we only consider the public attitude at the point of a choice regarding whether to take up or not the outputs of genomics? As Sturgis & Allum highlight, the measure of public opinion of new and emerging technologies is particularly difficult as most members of the public have little knowledge of them.²⁵⁸

One presupposes that in order for regulators to recognise any kind of prevailing attitude, it is necessary to have a stable attitude mood which is easily identified by polls and surveys. Two important factors are the level of polarisation and the stability of the attitude over time.²⁵⁹ Dicey introduces the concepts of counter-currents and cross-currents of opinion. Counter-currents may act as a check upon the prevailing dominant opinion, and may delay a reform or an innovation. In some circumstances, the effect of this counter-current may be strong enough to delay the reform for so long that it is not put into effect, or by the time the reform is carried into effect, it has changed dramatically from the original form.²⁶⁰ Cross-currents do not directly oppose the dominant opinion, but may deflect or modify the dominant prevailing opinion.²⁶¹

Gauging the prevailing public attitude is an enormously complex task. It is argued that there is a stark contrast between opinions which reflect peoples' snap judgements based on limited information and opinions sought from people possessing a greater knowledge base. Additionally, the response to public attitude by the regulators may take many

²⁵⁶ Cobb & Ross, 1997, 'Cultural Strategies of Agenda Denial', University of Kansas Press, Chpt. 1, p6.

²⁵⁷ Cobb & Elder 1983 cited in Cobb & Ross 1997 op cit. at p.7

²⁵⁸ Sturgis, Patrick and Allum, Nick, 'A Literature Review of Research Conducted on Public Interest, Knowledge and Attitudes to Biomedical Science', (Wellcome Trust 2006) at p.2.

²⁵⁹ Hood et al, op cit. at p.97

²⁶⁰ Dicey, A.V. 'Legislation, Law and Public Opinion in England' (1905) in Aubert, Vilhelm, (Ed) 'Sociology of Law; Selected Readings', (1969, Penguin Books Ltd) at p.78.

²⁶¹ Dicey (1905) at p.79.

different forms. Van den Burg comments that there is often agreement to regulate without there being any consensus on the substantive content of such regulation. This, he argues, leads to vague and ambiguous regulation as policy-makers struggle to respond to public opinion. Such regulation ‘does not rest on very principled positions and often changes substantially during the public debate’²⁶². It is contended in Chapter 6 that this is in common with the earlier GM labelling regulations. Hood et al comment that regulators themselves are ambiguous about the definition of ‘public attitude’. Indeed, they argue further that policy makers appear more likely to respond to protesters’ and critics’ views than to attempt to establish the preferences of the public more widely.²⁶³ This has also been a point made in relation to GM foods, where it is argued that the section of the public opposed to GM foods are consistently taken to be the dominant public, even though in more recent years this is not the case as will be shown in Chapter 5.

A further issue relates to the marrying of public attitudes to suitable regulatory output. Dicey raises this issue when he argues that there may not be a mechanism that can meet the change in regulation demanded by public opinion.²⁶⁴ I believe this is the case for GM foods where only the EU de facto moratorium fully met the remit in terms of responding to the dominant public attitude. Hood et al describe a scenario where regulators respond to the public mood but where there are side-effects as a consequence of regulatory short-falls: thus as the novelty of the regulation wears off, the public become aware of these side-effects and their initial support for such a policy direction fades.²⁶⁵ The form of regulation is therefore critical if it is the objective of policy makers and regulators to act in a truly responsive manner which moves beyond a notional half-hearted attempt to appease the public.

Regulatory output plays a significant role in the removal of an issue or lowering of its political importance: it may act as a mechanism to provide reassurance; it may comfort the public simply by looking rational or modern; it may appease certain factions or form

²⁶² Van Den Burg, op cit. at p. 33

²⁶³ Hood et al (2001), op cit. at p.91

²⁶⁴ Dicey, (1905) op cit. at p.72.

²⁶⁵ Hood et al (2001) op cit. at p.96.

a compromise between factions. Bernstein's life cycle model is pertinent to this discussion. This model is based upon the premise that regulation is produced in response to disaster, which may be interpreted as scandal or catastrophe. It is feasible to argue that the model could be applied to the high levels of opposition to GM foods in the late 1990s. These disasters become means by which to bypass traditional regulatory agenda setting; regulators are forced to react to them. Bernstein's model includes the requirement of an external catalyst which triggers the public or the legislators and propels the regulatory process into action. A persistent, high level public mood could be interpreted as such a trigger. It is anticipated that this mood would then diminish in response to the implementation of appropriate regulation. The critical point in this model is what happens subsequently to the nature of the regulation. Bernstein purports that the regulators respond to subsidence of the public opposition by adapting the regulatory output accordingly.²⁶⁶

4.5 Conclusions

This chapter has examined the theory surrounding the interaction between public opinion and regulation. It is clear that the policy and regulatory approach relating to genomics is still in a state of flux reflecting the speed of technological development. The products and techniques emerging from genomics present novel issues for policy makers to deal with and are often difficult to incorporate within a predetermined system. The structural limits of the regulatory system are being stretched to accommodate the novel objects of regulation. In addition to the speed of technological advances is the subsequent and equally rapid commercialisation of products. There are several standard accepted types of policy change and these include: ideas, interests, nature of policy issues, policy and political actors, institutions, socio-economic conditions and public opinion. I wish to add technological developments to this list with a nod to Capano and Howlett's advice that one should note the favouring of one driver over the others.²⁶⁷ An additional factor is that it is argued that the technology in question is still in a state of development and transformation and has not yet reached 'closure'. This is mirrored in

²⁶⁶ Bernstein M.H. 'Regulating Business by Independent Commission', (Princeton University Press, 1955) cited in James, Oliver 'Regulation inside Government: Public Interest Justifications and Regulatory Failures', *Public Administration*, Vol.78, No.2, (2000) pp.327-342 at p.335-6.

²⁶⁷ Capano, Giliberto & Howlett, Michael, 'The Determinants of Policy Change: Advancing the Debate', ECPR Workshop, Helsinki 2007.

the framing of the issues in the public arena.²⁶⁸ Technology does embody specific forms of power and authority and the social construction of technological developments means that it can be seen as a political artefact.²⁶⁹ Thus in the context of attention cycles, it is interesting to assess the control that technology can exert upon the public and the regulatory system.

Levels of congruence between public opinion and regulation differ across issues and sectors. I wish to isolate the idiosyncrasies of the regulation-opinion inter-relationship identifiable in the regulation of genomics. Schattschneider's argument about the scope of conflict is an area that I wish to test in the course of this thesis. He argues that:

'On issues about which the public has more well-defined opinions and shows more concern, where the scope of conflict is broad, policy tends to move in harmony with public opinion'.²⁷⁰

It is interesting to address these thoughts in relation to the case-studies of prenatal testing and PGD and GM foods in the next chapters. In addition, in the next couple of chapters, the opinion-responsive models outlined above are reviewed in terms of how they relate to the mapping of the interactions between regulation and public opinion.

²⁶⁸ Cheveigné, Suzanne de, Einsiedel, Edna and Hampel, Jürgen, 'Spare Parts for Human Bodies', Chpt.3 in Gaskell & Bauer 2006 *ibid.* at p.29.

²⁶⁹ Winner, Langdon, 1980 'Do Artifacts have Politics', Chpt. 1 in MacKenzie, Donald & Wajcman, Judy, 'The Social Shaping of Technology' (2nd Edition) (Open University Press, 1999) *passim*.

²⁷⁰ Page, Benjamin I. & Shapiro, Robert Y. 'Effects of Public Opinion on Policy', *The American Political Science Review*, Vol. 77, No. 1 (March 1983), pp.175-190 at p.182.

Chapter 5

The Interaction between Public Opinion and the Regulation of Genetically Modified (GM) Foods

5.0 Introduction

It is now well over a decade since the issue of GM foods was thrust onto the political agenda and in many senses there has been a regulatory deadlock ever since. The crux of the issue remains the tussle between the biotech industry and producers who wish to open up the UK markets to GM products and those sections of the public who are concerned over the safety of GM foods. The regulators are forced to balance the competing demands of protecting the public while at the same time maintaining a level of access for the biotechnology companies to the European markets. Without some level of regulatory resolution GM foods will remain problematic. Over the last couple of years, it has become increasingly difficult for farmers to get hold of non-GM animal feed and this shortage, and this, combined with an increased public awareness that products in our supermarkets contain ingredients from animals fed GM food, has led to commentators stating that this issue will reach a head in the next five years. Keith Hawkins' view is very pertinent; he was the Director-General of the British Retail Consortium at the time of these comments:

'There is an issue coming to the boil that, when it does, will dwarf all else – the rehabilitation of GM food. The science has moved decisively in its favour, while the government is hoping someone (the industry) will take the plunge and start selling GM lines again. When that happens the tabloids will scream, flat earthers will rage, Prince Charles will make a speech. But it's coming, all the same'.²⁷¹

For this reason, it is argued in this thesis that GM foods is an incredibly rich choice of case-study and offers policy makers insights into the reasons why regulation has not managed to placate public concern. The relationship between public opinion and regulation is absolutely central to any discussion of the GM food issue.

A Defra official stated in interview that: 'GM is a lightning rod for other novel technologies'. This provides a further reason why it is important to revisit the regulation of GM foods, which is the argument that this case-study will throw light on

²⁷¹ Hawkins, Keith, 'Troubles Galore and GM Food too!' *The Grocer*, 25th January 2008.

the best ways to regulate new technologies. Synthetic biology is described as the ‘new GM’ and indeed currently falls under the same regulation as GM.²⁷² There is a commonly held belief that lessons learned from the GM food case could be applied to future technologies. Here it is asked, what are these lessons and how can the application be made? Indeed in April 2011, The FSA warned that ‘new nanotechnology-based food products risk being rejected in a similar way to GM foods unless they start engaging with consumers over their perceptions of the risks involved’.²⁷³

Central to any discussion of GM foods is whether the products cause harm, and this hugely contested area is the opening for this chapter. Difficulties abound in attempting to give a balanced overview of the debate as there are scientists on both sides of the argument. What is clear is that the debate over the harm posed by GM foods, be it perceived or actual, is absolutely critical to how the regulation has been enacted. The lack of consensus on the issues of harm and risk, while colouring the regulatory approach, has also led to public confusion and anxiety. Indeed, without the idiosyncratic reaction of the European public to GM, we would probably have adopted a regulatory system more on a par with that adopted by the USA. In the USA, the general food regulations have been extended to include GM foods, and hence GM foods as a category are not as distinctive as they are in the EU. Following the discussion of contested harm, the regulation is set out and it is apparent that in the UK there has been a high level of special regulatory handling of GM relative to other novel foods. The regulation is discussed in relation to two time periods which are basically split by the ending of the moratorium on GM foods entering the EU in 2003. The first period covers the years from 1999-2003 and looks at the early labelling regulations and the events leading to the moratorium, whereas the second period examines the regulation post-moratorium and the subsequent second phase of labelling regulations: 2003-2011. These two periods are later mirrored in the discussion of public opinion data. They show significant differences in the public opinion and the responsiveness of the regulation to such. Throughout the chapter the five understandings of public opinion

²⁷² Although my colleague Steve Hughes believes that Synthetic biology is ‘old GM’ if relating to putting cassettes into plants but could be called the new eukaryotic GM! Jim Haseloff discussed synthetic biology as the next generation of GM at the Sydney Science Forum Talk, University of Sydney, 10/8/11.

²⁷³ Food Standards Agency, 2011

described in Chapter 2 are returned to as a reference point, and some data showing the coverage of GM in the media is analysed as a means to examine the idea that one understanding of public opinion is that it is the media opinion. The next section of the chapter is devoted to examining whether regulation has helped to placate public concerns over GM foods and in doing so the principal findings of the interaction between public opinion and regulation of GM foods are summarised. Further to this, the interview data is explored as a means to identify the understandings of public opinion which are held by the regulators. The importance of public opinion to the IRAs is discussed in relation to the extensive efforts in collecting data relating to GM. There follows a final synthesis of the data findings and analyses in the chapter conclusion.

5.1 Contested Harm

For the remit of this thesis the environmental issues raised by the production of GM foods are not being addressed, the focus here is on the purchase and consumption of GM foods. While a response to the risk (perceived or actual) is at the heart of the regulatory approach to GM foods, the regulation of GM foods is not simply a case of risk regulation. As already discussed, it is argued in the thesis that the regulators are attempting to juggle two competing forces and this has led to a duality of regulatory approach. This involves on the one hand that regulators respond to the very powerful commercial lobbying from suppliers of GM products to enable product development and sales, and on the other hand, that they respond to what is in some quarters a high level of public uncertainty and concern over the safety of GM products. Within the regulatory arena, the problematisation of GMOs and of GM foods has been so strongly conceptualised and the parameters of the debate defined in terms of risk that it is difficult for the issue to be conceived differently. Critically, Black argues that within the regulatory fora it is agreed that GMOs pose a risk but the level of this risk is not agreed. However, interview data shows that senior regulators from the FSA and EFSA do not see any risk in the GM foods which are authorised for sale in UK shops.

Concerns pertaining to GMOs can be grouped into either environmental/biodiversity or human health. A third area of concern has been the role of multinational companies in pushing GM agriculture. I argue however that while the survey data alludes to public concerns it does not attempt to identify the specific concerns. In relation to the potential risks to human health of consumption of GM foods, I believe that members of the

public have a vague unease which is not generally voiced even to themselves in scientific terms. The public are not stating that the anxiety arises from their belief that consumption of recombinant DNA could lead to transgenic DNA being transferred across the gut wall and genetically interacting with their body. These concerns arise because they are levied on a number of well rehearsed discourses which stress that GM food is unnatural.²⁷⁴

The lack of unanimity over the science surrounding GMOs is a very important element in any discussion of GM foods. A strong criticism levelled at opponents of GM foods is that there is no evidence that these products cause harm to human health, and those who are pro-GM argue further that no harm has come to the American public who have been eating them for decades now. However, as survey data will show in the following section, the public are concerned, and as a consequence the EU has adopted a precautionary and cautious stance on GM foods in response to the level of public unease. A number of commentators stress further that if these foods were deemed unsafe by policy makers they would not be sold and labelling would have been replaced by prohibition.²⁷⁵ In order for a GM product to reach the market, it undergoes rigorous risk assessment and authorisation processes which are far more stringent than those applied to non-GM foods. As already stated, the concern centres on the risk that transgenic DNA could be transferred across the gut wall and detrimentally affect the consumer. The counter argument to this is that there is nothing special about transgenic DNA that would make it more harmful than other DNA that we consume daily without ill effect.²⁷⁶

Interestingly, the case of GM can be contrasted to other food safety controversies such as BSE, salmonella and E-coli in that these food 'scares' were grounded in 'identifiable and ultimately established risk'.²⁷⁷ Carson et al argue that the concept of GM foods is

²⁷⁴ See further: Lustig, B. Andrews, Brody, Baruch A. and McKenny, Gerald P. (Eds), 'Altering Nature: Concepts of 'Nature' and the 'Natural' in Biotechnology Debates, 2008, Springer.

²⁷⁵ Hansen, Kirsten, 'Does Autonomy Count In Favour Of Labelling Genetically Modified Food?' *Journal of Agricultural and Environmental Ethics*, 17, (2004), pp.76-76, at p.68.

²⁷⁶ Gasson, Michael & Burke, Derek, 2001, *op cit.* at p.219.

²⁷⁷ Carson, Lisa and Lee, Robert, 'Consumer Sovereignty and the Regulatory History of the European Market for Genetically Modified Foods' *Environmental Law Review*, Vol.7(3) (2005), pp.173-194 at p.174

‘rooted more in public perception of risk and public scepticism of science than in any discernible food risk’.²⁷⁸ I contend that the concept of ‘GM food’ becomes a discursive space into which people project their own, often negative, ideas about modernity, technology, unnaturalness and artificiality. As such, it stands in direct contrast to organic foods where the discursive space is one into which people project concepts of natural goodness, wholesomeness, and wellbeing. It is commonly felt that a level of ambiguity surrounds the concept of GM foods in people’s minds. I argue that a combination of factors has exacerbated this confusion: reduced trust in the authority of science, lower levels of trust in regulation and the very nature of the development of the labelling of GM foods. This argument is developed throughout this chapter. As an interesting aside, it is possible to purchase an organic product which may have GM content, albeit at very low levels. Additionally, while it is accepted that our relationship with food products is different to our relationship to other products, why is it that when GMOs are used to produce medical products such as insulin, the concerns of the public are seemingly nonexistent? People make a judgement, and the benefits of GM foods are not clearly defined, whereas the benefits of taking insulin for someone suffering from diabetes are very clear. While there is a high level of speculation that GM food products would be cheaper than their non-GM equivalents, and also have the advantage of a longer shelf life and potentially an increased nutritional value, it appears that the public are not aware of or convinced by such potential benefits.

Martin and Tait argue that the risks of GM have hardened along disciplinary lines, with laboratory based scientists who do not believe the risks exist, and ecologists who are convinced that there are risks.²⁷⁹ Whatever opinions may be held with regard to the perceived or actual risks posed, it is noteworthy that such public discourses play a critical role in the development of regulation in this field. The ‘yuk factor’ attached to GM foods carries political clout. Hughes and Bryant stress that however illogical and inconsistent the natural/un-natural boundary may seem, it ‘does highlight the need for ethical principles to support the drawing of lines between socially acceptable and non-

²⁷⁸ Carson & Lee 2005 at op cit. p.174.

²⁷⁹ Martin, Sam and Tait, Joyce, ‘Attitudes of Selected Public Groups in the UK to biotechnology’, in Durant, John (Ed), ‘Biotechnology in Public: A Review of Recent Research’, (Science Museum, 1992) at p.28.

acceptable intervention, and between reasonable and overbearing regulatory imposition'.²⁸⁰

5.2 Science and Regulation

There are a number of difficulties surrounding the marrying of the regulation to the science in the area of GMOs. It is often argued that a 'regulatory science' ensues which is a compromise of the two epistemic areas, attempting to create something akin to the science which can also be incorporated into the regulatory system. The second issue of importance with reference to the science of GM relates to how informed survey respondents are about GM foods. Firstly it is important to analyse the controversy surrounding the science. Many would argue that the GM foods case gives weight to the argument made by scientists and policy makers that it is frustratingly difficult to 'get the message of science across to the public'.²⁸¹ However, in the GM debate, the use of science as a political tool is particularly noteworthy and suggests a novel approach to campaigning and public engagement. In the midst of such persuasive arguments on both sides, we have to ask what is 'sound science'? The lack of scientific unanimity in this area has served to inflame public debate and increase public anxiety. The traditional construction of science as a homogenous entity which carries authority and is the ultimate arbiter in decision-making no longer appears to be widely accepted.

The Bioindustry Association states that 'much of the regulation put in place by the European Commission is based on old science and reflects concerns that have not proved justified'.²⁸² A different slant on this might be that the EU adopted its stance as a strategic move in a bid to enable the development of the technologies while at the same time offering some reassurance to the public²⁸³. From the very stringent risk

²⁸⁰ Hughes, Stephen & Bryant, John, 'GM Crops and Food: a Scientific Perspective', in Bryant, John, Baggott la Velle, Linda & Searle, John (Editors), *Bioethics for Scientists*, (2002, John Wiley & Sons Ltd.)

²⁸¹ Bucchi, Massimiano, 'Can genetics help us rethink communication? Public communication of science as a double helix', *New Genetics and Society*, Vol.23, No.3, December 2004, pp.269-270.

²⁸² The BioIndustry Association, 'a Charter for Biotechnology', 1997, p.9 cited in Black, 1998, op cit. at p.38.

²⁸³ This line of argument is reminiscent of Joyce Tait's thoughts in relation to the adoption of the precautionary principle, see further: Tait, Joyce, 'More Faust than Frankenstein: the European debate about the precautionary principle and risk regulation for genetically modified crops', *Journal of Risk Research*, 4(2), pp.175-189 (2001).

regulation of the late 1990s, we have seen some relaxation in terms of a shift of the burden of risk quantification onto the public in the form of the labelling regulations. Thus the public become more responsible and autonomous, in line with the current thinking that we are moving from a system of risk regulation to the regulation of uncertainty. While the 'regulatory fix' provided by the 'old science' enables GM products to enter the shops, it does not serve to alleviate public concern. Regulators have adopted this approach with the hope that the process of familiarisation with a product will lead reduced hostility to GM foods.²⁸⁴

There is a gap between the science utilised for regulatory purposes and the science advocated by scientists. This is illustrated by the technology adopted and the science used by the regulatory system in the measurement of the adventitious threshold. This has been heavily criticised and the most vocal comments refer to the use of certified reference materials (CRMs). There appears to be an area of incommensurability where the cognitive realms of policy makers jar with those of scientists. There is a lack of recognition of the cognitive differences at work and little attempt to bridge the epistemic divide. Weighardt, writing on the use of CRMs, expresses concern over the translation of the 'gross genetic definition of 'ingredient' into something which makes sense at a molecular level', and arguing that the level of error in the quantification of GM content makes the use of the technique inappropriate.²⁸⁵ He suggests that 'the regulations are unenforceable using the molecular tools available'.²⁸⁶ He lists a number of reasons to support this view but the essence of the argument rests upon the definition of relative GMO content in a product. The current system relies upon the concept of an 'ingredient versus gene dosage ratio'. This implies that there is some correlation between the weight of the ingredients and the total number of modified genes in the

²⁸⁴ This assumption relating to ambivalence towards GM foods is taken from findings from the British Social Attitudes Survey, see: Patrick Sturgis, Helen Cooper & Chris Fife-Shaw, 'Attitudes to Biotechnology: estimating the opinions of a better informed public', *New Genetics & Society*, Vol.24, No.1, April 2005. On the scientific consensus see the debate amongst a number of prominent scientists in House of Lords, Select Committee on the European Communities, 'EC Regulation of Genetic Modification in Agriculture', Session 1998-9, 2nd Report, 15 December 1998.

²⁸⁵ Weighardt, F. (2006) 'GMO Labelling Thresholds Impractical and Unscientific', *Nat. Biotechnology*, January vol.24(1) at p.24

²⁸⁶ Weighardt (2006) op cit. at p.25

product.²⁸⁷ This leads to results which are inaccurate and thus it is argued that the CRM method does not enable an accurate GMO content to be calculated. As such the threshold level is not being enforced. However, there does not appear to be a technological fix to this problem and as such the regulation relies upon technology that has inherent imperfections. As technological developments are made hopefully the regulatory sphere will respond, and will improve the accuracy of the measurement of the GMO content.

It is argued here that the regulators have used scientific information in a very pragmatic way in order to balance the competing demands of the public and biotech companies. Science is used as a means to give authority to an argument. Pestre comments that:

‘Since science is a discourse that claims not to depend on partisan decisions, it enables one to ‘technicalise’ public action or to render it impersonal, to bypass the democratic rules of accountability...it gives to political decision the force of necessity’.²⁸⁸

An example of the pragmatic and selective design of the regulation relates to the definition and categorisation of GMOs. This argument is equally valid in relation to the number of exemptions made to the applicability of the mandatory labelling regulations. If the purpose of the regulation is to protect the public from potential risks, then the exemptions to the legislation appear very arbitrary. Evidently, successful lobbying from industry and trade issues take precedence in such matters. Such exemptions include organisms obtained through certain techniques of genetic modification. Thus, the mutagenesis and cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods are exempt.²⁸⁹ The categorisation of a GMO is a regulatory device, and for this reason a number of commentators question the more stringent regulation applied to GM foods over other novel foods. They argue that GM foods are equivalent to products produced by radiation or hybridisation resulting from classical breeding techniques.

²⁸⁷ For a full account of the argument against the use of the CRM method, see Weighardt (2006) op cit.

²⁸⁸ Pestre, D. ‘Science, Political Power and the State’ in Krige, J. and Pestre, D. (eds), ‘Science in the Twentieth Century’, (Amsterdam, Harwood, 1997), p.65

²⁸⁹ Exemptions listed in Annex 1B, Directive 2001/18/EC op cit. As stipulated in Article 3(1) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC Official Journal L 268. 18/10/2003 P. 0024 – 0028.

5.3 The Regulation of GM Foods in the UK

As discussed in Chapter 3, the dominant themes of the regulation of Genetic Modification can be traced back to the Asilomar Conference of 1973. With regard to GM food products the regulation in recent years has primarily focussed on the rhetoric of consumer choice through the labelling of products. The regulatory stages can be separated into the years from 1997 to 2003 (to include the moratorium years) and from 2003 onwards. How labelling became the central approach in the regulation of GM foods will be examined here. Indeed there was a distinct backlash to the suggestion in the 1990s when the system of ‘substantial equivalence’ was preferred. At this time, the Ministry of Agriculture, Fisheries and Food (MAFF), issued a press release that disputed the need to introduce a labelling regime for GM foods unless the process of genetic modification produced food in such a way as to make it substantially different from its non-GM antecedents.²⁹⁰ The authorisation of GM foods operated instead under the principle of ‘substantial equivalence’. Thus if a GM product was deemed substantially equivalent to its non-GM counterpart in terms of its composition, nutritional value, or intended use, then it was authorised for sale, a good example being sugar from GM sugar beet. Interestingly, it is argued that biotech companies and food producers were opposed to the introduction of labelling as it was seen as a means of inculcating a greater adverse public reaction to the products.²⁹¹ The former President of the US Biotechnology Industry Organisation contends that a label is viewed by a customer as ‘a stigma, like a skull and crossbones.’²⁹² This is a commonly held view and runs with the idea that to label an item, ‘free of GM ingredients’ implies product superiority. Additionally, biotech companies found that public relations exercises backfired as the public view was ‘if it’s as safe as you claim then why do we have all these precautions in place?’²⁹³

²⁹⁰ MAFF, ‘New Guidelines Introduced for the Labelling of Foods Produced Using Genetic Modification, 17 January 1991, Press Release No. FSD/5/91 (London: Ministry of Agriculture, Fisheries and Food) cited in Millstone, *ibid.* at p. 118.

²⁹¹ Weiss, R. ‘Giant US food corporations and biotech industry are terrified of mandatory labels on GE food’, *Washington Post*, 15 August 1999, p.A17 http://home.intekom.com/tm_info/rw90818.htm#04 (accessed 09.10.06)

²⁹² Carl Feldbaum, Former President Biotechnology Industry Organisation, quoted by Weiss, Rick in *The Washington Post*, *op cit.*

²⁹³ Tait, Joyce, ‘Who’s afraid of biotechnology: How can we sensibly regulate biotechnology’, *New Scientist*, 27 June 1992.

Figure 6 summarises the principal regulatory developments in the labelling of GM foods and illustrates the volume and complexity of legislative developments which is a corollary of the attempts by regulators to appease all factions of the GM debate.²⁹⁴ The regulatory approach operates by oversight to protect from perceived or actual harm through a system of product assessment, authorisation and labelling. Post-market regulation includes the traceability of GM foods and ingredients. What will be asked here is whether this regulation pulls together and functions coherently in order to aid the consumer or the member of the public in the purchase of food, be that GM or non-GM.

Figure 6: EU legislation relating to the labelling of GM foods

Time - frame	Legislation	Nature of Laws Introduced	Exemptions to labelling
PHASE I			
1997	Directive 1997/35	Introduces Annex III to Directive 90/220 and thus proposed labelling must be supplied at notification stage of GMO products	Catering suppliers
1997	Regulation (EC) 258/97 concerning novel foods and novel food ingredients	Review and approval of novel foods introduced after 15 May 1997	GM soya/ maize on market pre 15 May 1997 (addressed in Regulation 1813/97). Food additives, flavourings and extraction solvents
1997	Regulation 1813/97	Attempt to impose labelling regulations upon pre-1997 GM food products. Repealed by Regulation 1139/98.	
1998	Regulation 1139/98	Closes the loophole regarding GM maize and soya products which had been authorised pre-15 May 1997. Applies to GM maize and Soya unless there is no GM DNA/protein present. Repealed by Regulation 2003/1829.	
1998	Directive 98/81	Amends Directive 90/219/EC, the contained use directive. Simplifies the administrative procedures, introduces a list of GM micro-organisms believed to pose a risk to human health or to the environment.	

²⁹⁴ MacMaolain, Caoimhin, 'The New Genetically Modified Food Labelling Requirements: Finally a Lasting Solution', *European Law Review* 2003, 28(6), pp.865-879 at p.865.

2000	Regulation 49/2000	Relates to Animal Feed	Food products derived from animals fed on GM feed may be labelled as GM free.
2000	Regulation 50/2000	De minimis threshold introduced to GM additives/ flavourings labelling. Catering establishments labelling obligations	No labelling on additives or flavourings unless there is GM DNA/ protein present
2001	Directive 2001/18/EC of the European Parliament and of the Council of March 12 2001 on the deliberate release into the environment of genetically modified organisms and replacing Directive 220/90/EEC [2001] O.J. L106/1	Repeals Directive 90/220, the Deliberate Release Directive	Highly processed ingredients such as refined vegetable oils produced from a GM source but not if they contain GM DNA/protein.
PHASE II			
2003	Regulation on Food & Feed 1829/2003	Adventitious threshold changed to 0.9 per cent. Expansion of compulsory labelling to include GM food and feed regardless of whether it can be detected or not. Therefore includes highly refined and processed products, additives and flavourings. Extends application to the labelling of GM animal feed.	Only applies to food and feed 'containing' or 'derived from' GMOs. Does not apply to food or feed made 'with' a GMO (such as a processing aid or an enzyme). There is no obligation upon the supplier to label as GM the end product as a consequence of animals fed on GM feed.
2003	Regulation 1830/2003 on Traceability and Labelling	Amends and extends traceability regulations introduced under Directive 2001/18. Introduction of unique identifier codes for certain products. Implements provisions of the Cartagena Protocol on preventing Biotechnological risks.	

Regulation relating to GMOs prior to 1997 focused upon the containment and deliberate release procedures in anticipation of the planting of GM crops in Europe. Until 1997

there was no regulation relating to the marketing of GM products. At this time, however, a shift in regulatory focus was apparent and preparation made for the marketing of GM foods in the form of the Novel Foods Regulation. This Regulation relied on the substantial equivalence test as already mentioned and introduced labelling rules which Friant-Perrot argues 'went beyond safety for human health'.²⁹⁵ It should be noted however, that entry into the EU market of GM foods preceded the transposition of this Regulation, as the first GM products had already received EC marketing licences. Monsanto's 'Round-up Ready' soybean, for example, had received an EC marketing licence in 1996 for grain importation, storage and agricultural use. This first shipment of GM produce to the EU resulted in huge public protest and there is no doubt that public pressure had a high level of influence at this time and is discussed in greater depth later in the chapter.²⁹⁶ Indeed evidence of the influence of public protests is clear at this time as by the end of 1996 a number of processors and distributors, including Unilever and Nestle, removed GM soybeans from their ingredients.

In 1997, there was a flurry of regulatory activity at EU level resulting in the Novel Foods Regulation²⁹⁷, the Directive 97/35²⁹⁸ and Regulation 1813/97²⁹⁹. There is no doubt that this flurry of EU regulatory output was a response to the high levels of consumer anxiety over GM foods in this period which had been displayed through very

²⁹⁵ Friant-Perrot, Marine, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration into Community Food Law and Policy', Chapter 4 in Bodiguel, Luc and Cardwell, Micheal, 'The Regulation of Genetically Modified Organisms: Comparative Approaches', Oxford University Press, 2010, at p. 88.

²⁹⁶ There was widespread planting of crops in the late 1990s: Farmers in the US, Canada and Argentina grew an estimated 27.8 million hectares of GM crops by 1998 and 39.9 million hectares in 1999. Gene Watch UK, 'GM Crops and Food: A Review of developments in 1999', Gene Watch UK Briefing No.9, Tideswell, 2000. Cited in David F. Smith & Jim Phillips, 'Food, Science, Policy and Regulation in the Twentieth Century: International and Comparative Perspectives', at p.248.

²⁹⁷ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients *Official Journal* L 04 , 14/02/1997 P. 0001 - 0006

²⁹⁸ Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. OJ L 169, 27/06/97, p.0072-0073.

²⁹⁹ Commission Regulation (EC) No 1813/97 of 19 September 1997 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC. *Official Journal* L 257 , 20/09/1997 P. 0007 - 0008

successful public protests.³⁰⁰ The question of whether the public protests are better described as NGO-led protests ties in with the categories of public opinion which were outlined in chapter 2 and this point will be picked up in the analysis section below. Directive 97/35 introduced Annex III to the Deliberate Release Directive³⁰¹ which established the first compulsory labelling requirements and applied to foods produced from or containing GMOs listed under Directive 90/220. Additionally, Directive 97/35 prescribed a number of notification requirements for the placing on the market of a GMO including the requirement that the company responsible must inter alia supply labelling proposals that indicate:

‘...that the product contains, or consists of genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, information on the possibility that the genetically modified organisms may be present, is sufficient’.³⁰²

The Novel Foods Regulation further tightened up the GM regulation. This legislation applied to six categories of novel foods, including foods which contain or consist of GMOs. A GMO is defined in accordance with the 1990 Deliberate Release Directive as:

‘an organism with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’.³⁰³

A second category is specified as foods and food ingredients produced from, but not containing GMOs. The Novel Foods Regulation introduced a system of assessment and authorisation procedures for novel foods. The Novel Foods Regulation is significant in that through the introduction of new labelling requirements, it enabled the large-scale entry of GM foods into the European market.

³⁰⁰ Carson & Lee support this argument: Carson, Lisa and Lee, Robert, ‘Consumer Sovereignty and the Regulatory History of the European Market for Genetically Modified Foods’ *Environmental Law Review*, Vol.7(3) (2005), pp.173-194 at p.175.

³⁰¹ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms OJ L 117, 8.5.1990, p. 15–27

³⁰² Article 5C of Directive 97/35 op cit.

³⁰³ Article 2(2) of Directive No. 1990/220/EC on the deliberate release into the environment of genetically modified organisms.

The Novel Foods Regulation does not apply to food additives, flavourings and extraction solvents. A number of regulatory developments ensued in an attempt to close regulatory holes such as the problem of the products which were authorised for market prior to the Novel Foods Regulation. Regulation 1913/97 tidied up this lacuna and applied an exemption to Monsanto's 'Round-up Ready' Soya and Novartis BT Maize.³⁰⁴ However, this Regulation was repealed in 1998 by Regulation 1139/98³⁰⁵ which applied the labelling requirements set out in the Novel Food Regulation to foods containing GM soya and maize. The impact of these regulations upon public opinion is nebulous in part because the supermarkets took it upon themselves to respond to the public mood in a number of ways. Even before the regulatory developments of 1997, a number of UK supermarkets established voluntary labelling codes.³⁰⁶ In doing so the supermarkets argued that this was a result of public demand which had been identified in a survey of consumers.³⁰⁷

It is noteworthy that there are a large number of exemptions to the scope of the 1997 regulations and in 1997 a number of GM foods had been formally permitted for use in the food processing industry in the UK. These include: GM soya, maize, products made with a GMO enzyme (such as chymosin which is used widely to make vegetarian cheese), and tomato paste. Consumers were able to exert power with the aid of the labelling mechanism and this led supermarkets and the food processing industry to

³⁰⁴ Monsanto's Ready Round-up Soya by Decision 96/28: the placing on the market of GM soya beans (*Glycine max* L) with increased tolerance to the herbicide glyphosate, pursuant to Directive 90/220; and Novartis BT Maize by Decision 97/98: the placing on the market of GM maize (*Zea mays* L) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Directive 90/220.

³⁰⁵ Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC Official Journal L 159 , 03/06/1998 P. 0004 – 0007.

³⁰⁶ For example, the Co-operative Wholesale Society, April 1994 and Iceland. The supermarket Iceland was at the forefront of a non-GM consumer movement and this is evident in the move to source non-GM soya for their own-brand products. See further: Buffin, D. 'Genetic Segregation: an Interview with Malcolm Walker', *Pesticides News*, 1998, vol.40, pp.6-7.

³⁰⁷ Millstone, Erik, 'Analysing Biotechnology's Traumas', *New Genetics and Society*, Vol.19, No.2, (2000) pp.117-132 at p.119. Millstone cites a paper by L. Dughan which states that survey data showed that 85% of British consumers would like labels on GM foods. See Further; Dughan, L. (1994) 'UK Supermarket labels recombinant foods' *Bio/Technology*, 12, p.351.

source non-GM ingredients. Barling argues that 'in effect, a private system of market-led regulation appeared.'³⁰⁸

The story of Zeneca Plant Science's tomato paste, the first GM product to receive authorisation for sale on both sides of the Atlantic, illustrates the food industry's changing perspective on GM foods during the 1990s. At the end of 1996 this tomato paste, a pioneer of GM produce, arrived on the shelves of UK supermarkets. However, by the end of the decade the product had been withdrawn due solely to consumer protest. Sainsbury's initially attributed the lack of consumer backlash to the product to the clarity of the labelling. Sainsbury's stated:

'Sainsbury's are able to clearly label the genetically modified tomato puree only because we worked in partnership with the grower and planned for segregation and appropriate labelling. This is the exact opposite to the way in which the genetically modified commodity crops are being introduced to the market and why consumer acceptance of these products is markedly lower'.³⁰⁹

The picture had changed dramatically by the end of the decade when the following statement was issued by Sainsbury's:

'In response to overwhelming customer concern, Sainsbury's has eliminated genetically modified ingredients from all own brand products. This was a considerable task, involving over 10,000 products and was achieved by replacing soya and maize ingredients with alternatives or by using guaranteed non-GM sources'.³¹⁰

The level of consumer opposition is evidenced by the introduction by Sainsbury's of a customer helpline solely for calls relating to GM products. Astoundingly, this received approximately 300 calls in the first four hours of opening.³¹¹ The tomato paste case is clear evidence of the influence of public attitudes over commercial development.

³⁰⁸ Barling, David, 'Regulating GM Foods in the 1980s and 1990s', in Smith, David F. and Phillips, Jim (Eds), 'Food, Science, Policy and Regulation in the Twentieth Century: International and Comparative Perspectives', (London: Routledge, 2000) at p.250

³⁰⁹ Letter from J.Sainsbury plc. in 'EC Regulation of Genetic Modification in Agriculture', House of Lords Select Committee on the European Communities, Session 1998-99, 2nd Report Appendix I, P.388, at para.5

³¹⁰ Memorandum submitted by J. Sainsbury plc (1999), *ibid.* at para. 1.2

³¹¹ Memorandum from J. Sainsbury plc to the House of Commons Select Committee on Agriculture, 15 November 1999;

5.3.1 The Regulators

Figure 7: The regulators of GM foods

Regulatory Activity	GM Foods
Public Regulation of the Public Sector	
European	European Food Safety Authority (EFSA) The European Commission, DG Health & Consumer Protection (SANCO)
Central Government	Department for the Environment, Food and Rural Affairs (Defra)
Statutory Bodies	Food Standards Authority (FSA)
Non-statutory advisory organisations/committees	Advisory Committee on Novel Foods and Processes (ACNFP)
Private Regulation of the Public Sector	
Industry	Producers, Manufacturers & Retailers
Self-regulation	Retailers
Oversight by interest groups ³¹²	Greenpeace, Friends of the Earth (FoE) Consumer Organisations

As discussed, the role played by retailers in this sector has been very important. The acts of self-regulation by the retailers prior to the moratorium related to the removal of GM produce from their stores are very significant. In terms of the thermostatic control model, it is argued that this demonstrated a higher and speedier level of responsiveness to public opinion than shown by the regulatory agencies. Indeed this is in keeping with Scott's thoughts on 'co-regulation' where actions of the private sector stimulate public involvement and I contend that the actions of the retailers increased the pressure on the regulators and politicians on this issue bringing about the moratorium on GM.³¹³

<http://www.publications.parliament.uk/pa/cm199900/cmselect/cmagric/71/71ap17.htm> (accessed 2.10.06)

³¹² Scott, Colin 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance' Journal of Law and Society, Volume 29, Number 1, March 2002, pp.56-76, at p.66.

³¹³ Scott, Colin, 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance' Journal of Law and Society, Volume 29, Number 1, March 2002, pp.56-78 at p.76.

5.3.2 Phase 1 of the Regulation of GM foods: (1997 – 2003)

‘Through the vehicle of regulation, states provide assurance that the risks of new technologies can be contained in manageable bounds’.³¹⁴

It is all too clear that despite the introduction of the first labelling regulations in 1997 the public were not placated and these regulations did not prevent a huge public outcry against GM food in the late 1990s. It is argued here that while the politicians and regulators were slow to respond to the public mood of the late 1990s, public opinion in the form of consumer demand conferred a significant level of leverage and influence over the supermarkets. This in turn has had ramifications further down the supply chain and upon the biotech industry at large. There is no doubt that the public have played an enormous role in the regulation of these novel GM foods. It is due to the shortcomings of the 1997 Novel Foods Regulation that six nations (Austria, Belgium, France, Germany, Italy and Luxembourg) decided to instigate a moratorium on GM food. These Member States declared that they had acted in response to consumer concern. Friant-Perrot argues that the Novel Foods Regulation ‘did not adequately assure that foodstuffs are free from risk or guarantee to the consumer either a sufficiently robust regime in terms of traceability or sufficient level of information’.³¹⁵ The consequence of this is that in June 1999, the Council of Ministers declared a de facto moratorium upon further approvals of GM products. This meant that consideration of all new applications for GM food products and crops were suspended. The moratorium ran from June 1999 until August 2003.³¹⁶ Surprisingly, promoters of the biotech industry also backed the move in the hope that a more codified system would emerge from such a development.

In 2000, two Regulations were issued in an attempt to remove a few of the caveats inherent in the earlier legislation: The Animal Feed Regulation and the Labelling

³¹⁴ Jasanoff, Sheila, ‘Product, Process, or Programme: three cultures and the regulation of biotechnology’, Chapter 15 in Bauer, Martin, ‘Resistance to New Technology: Nuclear Power, IT and Biotechnology’, (Cambridge University Press, 1995) at p.311.

³¹⁵ Friant-Perrot, 2010 *ibid.* at p. 88.

³¹⁶ The WTO filed a case against the EU claiming that the moratorium was a breach of international trade rules. For a full review of the ruling: ENDS Europe DAILY 2096 12/05/06, ‘No Clear Victory in Final WTO Gene Crops Ruling’ at <http://www.endseuropedaily.com/20342> and for full text of the ruling at <http://www.wto.org/index.htm> (both sites accessed 03.10.06)

Regulation. The Labelling Regulation 49/2000³¹⁷, which extends the labelling requirements by requiring catering establishments to label their produce, introduced a single authorisation procedure and additionally introduced the adventitious threshold concept. This is a de minimis threshold level, originally set at 1 per cent, for the accidental or adventitious content of DNA or proteins resulting from the genetic modification of food. The intention of this provision is that it would lead to a more transparent self-auditing system across the supply chain. Regulation 50/2000³¹⁸ also closes the loophole relating to the labelling of foods containing or produced from GM additives and flavourings. This first phase of the labelling period closes with Directive 2001/18, the new Deliberate Release Directive.³¹⁹ This Directive establishes a new regime for the marketing of GM foods, including minimum labelling requirements. These include a statement to be placed on the product that reads: ‘this product contains genetically modified organisms’.³²⁰ An exemption applies to products with levels of GM below the adventitious threshold. The Directive imposes a clear duty upon the producer to specify a product as being or containing GMOs.³²¹ The Directive also enables the consumer to access additional product information pertaining to the genetic modification from a public register.³²² The most significant aspect of Directive 2001/18 is that it lays the ground for further regulation in this area paving the way for the 2003 Regulations introduced in the second phase of labelling of GM foods.

³¹⁷ Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC. Official Journal L 006 , 11/01/2000 P. 0013 - 0014

³¹⁸ Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms. Official Journal L 006 , 11/01/2000 P. 0015 - 0017

³¹⁹ Directive 2001/18/EC of the European Parliament and of the Council of March 12 2001 on the deliberate release into the environment of genetically modified organisms and replacing Directive 220/90/EEC [2001] O.J. L106/1

³²⁰ Article 27 & Annex IV para. 8 of Directive 2001/18 op cit.

³²¹ MacMaolain, Caoimhin, ‘The New Genetically Modified Food Labelling Requirements: Finally A Lasting Solution. European Law Review, 28(6) 2003, pp.865-879.

³²² See further Article 31(2) and Annex IV of Directive 2001/18 op cit.

5.3.3 Phase 2 of the regulation of GM foods: 2003 – 2011

The year 2003 is taken as our marker of the new regulatory phase for GM food and the harbingers of this change are the introduction of two substantive pieces of legislation: Regulation 1830/2003 relating to traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs,³²³ and Regulation 1829/2003 pertaining to genetically modified food and feed.³²⁴ It is argued by Durrant and Legge that these Regulations prepared the public for the end of the moratorium. On the basis of such comments it can be inferred that Durrant et al believe the 2003 Regulations provide the public with some level of reassurance that they are protected from any harm posed by GM foods. Interestingly, Durrant et al posit that the period of the moratorium was an important time for the Governments of the Member States to increase public trust in their abilities to regulate GM foods.³²⁵ This relationship between public opinion and strong regulation ties in with Lofstedt's views which were introduced in Chapter 4, Lofstedt contends that the public felt reassured by strict regulation and strong regulatory stances. Despite the volume of regulation prior to 2003, Member States were keen to tidy up the GM problem, and the introduction of further regulation was viewed as a means to both consolidate the existing regulations and to close lacunae within them. The EU chose to introduce these provisions in the form of Regulations to ensure that they were applied uniformly across the Member States.³²⁶

³²³ Regulation (EC) number 1830/2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, Official Journal L 18/10/2003, pp. 0024-0028. This Regulation amends Directive 2001/18/EC relating to the deliberate release into the environment of genetically modified organisms. The 2001 Directive repeals Directive 90/220/EEC. Official Journal L 106, 17/04/01, pp. 0001 – 0039.

³²⁴ Regulation (EC) No. 1829/2003 on genetically modified food and feed, Official Journal L 268, 18/10/2003, pp.0001-0023.

³²⁵ Durrant, Robert F. and Legge, Jerome S. 'Public Opinion, Risk Perceptions, and GM Food: Reassessing the calculus of Dissent among European Citizens', *European Union Politics*, Vol.6(2) pp.181-200, 2005 at p195-197

³²⁶ Regulations are directly effective therefore enter into force across the Member States at the same time as the Regulation itself. Directives do not have this requirement and lead to a less harmonized legal system in that Member States have different dates for entry into force and different regulations to enact the requirements.

Carson et al argue that the focus of the labelling Regulations places the emphasis on the consumer's right to know rather than any attendant concerns with the safety of the products.³²⁷ In support of this they point to the shortfalls in the labelling Regulations: the unreliability of the traceability and testing methods combined with the exemptions to the Regulations.³²⁸ Clear evidence that the regulators wished to respond to public opinion is found in the preamble to the Food and Feed Directive 1829/2003, which states that:

'Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, *meets the demands expressed in numerous surveys by a large majority of consumers*, facilitates consumer choice and precludes potential misleading of consumers as regards methods of manufacture or production.' (emphasis added)³²⁹

It is of particular note that mention is made of the survey data and this promotes the argument that this is both the principal source of public opinion data referred to by regulators and the one they view as 'public opinion'. All foods within the scope of the 2003 Regulations must be labelled appropriately, regardless of whether they are pre-packaged. The most common examples of label content are 'produced from genetically modified (name of the ingredient)' or 'genetically modified'.³³⁰ The exemption to foods made with the aid of GMOs, remains however, and Carson et al ask whether consumers understand the distinction between food 'from GMOs' and food 'made with GMOs'.³³¹

What is not clear from the Regulation is whether the consumer surveys mentioned showed high levels of public opposition to GM foods or a definitive call from the public for the labelling of GM food. This is an important distinction as there is no consensus about whether the labelling mechanism is the appropriate legal form with which to

³²⁷ Carson & Lee 2005 op cit. at p. 182.

³²⁸ Carson & Lee 2005 op cit, at p.182.

³²⁹ Para.21 of the preamble to Regulation 1829/2003

³³⁰ Article 13(1)(a)-(e), Regulation (EC) No. 1829/2003 on genetically modified food and feed, *ibid*. Regulation 1829/ 2003 defines a 'GM food' as a 'food containing, consisting of or produced from GMOs'. Article 2(6), Regulation (EC) No. 1829/2003. A 'GMO' is defined as 'an organism with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' at Article 2(2) of Directive No. 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

³³¹ Carson & Lee 2005, op cit. at p.183.

placate the public. Suggested alternatives to the current system include a negative labelling process in which the GM-free foods are the products subject to labelling.³³² The 2003 Regulations introduced a new dimension to GM food labelling in that even if the GM content is undetectable in the final product, there is a duty upon suppliers to declare that it contains GM. This extends the scope of the regulation to include processed foods. The exemption to the labelling of animal products reared on GM food remains, although within the Regulation is the preparatory work for more stringent requirements. Regulation 1829/2003 obliges suppliers of animal feed to declare by labelling whether the produce contains GM, which is the first stage in increased transparency across the food supply chain.

The Food and Feed Regulation abandons the notification procedure for novel foods considered substantially equivalent to existing foods and also it extends to feed produced from GMOs which had not previously been subject to an authorisation procedure. Within the authorisation of GM products there is an opportunity for members of the public to give their views on individual products which are under consideration for EU approval. An open consultation is established once the EFSA have produced an opinion on a GM product application. The opinion is made public on the European Commission website for thirty days and responses are invited from members of the general public which have to be considered by the European Commission in consultation with EFSA to determine whether these comments have an impact on the final decision. I have analysed these responses from 2005 to 2010 and the majority of the responses are from NGOs. However, there is not one case where it appears that the input from the NGOs has impacted the authorisation process, as all the products to date have been given approval. A regulator from EFSA agreed in interview that due to the very low numbers of responses to this on-line feedback system it was not a worthwhile process.

The enforcement and effectiveness of the traceability Regulations are often criticised as it is argued that there are many cases where GM foods are entering the European markets and not being detected. Pertinent to the thesis is whether there is any public awareness of such events. NGOs argue that GM foods are regularly entering the EU

³³² Hansen, Kirsten, 'Does Autonomy Count In Favour Of Labelling Genetically Modified Food?' *Journal of Agricultural and Environmental Ethics* vol. 17, (2004), p.76.

undetected. It has become the role of the NGOs to publicise the failings of the IRAs and take on the role of a watchdog.³³³ Thus while the public may gain a level of reassurance from the knowledge that regulation exists which authorises foods in the shops, it seems that this can be misplaced trust if that system does not function as effectively as expected. It can be argued that the regulation and the regulatory structure have the capacity to engender public trust regardless of the effectiveness of the regulations in practice. However I contend that the labels are misleading to consumers, and while a consumer can avoid those products with labels, it is questionable whether the consumer is aware that there are GMOs in the unlabelled products. Exemptions to the mandatory labelling requirements apply *inter alia* to a variety of biotech products, such as enzymes, vitamins and amino acids, which occur in a wide range of products including beer and processed cheese. It was estimated that at the end of the last century, approximately 60 per cent of foodstuffs on sale in Europe contained GM soya derivatives but were not labelled as such.³³⁴

5.4 The Public Opinion of GM Foods

The analysis of public opinion in both this chapter and the prenatal and PGD Chapter is framed by the five understandings of public opinion which were discussed in Chapter 2. The table below sets out the public opinion data relating to GM foods which is reviewed in this chapter and attempts to classify them by the five understandings of public opinion. However, it is evident that the choice of one understanding instead of another is not always clear. For instance, the understanding that public opinion is the majority view could be held to be true in the late 1990s yet is arguably not the case now. Equally, survey data, while it is a measure of the aggregation of individual opinions, may identify a majority view. Finally, in the light of the complex shifting of public opinion data in the thesis and arguments about the representativeness of the data used in the regulatory process, the view that public opinion is a fiction may retain a certain appeal. The table is therefore posited here as a discursive tool only.

³³³ Friends of the Earth took out a judicial review against the Food Standards Agency in 2007 in relation to rice which was contaminated by GM, the GM Rice LL601 case. See further GM Freeze who called for a committee to oversee the FSA: <http://www.gmfreeze.org/news-releases/96/>

³³⁴ Smith, M. 'Novel Foods Create Novel Dilemmas for Trade Partners', *The Financial Times*, 22, June 1998, p.7.

Figure 8: The five principal understandings of public opinion

Understanding of Public Opinion	Measure of Public Opinion	Examples: Use of Formal Channels or Informal Means
Public opinion is the aggregation of individual opinions	The British Social Attitudes Survey (BSA), Eurobarometer and the Food Standard Agencies' Consumer Attitude Survey (CAS)	Formal channel
Public opinion is the majority view		
Public opinion is the result of the channelling of the public voice by interest groups	Discussion relating to GM Nation? Debate	Informal means – protests Formal channels – EFSA on-line feedback to authorisation of GM products Formal –asked to join a consultation exercise as a stakeholder
Public opinion is a construct created by elite groups and the media	Media – Lexis Counts of pro & anti GM stories Regulators Scientists	
Public opinion is a fiction as it is simply a construct.		

Survey data may or may not be picked up by the formal policy and regulatory channels. Additionally, it is argued by Mayer and Stirling that scientists do not look at the public opinion data either. They argue that:

‘A large body of research on public attitudes and perceptions has direct relevance to these questions [relating to the rationality of the public’s attitude towards GM]. Unfortunately, scientists who comment on the GM debate often ignore this’.³³⁵

The review of the public opinion data mirrors the two time-periods for the regulation as a means to view more clearly whether the change in regulatory style and the ending of the moratorium has had an impact on public opinion.

³³⁵ Mayer, Sue and Stirling, Andy, ‘GM Crops: Good or Bad?’ Nature, EMBO reports (2004) volume 5 (11) pp.1021-1024 at p.1021.

The first measure of public opinion reflects the most commonly used understanding of public opinion, the aggregation of individual opinions, and can be measured by survey data. As already outlined in the methodology in chapter 1, the principal sources of public opinion data under review are the BSA survey which included questions in the years 1999 and 2003 and the Eurobarometer covering seven surveys in the year: 1991, 1993, 1996, 1999, 2002, 2005 and 2010. Critical to the study of interaction between regulation and public opinion is the issue of whether the data analysed is indicative and correlates with the public mood as measured or picked up by the regulators. Of additional interest is whether the survey data reviewed here was known by the regulators, and indeed the Eurobarometer was known to all the regulators interviewed here. In fact an official at Defra mentioned Eurobarometer in relation to public opinion. He stated that:

‘GM is certainly not as hot as it was in certain polls such as Eurobarometer and they do seem to suggest that for most people it is not a big issue in the public’s mind or media’s mind as it was ten-twelve years ago but over the last few years it has increased...’

5.4.1 Public opinion of GM foods: Phase One: 1999- 2003

‘We did the first ever public attitudes to GM survey in the 1980s for the DTI [Department of Trade and Industry] and we found everything that has been found in subsequent surveys – you know – the public don’t know much about GM, they might like it if there was something in it for them, they wanted to be sure it would be well regulated, they didn’t think it would be well regulated. If they wanted more information about GM they would go to NGOs and wouldn’t go to Government Agencies’ (Tait 2011 interviewed for this thesis).

These comments made by Joyce Tait give the impression that public opinion on GM has been very stable over the last three decades. While in general terms, one can agree with Tait’s statement, the public opinion data does show a variation across the years studied here. The survey data for the years 1999-2003 demonstrates high levels of opposition to GM foods and additionally the responses are highly polarised.

Throughout the 1990s, Eurobarometer data highlights a significant and growing level of opposition towards GM foods across the EU Member States which peaks in 1999. 1999 is notable for a very significant growth in public opposition towards biotechnologies.

This trend is picked up by the BSA survey data on GM foods. The Eurobarometer data shows a shift in attitude from 1999 with the levels of opposition to GM foods and biotechnologies generally decreasing until 2002. In the same period, the data reflects a

moderate rise in levels of support for GM foods and other biotechnologies.³³⁶ This is mirrored by the BSA surveys of 1999 and 2003 which reflect the same trend in the UK. In the late 1990s the public responded strongly to the introduction of GM food imports into the EU and the appearance of such products on supermarket shelves. It should be remembered that the late 1990s saw a number of very successful civil protests, such as the destruction of GM crop trials in the UK. The radicalisation of NGOs around the issue was very clearly responded to by regulators and politicians and this is portrayed nicely by Tony Blair's radical shift on the subject which was highlighted by the Independent on Sunday in February 2000 when Blair wrote a piece on GM foods in the paper. The Independent on Sunday identified the comments Blair had made a year earlier when he stated that 'GM foods are safe' and that he happily ate GM foods. He referred to the 'tyranny of the pressure groups' for questioning the promotion of GM by his Government.³³⁷ In the following year, in a volte face position, Blair talked instead of the 'Government's determination to have as informed and balanced a debate as possible on GM and commented on the 'potential harm' of GM foods.³³⁸ The Director of Friends of the Earth stated that 'for the first time, Mr Blair seems to be listening to the people on these issues'.³³⁹ The summer of 1999 was a time of heated debate on GM and crop destruction in the UK by Eco-Warriors. This was compounded by the actions of Sainsbury's who removed all GM foods from its stores and the decision by the Local Government Authority to prohibit GM ingredients in school meals.

³³⁶ Gaskell, George, Allum, Nick, Bauer, Martin, Jackson, Jonathan, Howard, Susan, Lindsey, Nicola 'Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002', Life Sciences in European Society Report: London School of Economics and Political Science, 2003 at p.2; Gaskell, George, Allum, Nick & Stares, Sally, 'Europeans and Biotechnology in 2002' (2nd Edition; 21/03/03) A report to the EC Directorate General for Research from the project 'Life Sciences in European Society' QLG7-CT-1999-00286; Sturgis, Patrick, Cooper, Helen & Fife-Shaw, Chris, 'Attitudes to Biotechnology: estimating the opinions of a better informed public', New Genetics & Society, Vol.24, No.1, April 2005.

Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris, Shepherd, Richard, 'Genomic Science: Emerging Public Opinion', from Park, A., Curtice, J., Thompson, K., Bromley, C. and Phillips, M. (Eds) (2004) British Social Attitudes - the 21st Report. (London: Sage)

³³⁷ The Independent on Sunday, 27/2/00.

³³⁸ The Independent on Sunday, 27/2/00, p.28.

³³⁹ Charles Secrett, Director of the Friends of the Earth, quoted from the Independent on Sunday, 27/2/00, front page.

Returning to the five understandings of public opinion, the NGO activities in the late 1990s correspond to the third understanding of public opinion where public opinion is not deemed to be what individuals think but the reflection of these views as they are ‘cultivated, crystallised and eventually communicated by interest groups’.³⁴⁰ Glynn et al argue that people who adhere to this version of public opinion do not deny that there are individual opinions but suggest that it is when they become represented by NGOs that they gain some political force and are more likely to be heard by the regulators.³⁴¹ In terms of the GM protests which began in Europe in 1995 and 1996, Imig and Tarrow contend that the issue of GM attracted such high levels of attention because of an ‘unusual number of dimensions’. These include the fact that ‘the issue was unknown and full of potential risks yet potential promise; there was an identifiable villain – vast multinational corporations’.³⁴² Additionally and very pertinent in the UK is that the GM controversy arose in a political environment ripe with public anxieties over food following the BSE scandal.

1999 is a critical point in terms of analysis of the role of public opinion on regulatory decision-making relating to GM foods. The regulators made a clear and very strong response to the public outcry, and 1999 marks the beginning of the de facto moratorium on cultivation and selling of GM foods across the EU which Durrant and Legge argue gave the Member States the chance to rebuild citizen trust in Government in relation to this issue.³⁴³ In 1999 the BSA survey data reflects this with very low levels of trust in the UK Government’s ability to regulate on biotechnology.³⁴⁴

³⁴⁰ Glynn et al, 2004, op cit. at p.22.

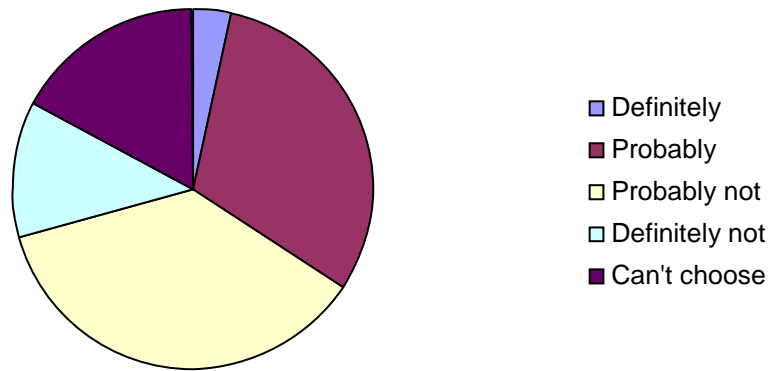
³⁴¹ Glynn et al, 2004, op cit. at p.22.

³⁴² Imig, Douglas R. and Tarrow, Sidney, G. (Eds), ‘Contentious Europeans: Protest and Politics in an Emerging Polity’, 2001, Roman and Littlefield Publishers, Inc.

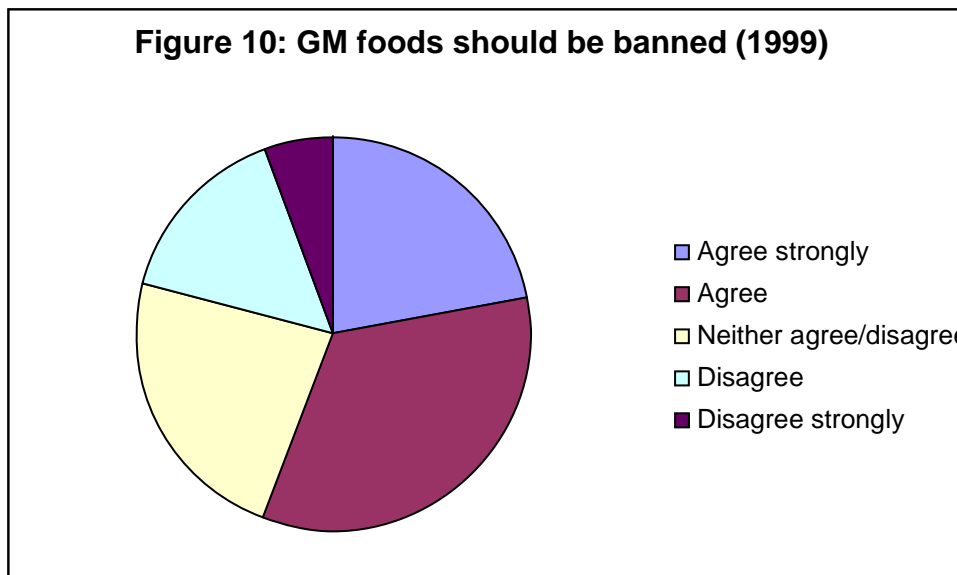
³⁴³ Durrant, Robert F. & Legge, Jerome S. ‘Public Opinions, Risk Perceptions and Genetically Modified Food Regulatory Policy: Reassessing the calculus of Dissent among European Citizens’, European Union Politics, Vol, 6(2), 2005, pp.181-200 p. 195.

³⁴⁴ Gaskell et al 2003, op cit. at p.15 with reference to the Eurobarometer survey data.

Figure 9: GM foods in the shops are safe to eat (1999)



The BSA survey data for 1999 highlights strongly polarised views in relation to whether GM foods in the shops are safe to eat. At this time, as discussed above, labelling regulations came into force in the UK. With regard to the survey statement 'GM foods in the shops are safe to eat' thirty five per cent of the people surveyed agreed that this was definitely or probably the case in 1999 rising to forty eight per cent stated in 2003. This attitude measure is significant in terms of its basis in a level of trust in regulation, because by agreeing with the statement, an individual implicitly acknowledges his/her trust in the regulatory processes relating to the assessment and authorisation of GM foods. Combined with the low levels of public trust in GM foods, the BSA survey data for 1999 revealed evidence of strong opposition to the introduction of GM foods on to the UK market. In 1999, 51.8 per cent of the BSA survey respondents supported an outright ban of GM foods even if this entailed knock-on effects on food prices, with 22.1 per cent undecided and 19.4 per cent in disagreement with the statement.



The ‘natural/ unnatural’ discourse which surrounds GM foods was examined in the survey with 63.1 per cent of respondents in agreement with the statement that ‘we should never interfere with the genes of plants and animals’.³⁴⁵ This is a strong indicator of the pre-existing attitude to biotechnologies. Further results from the BSA survey are equally reflective of strong opposition to GM foods at this time.

The ‘don’t know’ response in a survey is significant as an indicator of people’s confidence in their knowledge on a subject and whether they feel they can have a view based on this knowledge. In the Eurobarometer report of 2010, one fifth of those questioned answered that they ‘don’t know’ whether biotechnology and genetic engineering will improve their way of life or not. This figure has remained pretty stable since 1999.³⁴⁶ A further noteworthy point is that the survey findings showed that people made application-specific judgements and did not hold an overarching opinion on biotechnologies. The report found that in 2002 the majority of Europeans do not support GM foods. Gaskell et al summarise the Eurobarometer 2002 data findings by

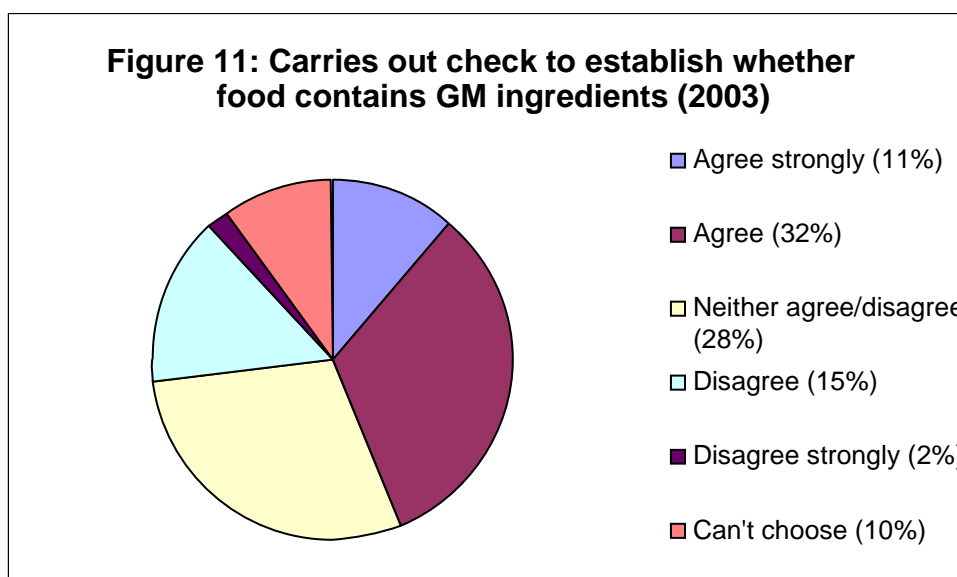
³⁴⁵ For further on the unnatural discourse surrounding GM foods, see further: Latour, Bruno, ‘We have never been modern’, (Cambridge: Harvard University Press, 1993). With reference to the BSA question for the number who ‘agree’, I have combined the respondents who stated they ‘agree strongly’ and ‘agree’ with the statement.

³⁴⁶ Gaskell, George, Allum, Nick & Stares, Sally, ‘Europeans and Biotechnology in 2002’ (2nd Edition; 21/03/03) A report to the EC Directorate General for Research from the project ‘Life Sciences in European Society’ QLG7-CT-1999-00286, at p.1.

stating that the majority of Europeans believe that GM foods are ‘judged not to be useful and to be risky for society’.³⁴⁷

5.4.2 Public opinion of GM foods: Phase 2: 2003 – 2010

The BSA survey of 2003 contains a statement in relation to the labelling of GM foods which is very apposite here: ‘it is important to me to check whether or not foods contain genetically modified ingredients’. This attitude statement produced some interesting results, with 44% of those surveyed stating that they strongly agreed or agreed that this is important compared to 17% who strongly disagreed or disagreed with the statement. Yet a significant proportion of the people surveyed, 28 per cent, held no view on the matter. This high proportion of undecided people is a trend reflected in further GM food questions from the 2003 BSA data.



In stark contrast to the statistics in 1999 when 23 per cent of those surveyed disagreed strongly with the assertion that ‘on balance, the advantages of GM foods outweigh any dangers’, the 2003 figure for this is only 8 per cent of respondents. Additionally, in 1999 those in favour of banning GM foods accounted for 51 per cent of the people surveyed and yet by 2003 this had reduced to 29 per cent.³⁴⁸ The data findings show very clearly that public opposition to GM foods has reduced dramatically in the years

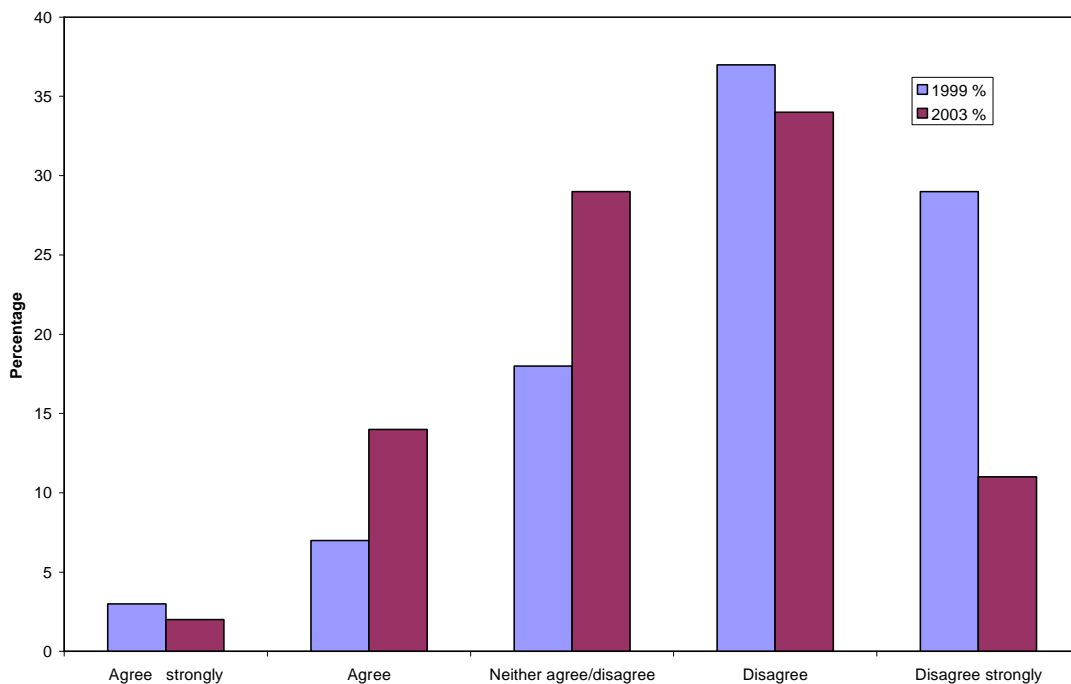
³⁴⁷ Gaskell et al, 2003, *ibid.* at p. 2

³⁴⁸ 51 per cent is the sum total of those who agree or agree strongly to statement that GM foods should be banned even if food prices suffer as a result.

from 1999 to 2003. An interesting finding relates to the levels of ‘neither agree nor disagree’ response given in the BSA survey. For instance in figure 12, in answer to the statement ‘in order to compete with the rest of the world, Britain should grow GM foods’, the levels have increased by 12 percent. This trend is also shown in the results to the statement: ‘GM foods should be banned even if food prices suffer as a result’, where there was an increase of 11 per cent. The statement ‘On balance, the advantages of GM foods outweigh any dangers’ produced an increase of 14 per cent in the ‘neither agree nor disagree’ responses. This finding I argue is in line with Gaskell et al’s contention that people are becoming more ambivalent about GM. Gaskell et al reviewed Eurobarometer data in 2002 at the time just before the moratorium was to be lifted and while at this point the Eurobarometer showed lower levels of opposition to GM than had been evident in the 1990s, yet the data shows a 50/50 split on GM and this Gaskell et al attribute to ambivalence over the issue.³⁴⁹ The increase in numbers of ‘neither agree/disagree’ could however be a result of higher levels of public uncertainty and confusion.

³⁴⁹ Gaskell, G., Allum, N., Bauer, M. W., Jackson, J., Howard, S., & Lindsey, N. (2003). *Ambivalent GM nation? Public attitudes to biotechnology in the UK, 1991-2002*. Life Sciences in European Society Report: London School of Economics and Political Science.

Figure 12: In order to compete with the rest of the world, Britain should grow GM foods



The BSA survey data shows that in 1999, 36 per cent of people surveyed thought that the GM foods available in the shops were safe to eat. In 2003, this figure had risen to 46.6 per cent, a marked increase which reflects heightened trust in the regulations relating to authorisation and approval of GM foods.

Figure 13: GM foods should be banned, even if food prices suffer as a result

Agree strongly	20	8
Agree	31	21
Neither agree/disagree	22	33
Disagree	14	22
Disagree strongly	5	3

Figure 14: On balance, the advantages of GM foods outweigh any dangers

Agree strongly	2	1
Agree	10	13
Neither agree/disagree	23	37
Disagree	33	24
Disagree strongly	23	8

The Eurobarometer data offers an insight into public attitudes in the EU and UK beyond 2003 and identifies a post 2003 shift in attitude. Furthermore, the Eurobarometer data highlights decreasing levels of support in the UK and increased opposition to GM foods across the EU. Unfortunately, the Eurobarometer has not covered levels of opposition to GM foods in the same format since 2005, so while this data is useful it is a noticeable limitation of the Eurobarometer survey that it has failed to incorporate consistent questions across the years.

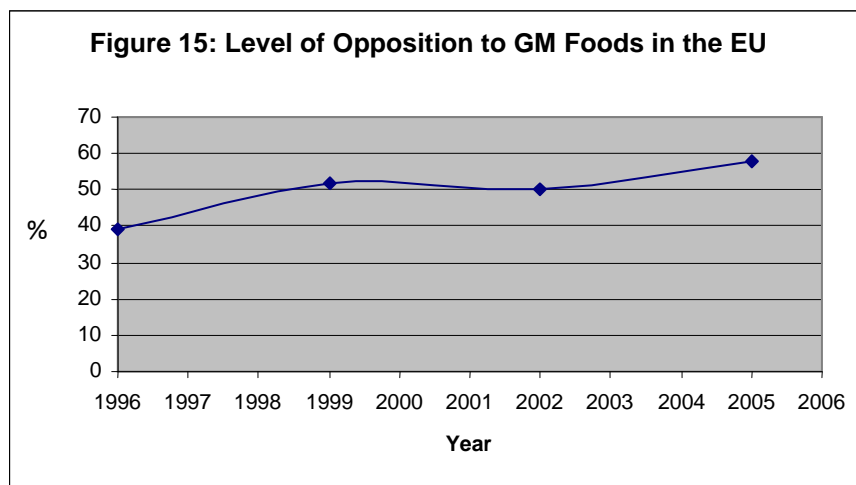
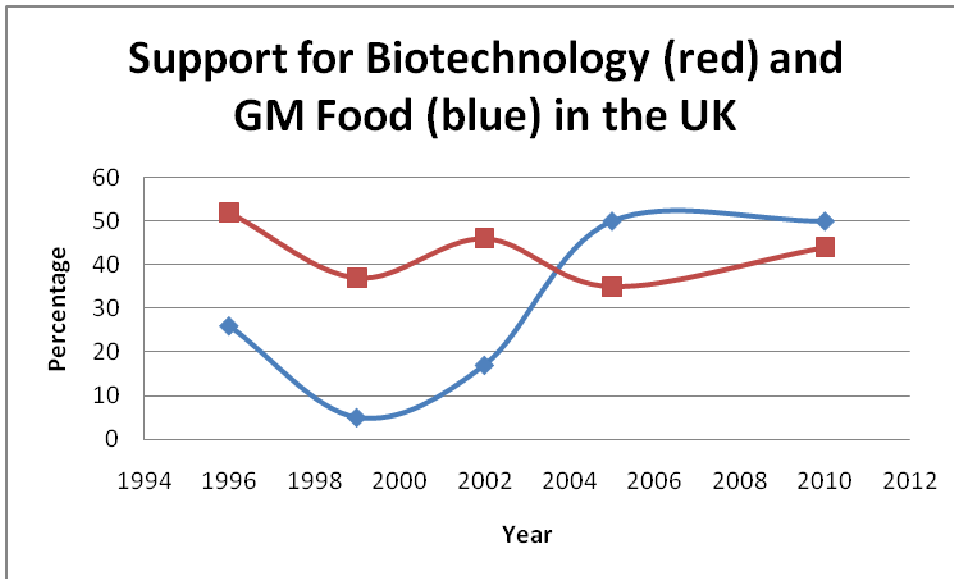


Figure 15 shows the trend in opposition to GM foods over time. Using the BSA data from 1999 and 2003, it can be seen that the UK has kept in step with the mean for the Member States up to 2003. The graph below highlights levels of support for biotechnology and more specifically GM foods in the UK. The principal point of note is that both measures show very labile levels of support; the levels of support for GM foods are considerably more erratic and unstable across the time frame shown.

Figure 16: Support for biotechnology and GM food in the UK



Interestingly, the Eurobarometer data from the 2010 survey shows that the UK had the highest levels of support for GM food across the 27 countries surveyed, yet when the survey respondents were asked to respond to ten statements on GM food this support is not as clear cut. This is a critical point in relation to survey data; one should not just respond to the headline data. Analysis of the results from the additional survey statements show inconsistencies but generally the results were approximately two fifths pro and two fifths anti-GM with one fifth responding as ‘don’t knows’. For example, 46% agree that ‘GM food is good for the UK economy’ and 36% disagree, yet when asked to respond to the statement that ‘GM food is not good for you and your family’, 40% agree and 39% disagree. A startling result is that 59% agreed with the statement that ‘GM food helps people in developing countries’ but equally 55% agree that ‘GM food benefits some people but puts others at risk’. These results are surprising in that they seem to suggest a view that GM food is acceptable for other people to eat but not for the UK public. The survey shows that people still hold that GM food is ‘unnatural’, since 65% felt this to be true, and 49% agreed that GM food made them feel ‘uneasy’. The correlation in the data between awareness of GM food and an anti-GM food opinion is interesting. Across the 27 countries participating, those who were aware of GM foods were more likely to disagree with the statement that GM food is good for

their nation's economy (53%), than those who were not aware of GM foods, where 37% disagreed.³⁵⁰

It is common to discuss levels of familiarisation with technologies in relation to support or opposition to them. It is often held that increased familiarity with a new technology can overcome resistance and lead to the assimilation of the new technology into daily life. This does not appear to have happened in the UK in relation to GM foods where the pattern is much more erratic. Since the end of the EU moratorium there has been a visible decrease in support for GM foods. Across the EU, the new member states show the least public support for GM foods. The markets of these states have been less tightly regulated than the EU in terms of authorization, approval and labelling of GM products. This may indicate that the regulation has some influence over attitudes, as nations such as Latvia, Estonia and Slovenia were not subject to this type of regime prior to entry to the EU. However, the Czech Republic which had quite stringent labelling regulations before accession to the EU demonstrates the highest levels of support for GM foods across the whole EU and there are a high number of GM products available in the shops.³⁵¹ Eurobarometer data shows, however, that compared to other biotechnologies, the public is most familiar with GM foods, yet are also most opposed to the technology, refuting the familiarisation narrative. The data shows that 80 per cent of respondents are familiar with GM foods, 45 per cent with gene therapy, 44 per cent with nanotechnology and 27 per cent with pharmacogenetics.³⁵²

A useful heuristic is to stratify the public opinion data into those in opposition, those in support and those who are undecided about GM foods. In terms of constructing narratives around these publics, I would like to stress that the narratives are not in competition with each other but mutually coexist. Three narratives are evident: the idea that labelling leads to the entrenchment of opposition; the concept of increased support for GM foods through familiarisation; and the suggestion that increased knowledge leads to increased uncertainty. While it is established that two of these are visible in the data, it is evident that familiarisation with GM foods is not leading to increased support.

³⁵⁰ P.13-18 of Special Eurobarometer on Biotechnology 341/ Wave 73.1 – TNS Opinion and Social, European Commission, published October 2010.

³⁵¹ European Commission: Framework 6, Project number 518435, 'Do European Consumers buy GM Foods?' (Consumer choice) Kings College London, 2008.

³⁵² Eurobarometer data cited in Gaskell et al 2006, op cit. at p.16.

In line with the deficit model, it is often assumed that those more informed will be the more enthusiastic supporters of new technologies. This is premised by the concept that science is rational and informed by ‘fact and reason’ rather than by uninformed opinion based on emotion.³⁵³ However, it is important to differentiate between attentiveness and knowledge; perhaps surprisingly, the relationship between attentiveness and attitude does not hold for GM foods. The research conducted within the remit of the BSA survey finds that those people who are most attentive to GM foods are least likely to support the development of them.³⁵⁴ This runs counter to the relationship found in the same survey for human genetic technologies. The BSA survey found additionally that in relation to GM foods, those who are more attentive are less trusting of the regulators of modern genomics.³⁵⁵

With reference to the levels of opposition to GM foods seen in figure 15, it is surprising that the 2005 rate of opposition is higher than the 1999 rate. This supports the entrenchment or deliberative model which I offer as an explanatory narrative. This narrative works on the premise that the regulation and attitudes are working together in a responsive, deliberative manner. Deliberative mechanisms are beacons of recent regulatory trends to increase proceduralisation of the law. Proceduralisation carries moral caché, in that it is subsumed within wider laudable motives such as increasing democratic accountability and transparency. Deliberative democracy refers to the concept that ‘legitimate lawmaking issues from the public deliberation of citizens’.³⁵⁶

In relation to one sector of the public, those opposed to GM foods, Figure 17 attempts to explain why the negative attitude remains entrenched by postulating a closed deliberative circle. I developed this model in response to the data I analysed in this thesis. At the outset there was a public outcry against GM foods which was noted by policy makers. The regulatory response was to remedy the situation by implementing a

³⁵³ Blair, A. ‘Science Matters’, Speech to the Royal Society, 10 April 2002 cited in Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris, Shepherd, Richard, ‘Genomic Science: Emerging Public Opinion’, from Park, A., Curtice, J., Thompson, K., Bromley, C. and Phillips, M. (Eds) (2004) *British Social Attitudes - the 21st Report*. (London: Sage) at p.134.

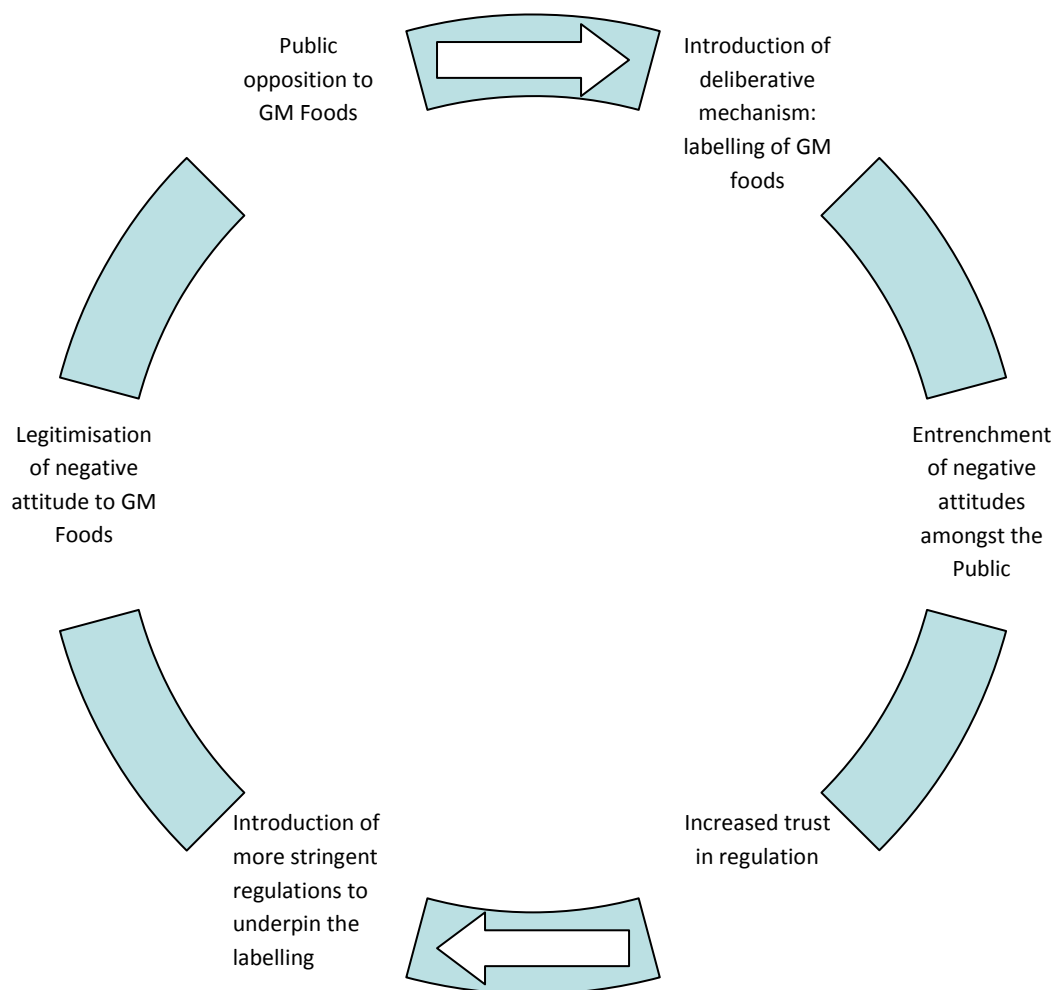
³⁵⁴ Sturgis et al, 2004, op cit. at p. 135.

³⁵⁵ Sturgis et al 2004, op cit at p. 136.

³⁵⁶ Bohman, J. & Rehg, W. (Eds) ‘Deliberative Democracy: Essays on Reason and Politics (MIT: Cambridge, MA. 1997) p.ix.

deliberative tool: the labelling mechanism. This mechanism provides the consumer with information, but the label reinforces the common narratives of nature and natural/unnatural discourses and the associated idea that GM is different, that it is something that deviates from the norm and that non-GM is superior. The consumer reacts on the basis of the information provided by the label, and their consumer habits influence the nature of the products available on the market with ramifications across the supply chain. This leads to entrenchment of the labelling process and to tightening up of the regulatory mechanisms which underpin it. In effect the regulatory process has enabled the legitimisation of public opposition to GM foods. Regulation has an influence upon attitudes but not in such a way as to allay concerns.

Figure 17: Opposition to GM foods as a deliberative circle (entrenchment model)



It has already been suggested that the high levels of regulatory activity themselves may have been one reason for the public feeling that GM foods are not safe. In line with such an argument is Watson's comment made in 1977 on the regulation of GMOs. He suggested that rather than alleviating public concern, the precautionary approach has had the response of 'If it's as safe as you say, why do we need all these precautions?'³⁵⁷

The BSA survey data shows a rise from 1999 to 2003 in the numbers of respondents who are undecided about where they stand on the issue of GM foods. In the case of whether the advantages of GM foods outweigh the disadvantages, the 'don't knows' figure rose from 23 per cent of respondents in 1999 to 37 per cent in 2003.

Interestingly, it has been shown that the higher levels of genetic literacy have increased the polarisation of the views of the public towards GM foods and as such a more divided public. On the one hand there are the ambivalent section and on the other the group who have quite strong anti-GM views. Research conducted by Durrant and Legge found that respondents with greater knowledge are less able to come to a decision on GM foods.³⁵⁸ This is particularly interesting in light of the findings on those numbers who 'neither agree/disagree' as combined with the increased 'don't knows' this is demonstrating an increase in respondents who do not wish to commit themselves on the issue.

Turning to information content, in 2003, 44 per cent of people surveyed incorrectly answered the following true/false statement in the BSA survey genetics quiz: 'Ordinary tomatoes do not contain genes, while genetically modified tomatoes do'.³⁵⁹ Much has been made of this statistic but is it really that significant? Also part of the quiz was the statement that: 'By eating a genetically modified fruit, a person's genes could also become modified' to which 57.3 per cent correctly answered that this was false.

A very significant filter in the case of GM foods is that they were introduced to the public in the wake of the BSE crisis. As a result of that episode the public climate

³⁵⁷ Watson, J. 'An Imaginary Monster: The Only Danger We face is the Spectre of Untested Regulations', *Bulletin of the Atomic Scientists*, 33, (1977) pp. 12-13. Cited in Tait, Joyce and Martin, Sam, 'Attitudes of Selected Public Groups in the UK to biotechnology' in Durant, John (Editor), 'Biotechnology in Public: A Review of Recent Research', Science Museum, 1992.

³⁵⁸ Durrant and Legge, 2005 op cit. at p.195

³⁵⁹ British Social Attitudes Survey 2003, for this statement n=3272.

became highly charged on the subject of food; this was not a neutral climate into which a new technology could be introduced. It is argued therefore that the appearance in the media of headlines referring to 'Frankenstein foods' served to ossify the opinions of the public as consumers, rather than strongly influencing them. In this second phase of the regulations, from 2002 to 2005, findings from the Eurobarometer data indicate decreased support and increased opposition to GM foods amongst the undecided sectors of the public.

Research conducted by the Institute of Grocery Distribution (IGD) suggests that consumer decisions about food and shopping are 'unashamedly selfish', based on value for money, health concerns, taste, appearance and convenience, rather than being driven by altruistic motivations such as animal welfare and care for the environment (IGD, 2002a). This finding is endorsed by FSA research which also highlights price, convenience and value as the three primary issues for consumers when shopping for food, as well as keeping within the family budget, satisfying children's demands, and getting the family to eat a balanced diet (FSA, 2000). In 2004, Sainsbury's introduced non-GM milk which they argued was in response to demands from customers. It was replaced in 2006 by 'Farm Promise' milk which is milk from farms which are in the process of becoming organic. Most pertinent is that while this milk is also non-GM, whereas the former milk had a 'hard to miss', non-GM label this does not. Such a move suggests that there was no real market for a premium costing milk (the non-GM milk cost 10% over the conventional milk). Further to this Sainsbury's state that 'several scientific studies by well-respected organisations have found no GM material in milk samples from cows fed on a GM diet'. Such comments raise the question: why did they market the product in the first place if this was their view?

5.5 The interaction between public opinion and the regulation of GM foods

Prior to the EU moratorium on GM products, the purpose of regulation was as a means to facilitate the sale of GM products and thus was related to the assessment and authorisation processes for GM products. Earlier in the 1990s, there were few warnings that there would be such vociferous and determined public opposition to GM foods. The public outcry was enough to dramatically alter the direction of the regulation. The regulators had no option but to respond to the high levels of public opposition and the response came in the form of the EU moratorium on GM foods. Once the moratorium came to an end however the demands of the biotech industry were tentatively embraced and the balancing of the regulation's dual demands shifted. The labelling regulations were deemed to be the means to enable the technologies to progress while also appeasing public concern. This to some extent explains the deliberate pragmatism and flexibility inherent in the regulations, illustrated by the exemptions to the scope of the regulation and the adventitious threshold levels.

The 2003 Regulations were viewed as a means of smoothing the end of the moratorium. These regulations are undoubtedly more codified and increase transparency across the supply chain. However, enforcement and traceability issues mean that they lack the underpinnings to work effectively. Exemptions include foods made with GMOs, GM animal feed and the adventitious threshold level. Importantly, Gaskell et al suggest that the de facto moratorium is being perpetuated to some extent by the supermarkets themselves in response to consumer preferences.³⁶⁰ The introduction of the 2003 Regulations led to less fuzzy levels of consumer autonomy. It remains the case, however, that consumers are not aware of the exemptions to and derogations from the labelling regime, and as such they are not in full possession of the knowledge necessary to make an informed choice in the supermarkets.

³⁶⁰ Gaskell, George, Allum, Nick, Bauer, Martin, Jackson, Jonathan, Howard, Susan, Lindsey, Nicola 'Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002', Life Sciences in European Society Report: London School of Economics and Political Science, 2003.

5.6 Public Opinion is Media Opinion

‘Some see the public as a victim of misleading information from non-governmental organisations (NGOs) or newspapers that are seeking to increase their circulation numbers’.³⁶¹

In terms of the influence of the media upon public attitude, Frewer, Miles and Marsh argue that ‘at least some demographic groups have become more convinced of the negative aspects of genetically modified foods’.³⁶² It is important to test whether most commentators would argue that generally public attitudes reflect the pattern of press coverage. Bodiguel and Cardwell argue that:

‘the heat of the debate has arguably been raised by the high media profile of GMOs. Again in the United Kingdom, the generally negative attitudes of journalists have incurred the criticism of the Government Chief Scientific Adviser, who had little sympathy with the Daily Mail for its use of such charged language as ‘Frankenfoods’ or with John Humphrys or the BBC Today programme for his pro-organic stance.’³⁶³

While Tait supports the argument that the media predominantly take an anti-GM stance, she presents a different slant in that she contends that there is a high level of opposition to any publications or reports which are neutral towards or pro-GM. Tait argues that this ‘attack’ on publications comes from public-interest groups and persists despite the controversy being at its most virulent between 1998-2002. Further to this Tait points to the large volume of web-based anti-GM information which she claims is reported ‘relatively uncritically in the media’.³⁶⁴ Interestingly and in contrast to this, Waltz writes in *Nature* that the publications of scientists which are deemed to be anti-GM are openly attacked by other scientists.³⁶⁵

³⁶¹ Mayer, Sue and Stirling, Andy, ‘GM crops: good or bad?’ *Nature EMBO Reports* (2004) 5, pp.1021-1024 at p.1021.

³⁶² Frewer, L., Miles, S., and Marsh, R. ‘The GM Foods Controversy. A Test of the social Amplification of risk Model’, *Risk Analysis*, 22: pp. 713-723, 2002. Cited in Frewer, Lynn J. ‘Trust, Transparency and Social Context’, Chpt. 5 in Pidgeon, Nick, Kasperson, Roger E. and Slovic, Paul, (Eds), ‘The Social Amplification of Risk, (Cambridge University Press, 2003) at p. 134.

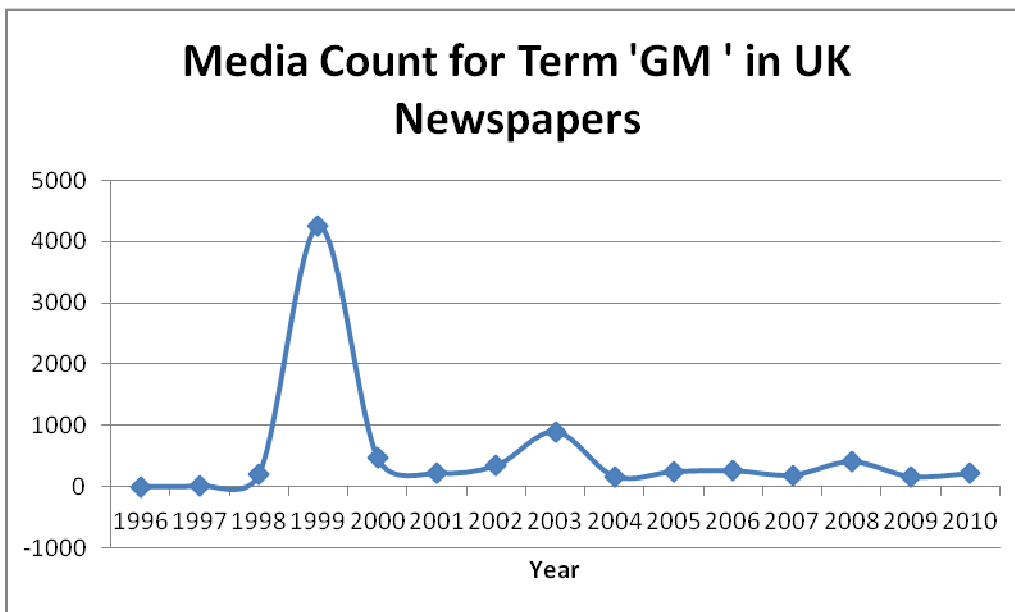
³⁶³ Bodiguel and Cardwell, 2010, *ibid.* at p. 11 citing Professor Sir David King.

³⁶⁴ Tait, Joyce, ‘Upstream Engagement and the Governance of Science: The Shadow of the Genetically Modified Crops Experience in Europe’, *Science and Society, EMBO Reports*, Vol. 10, 2009.

³⁶⁵ Waltz, Emily, ‘Battlefield’, *Nature* Vol.461, 3 September 2009.

In order to gain some idea of the level of media coverage relating to GM foods, I conducted a series of LexisNexis searches. In some years there was such a high volume of stories relating to GM foods returned that Nexis would not return a specific figure and in these cases the counts were conducted on a month by month basis and the total accounted. The counts were made for the term 'GM food' and 'GM'. The count for 'GM' is shown graph number 18. The period covered was from January 1996 to December 2010 and searches and represents UK newspapers both tabloids and broadsheets.

Figure 18: Media count for the term 'GM' in UK newspapers



Augoustinos et al argue that in 2004, public confidence and trust in the Government to act within their wishes is portrayed by the media as being very low.³⁶⁶ The Daily Mail was a particularly vociferous critic of the Government's stance on GM. On 20 February 2004 it produced its infamous headline: 'If you ever had any doubts about FRANKENSTEIN FOODS read this litany of deceit, cynicism and manipulation'. This article produced a chronological list of 40 significant events, findings and decisions relating to GM foods from April 1997 to January 2004 and reported that the Economic and Social Research Council stated that 'no scientific evidence exists to support the

³⁶⁶ Augoustinos, Martha, Crabb, Shona, LeCouteur, Amanda, 'Representations of Genomics in the UK: Media, Interest Groups and Government Texts', July 2005 (unpublished) at p.23.

growing of GM crops in the UK'.³⁶⁷ In terms of the enormous volume of newspaper coverage in the course of 1999, it would appear that indeed many journalists chose to emphasise and accentuate the risks rather than to reassure their readership. Significantly, this peak in media attention corresponds with the peak in opposition to GM foods highlighted by the BSA survey of 1999.

In examining the content of the stories using LexisNexis, of those from February 1999 when the volume of coverage peaks, the majority relate to plans to grow GM crops in the UK and to the Flavr Savr tomato paste fiasco. Further stories covered the direct action initiatives taken by Greenpeace and FoE which was documented in detail by the media. The Guardian stated that 'sheer confusion has been the GM debate's defining trait'.³⁶⁸ At the time, it is apparent that public anxiety was magnified by the constant press attention paid to it. Concerns range from safety issues to the dominance of global corporations such as Monsanto over the food industry. The BSE crisis added to the mix in terms of fears over food safety and was a critical factor in the formation of attitudes to GM foods, since, as Kasperson notes, 'publics typically have long memories'.³⁶⁹ Murdock explains that it is better to view the media coverage of risk;

'not as a series of discrete responses to bounded events, but as the latest episodes in an intersecting series of continuing narratives about chance, choice, science, power, and accountability'.³⁷⁰

The Independent interestingly questions who is in control of the GM regulation: the Government or the public.³⁷¹ Bateson pertinently noted that not a single story published in February 1999 was written by a science journalist.³⁷² During this time the term

³⁶⁷ The Daily Mail, 20 February 2004, cited by Augoustinos et al 2005, op cit. at p.25.

³⁶⁸ The Guardian, 20 February 1999.

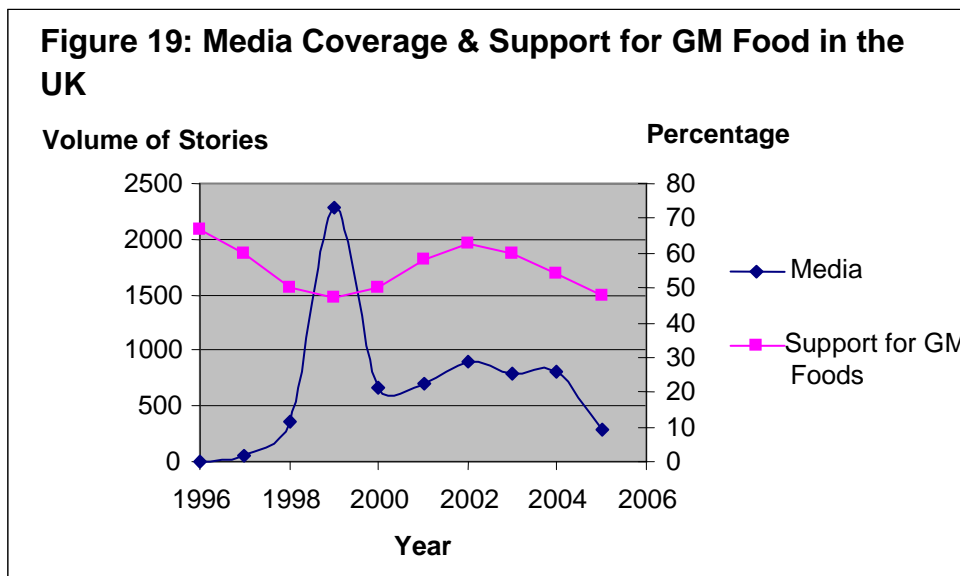
³⁶⁹ Kasperson, R.E. 'The Social Amplification of Risk: Progress in Developing an integrative framework of risk' in Krinsky, S. and Golding, D. (Eds) 'Social Theories of Risk', (Westport, CT: Praeger, 1992) at p.182 cited by Murdock, Graham, Petts, Judith and Horlick-Jones, Tom, in 'After Amplification: Rethinking the Role of the Media in Risk Communication', Chpt. 7 in Pidgeon, Nick, Kasperson, Roger E, and Slovic, Paul, 'The Social Amplification of Risk', (Cambridge University Press, 2003) at p.171.

³⁷⁰ Murdock et al 2003, ibid. at p.171

³⁷¹ The Independent, 28 February, 1999.

³⁷² Bateson, P.P.G. in Science and Technology Select Committee publication of March 2000 cited in The Independent, 25 March 2000.

‘Frankenstein foods’ was used repeatedly. However, a study by Cook, Robbins and Pieri shows that this term has been utilised more by the proponents than the opponents of GM foods.³⁷³



The Figure above compiled with data from Eurobarometer and Lexis count for ‘GM food’ shows a clear trend between the media coverage and support for GM food for 1999, where most intense media coverage corresponds with high levels of opposition and low levels of support for GM foods. In the second phase of the labelling regulation, the peaks for media coverage are in the months of March and April 2004. These peaks coincide with the lead up to the announcement by Margaret Beckett on the government decision to allow commercial planting of GM maize. The Government would ‘in principle’ agree to the commercial cultivation of GM herbicide-tolerant maize, Chardon LL by Bayer Cropscience, to be used in cattle feed. However, on 1 April 2004 Bayer withdrew its application to grow GM maize, stating that the restrictions imposed upon it by the Government had made it economically unviable. Also, at this time, a number of stories appeared in relation to labelling GM foods as this is the period when the 2003 regulations were implemented. However, it appears that in 2005 the media no longer considered GM foods newsworthy despite high levels of opposition across Europe and the low levels of support in the UK. Indeed from the graph above it is evident that

³⁷³ Cook, Guy, Robbins, Peter T. & Pieri, Elisa, ‘Words of Mass Destruction: British Newspaper Coverage of the Genetically Modified Food Debate, Expert and Non-Expert Reactions’, *Public Understanding of Science*, Vol. 15, No. 1, 5-29 (2006)

levels of support were parallel to that of 1999 which presents a mixed message in terms of the relationship between reading a paper and opinions surveyed.

5.6.1 Is there a link between Newspaper Read and Attitude to GM foods?

This section examines whether there is a correlation between the newspaper read and a person's attitude to GM foods with the view that the media opinion is often deemed to be public opinion. The BSA survey contains data on whether respondents regularly read a newspaper and which paper they read. By cross-referencing the respondents that agree or disagree with certain statements on GM food and the newspaper read, some very clear patterns emerged. In the BSA survey 1999, 55% of respondents said they read a newspaper more than three times a week. When all survey respondents are taken into account, so those who read a paper and those who do not, 65% disagree with the statement that GB should grow GM foods. However, if the respondent reads a newspaper regularly, the percentage that disagree with this statement are as follows: the Guardian, 88%, the Scotsman/ the Daily Mail 83%, the Independent 42% and the Financial Times 25%.

For the statement 'GM foods in the shops are safe to eat', the whole survey response for 1999 shows that 35% felt that GM foods were definitely or probably safe and 48% felt they were probably or definitely not. This was approximately the same as those respondents who read the Daily Mail but only 17.5% of Guardian readers considered GM foods in the shops safe to eat. These findings do show a sharp difference in view in relation to newspaper taken. In 2003, the findings for all respondents whether they read a paper or not was 47% thought that GM foods in the shops were definitely or probably safe. From those who read a paper regularly, the Mail came in at 37%, the Financial Times 60%, the Guardian 45% and the Independent at 50%. The BSA data gives us a very clear impression of the bias of the newspaper on attitudes to GM.

5.7 Public Opinion Data Collection by the IRAs

The principal IRAs overseeing the regulation of GM foods in the UK are the Food Standards Agency (FSA) and Defra and they have both made significant efforts to gauge public opinion. The most politically symbolic and attention grabbing attempt to gauge public opinion in this area was the GM Nation? debate of 2003. This was an ambitious nationwide project which had the purpose of facilitating open public dialogue

on the commercialisation of GM crops in the UK. It involved meetings across the UK where both anti and pro-GM information was presented and participants were asked to respond to 14 questions on GM. Unfortunately, high levels of controversy surround the findings of the GM nation? debate and it has now been all but rejected as being non-representative of the public and deemed to have been ‘captured’ by anti-GM interest groups. The GM Nation? debate concluded that the majority view was anti-GM with feelings ranging from ‘suspicion to scepticism, to hostility and rejection’.³⁷⁴ Campbell and Townsend argue that the data was misrepresentative mainly as the results were flawed was a consequence of the self-selection procedure which it is argued attracted people who have a strong opinion about GM.³⁷⁵ Very persuasive and strong critiques of the GM nation? debate have been produced by inter alia, Campbell and Townsend and Horlick-Jones and it is for this reason that this consultation is not analysed in depth in the thesis.³⁷⁶ The important issues are that the data was responded to by the regulators despite it generally being deemed to be misrepresentative of public opinion. The GM Nation? debate does clearly show the shifting understandings of public opinion as the findings were a reflection of the views of interest groups, which is one understanding of public opinion, and indeed the views of interest groups were a very vocal and active force in the shaping of the regulatory response to GM foods in the late 1990s and first few years of the 21st century. Tait argues that:

‘The trouble was that the GM dialogue in the UK was used in policy and it was based on bad data and everything that was done by the AEBC [the Agriculture and Environment Biotechnology Commission] was based on pretty bad science’.³⁷⁷

Tait goes on to say that the ‘focus group material is hugely open to bias by the people conducting it’ which is a common criticism of the focus groups carried out in the GM Nation? debate. Interestingly, Reynolds and Bronislaw discuss whether the GM Nation? debate should be measured against a quantitative survey as a means to establish the accuracy of its participants. In their opinion this would mirror the composition of a

³⁷⁴ Campbell, Scott and Townsend, Ellen, ‘Flaws Undermine Results of UK Biotech Debate’, Nature October 2003, Vol. 425 at p.559.

³⁷⁵ Campbell and Townsend (2003) *ibid*.

³⁷⁶ Campbell and Townsend (2003) *op cit*. and Horlick-Jones, Tom, ‘The GM Debate: Risk, Politics and Public Engagement’ (Routledge)

³⁷⁷ Joyce Tait in interview for the thesis on 1st May 2011.

wider general public. After toying with this and other potentially rewarding approaches such as measuring the GM Nation? debate against a deliberative ideal, Reynolds et al dismiss these ideas as abstract and argue that they would ‘obscure other important dimensions of the GM Nation? debate.

The Food Standards Agency has carried out eight Consumer Attitude Surveys (CAS) since 2000 and GM is included in each, although a different level of attention is devoted to it across the years reflecting its prominence to the public and regulators. Due to the fact that the questions posed were not uniform across the years the data is not easy to analyse and there is no method to gauge attitude change over time. However, the CAS data shows that in 2000, 43% of respondents were concerned about GM foods and that this had reduced dramatically to 20% in 2008. The data is robust and the sample size was around 2,500-3,000 respondents in each year.³⁷⁸ In 2003, the FSA produced a much more detailed report of the findings of their CAS survey and three focus groups entitled ‘Consumer Views of GM Food’. The principal findings were that in the three years anxiety about GM foods had decreased (from 43% of respondents to 36% who agreed that they were concerned). Consumers wanted more information and it was unclear what the benefits of GM foods were to UK consumers.³⁷⁹ The principal issue is the fact that the GM Nation? debate findings were very much at odds with both this data collected by the FSA and the BSA survey data from 2003. To reiterate, the BSA survey 2003 showed that 46.3% of respondents felt that GM foods sold in the shops were safe to eat. It is noteworthy that the FSA have made a very concerted effort to gauge the public opinion on GM foods and a commitment to reflexive practice on public engagement is demonstrated by the establishment of the Advisory Committee on Consumer Engagement (ACCE).

³⁷⁸ See further the surveys on the Food Standards Agency website:
<http://www.food.gov.uk/science/surveillance/fsisbranch2011/> (last accessed October 2011)

³⁷⁹ FSA report of 2003 ‘Consumer Views of GM Foods’ at
http://www.food.gov.uk/multimedia/pdfs/gm_rep.pdf (both sites last accessed October 2011)

5.8 The regulators' understandings of public opinion

The regulators interviewed for this thesis in relation to GM foods were senior officials in the regulation of GM foods from the Department of Environment, Food and Rural Affairs (Defra); the Food Standards Agency (FSA); the European Commission's Directorate General for Health and Consumer Policy (DG SANCO); and the European Food Standards Authority (EFSA). In addition to these were Professor Joyce Tait who is an academic and a member of the FSA steering group on GM; and Mr Phillip Cullum, the Deputy Chief Executive of Consumer Focus who chairs the FSA's Advisory Committee on Consumer Engagement (ACCE). The questions asked in the interviews are in Appendix 2.

One of the overriding themes from the interview data was that the regulation was discussed in terms of being evidence and science-based. A Defra official comments thus:

'We're very much an evidence-based organisation and you know we will always say that the...you know, the authorisation of GM foods should be based on...on scientific evidence basically and I suppose, you know, and that's really how we take the decisions in Brussels...'

It is contended that the regulators interviewed from EFSA and the FSA felt that the role of public opinion clouded the efficiency of the regulatory process. At the beginning of one interview, the regulator stated that:

'When thinking of primary legislation then ethical opinion as well as public opinion are important, but when we've actually got the rules it is not important in terms of the process'. (Official from DG SANCO)

This interviewee continued to discuss what takes place in practice by stating:

'In this case the law says to apply the science but what in practice happens is that you have public opinion making its opinion felt not by saying 'we don't like GM' but 'we don't think the science is set up in the right way' so public opinion then supports what is in effect scientific criticism of the process saying 'you ought to have done a 40 day rat feeding study' (...) so what we perceive as public opinion is not in an IPSO Mori sort of way so much as these scientific critiques which we have to take seriously because they are published in the general press and they are supported by the readership so it's a complicated interplay between insiders and a broader aura of disapproval of general public opinion.'

The critical points to be taken from this comment are that the EFSA official does not feel the public opinion derives from survey data, from 'an IPSO-Mori' public, and he states very categorically that the scientific criticisms are from 'insiders'. This suggests

two things: that the criticisms are issued by public interest groups and that these interest groups use formal channels in a highly effective manner which has to be responded to because, as the interviewee states, the regulators have to take these critiques ‘seriously’. A further point lies in the fact the regulator attributes the reasons for taking the criticisms seriously to the fact that they are published in the general press and are supported by the readership. The ideas of public opinion are further complicated by the introduction of the newspaper readership who might be viewed as the ‘general public’ and yet they have an indirect impact on the response of the regulators to the scientific criticisms levelled by the NGOs. Related to this idea of the point in the regulatory process at which public opinion should have an influence are the comments made by a regulator from the FSA:

‘when the voting process happens in Brussels there are a number of members who will vote against even though they acknowledge that they haven’t got any concerns about the safety assessment; everything they have asked has been addressed they will still vote for political reasons’.

This reinforces the regulatory stance that the regulation should be based on science and it is not correct for opposition which is derived from opinion, that is, anti-GM feeling, to be felt in what is a scientific procedure. It is clear that the ‘political reasons’ the interviewee refers to is public opinion. The interviewees highlight the ways that the regulatory process, despite its appearance as a robust and tightly framed procedural system, can be manipulated by NGOs.

The argument that the regulation should be led by the science returns again and again in the interviews, to the extent that once the authorisation process is established, there is no longer a role for the regulator. In relation to this, an interesting comment was made by a regulator at the FSA that:

‘whilst we are aware that there’s public concern about GM foods and the public saying ‘we don’t want to eat GM foods’ and some retailers responding to that, that isn’t a factor in whether a GM crop is authorised by us. As far as we are concerned its very much based on the science and it’s for the retailers to decide based on their market and their customers whether they want to stock GM foods and if they do then we can be confident that they are safe’.

This relates to the issue of public trust which repeatedly arose in conversation with the interviewees. An official from Defra commented that ‘regulation is only going to be successful if you’ve got public trust so you’ve got to have public input into the regulation’. The same interviewee stated further that the role of regulators at Defra is to ‘ensure safety and help ensure public trust, maintain innovation and guard the UK’s

interests – totally evidence based position, the policies we make and the decisions we make have got to be based on evidence and that includes people’s views.’

In the interviews the regulators were asked about the role of regulation in alleviating public concern over new technologies. The regulator from the European Commission states that:

‘regulation gives you a reasonable reassurance and then it opens up peoples minds to look at the benefits, you have to craft the regulation with the worries in mind and what we’ve learned from GM is that we haven’t dealt with all the worries ... we’d do better if we had correctly understood what the main problems were and then provided the answer to them.’

One final theme is the issue that the labelling regulations have resulted in public confusion, as an official from Defra states:

‘Talk about the confusion!....The rules that we’ve got....more than 0.9% GM then has to be labelled as such, that’s clear but um....then people start selling non-GM, GM-free, then people get confused, I know I do and I work on the stuff!’

Thus this regulator contends that the public are confused by the labelling regulations. This does not suggest that public anxieties would be placated by a form of regulation which confuses them, yet it is argued that the very existence of the regulation does have the capacity to reassure.

5.9 Analysis and Overview

The BSA survey of 2003 found that 50% of survey respondents felt that genetic science is too complex for the public to play a role in the regulation. If this view reflects the public view then it follows that there is faith in the regulatory system to protect the public from risk while giving them access to the benefits of novel technologies. It is argued in chapter 4 that public trust in regulation is necessary for regulation to have any influence over public opinion. Data collected shows that there are relatively high levels of confidence in the FSA with 48% of survey respondents rating the FSA as an organisation they can trust.³⁸⁰ Durrant and Legge argue that a combination of high levels of trust in Government and regulatory capacity can increase support for GM

³⁸⁰ FSA, ‘Quarterly Public Attitudes Tracker’, September 2009.

<http://www.food.gov.uk/multimedia/pdfs/fsatrackersurvey.pdf> (last accessed November 2011).

foods.³⁸¹ Higher levels of public trust are reported in the data, yet support for GM foods in 2005 is as low as it was in 1999, suggesting either that Durrant and Legge's contention is incorrect or that labelling as the regulatory form is an unsuitable mechanism to increase support for GM foods.

Undoubtedly, the levels of public opposition and the intensity of media coverage were of such magnitude in the late 1990s that they can be construed as a 'scandal' or a 'disaster' in policy terms a *propos* Bernstein's model.³⁸² In keeping with the model, the issue of GM foods was placed firmly on the political agenda thanks ultimately to public pressure, which over-rode the standard policy agenda setting procedures and regulatory output ensued.³⁸³ There is no doubt that it would have been in the consumer's interest had a systematic, cogent and comprehensive labelling system been implemented from the outset. It has been seen that beyond the public protests, the public had an enormous influence as consumers. Supermarkets responded by withdrawing all the GM products from their stores. Millstone states that in the final eighteen months of the twentieth century:

'consumers did not just indicate that they had misgivings about the introduction of genetically modified foods, they discovered that their choices could influence the research and innovation strategies of an entire industrial sector'.³⁸⁴

It is apparent that in some cases, while the regulation has been unable to keep pace with the consumer, the market has had the capacity to respond speedily. The self-regulation taken by the supermarkets added to the pressure on the politicians and regulatory bodies to respond to public concerns over GM foods. The regulation that ensued served only to tidy up what was happening in practice. The public protest brought about the

³⁸¹ Durrant & Legge, at p.197

³⁸² Bernstein, M.H. 'Regulating business by independent commission', (Princeton University Press, 1955) cited by James, Oliver, 'Regulation inside Government: Public Interest Justifications and Regulatory Failures', *Public Administration*, Vol.78, No.2, 2000 pp.327-343 at p.335-336.

³⁸³ Bernstein, M.H. 'Regulating Business by Independent Commission', (Princeton, NJ: Princeton University Press, 1955) cited in James, Oliver 'Regulation inside Government: Public Interest Justifications and Regulatory Failures', *Public Administration*, Vol.78, No.2, (2000) pp.327-342 at p.335.

³⁸⁴ Millstone, Erik, 'Analysing Biotechnology's Traumas', in *New Genetics & Society*, Vol. 19, No. 2, 2000 at p. 117-118.

moratorium on GM foods and in turn this moratorium created a refuge for campaigner and regulator alike.

The 2003 Regulations achieve a more codified and comprehensive labelling regime for GM foods than did the earlier labelling regulations. However, the impact of the labelling regulations on the public is not clear. Perhaps surprisingly, the Eurobarometer survey data shows that the level of support for GM foods in the UK was only marginally higher in 2005 than it was in 1999. This disproves the argument that an increased familiarity with a novel technology leads to increased acceptance for it. Opposition levels to GM foods in 2005 are also comparable to those in 1999. The high level of opposition in 2005 is again an unexpected finding and does suggest that the labelling regulations and the underlying ethos of enhanced consumer autonomy have resulted in confusion over GM foods. This idea that the public are confused about GM foods is supported by the regulators interviewed. Part of the confusion may stem from the fact that there are so few GM products on sale. A European Commission study found that in the UK in 2008, there were only two GM products on sale: soya oil, which is a cooking oil sold in large drums and is generally located in the Asian foods section of supermarkets, and an American product called Bac-Os (bacon-flavoured soya crisps). However, NGOs assert that there are GM ingredients in many foods from UK supermarkets and they attribute this to three factors: the adventitious presence, meat which comes from animals who have eaten GM fodder, and the GM which escapes the traceability regulations and enters the market illegally. In relation to the adventitious presence of GM, Bate takes issue with the setting of a threshold amount and describes it as scientifically illogical on the grounds that if there are health risks then even a miniscule amount of the product may have the potential to harm.³⁸⁵

It is additionally argued by some that rather than introducing customer autonomy, the labelling of GM foods stigmatises the technology.³⁸⁶ The labelling regime, by making visible the issue of segregation of GM from non-GM products has consequently deepened the divide and I contend has made the issue more visible to those people who may not have held a definite opinion beforehand. In a bid by the EU to avoid trade

³⁸⁵ Bate, Roger, 'The European Union's Confused Position on GM Food', *Economic Affairs*, Vol.23, No.1, (March, 2003), p.58.

³⁸⁶ Hansen (2003), *ibid.* at p.68-69.

problems and consumer backlash, consumers are not actively informed of certain exemptions. For instance, GM cattle feed is extraordinarily prevalent and meat reared on such feed is considered the 'norm'. However, it remains legal for food products derived from animals fed on GM feed to be labelled as 'GM free'. Additionally, consumers may not generally be aware that foods which have been produced using GM technologies may be labelled as 'organic'. Such pragmatic exercises cloud the labelling issue for consumers and lead to the development of fuzzy autonomy. The consumer feels more empowered in terms of information with which to make a choice between GM or non-GM produce, but actually the position is far more complex than they realise. It is clear that the self-regulation by the supermarkets has an enormously significant effect. While the food suppliers and producers may see a benefit in terms of a reduced price in using GM ingredients, there is not any demand for GM foods from the consumer.

5.10 Conclusion

This chapter has been divided into two time-frames which help to identify the different relationships between public opinion and regulation in the 'watershed years' of 1999-2003 and since the lifting of the moratorium.³⁸⁷ It is apparent that the public protests and the force of NGO lobbying in the 1999 and the early years of the 21st century created a very strong voice which was listened to by the regulators. At this time there was an enhanced reference to public opinion in the regulatory process which culminated in the moratorium on GM foods. The call for an in-depth public consultation came from the Government and the GM Nation? debate is a hugely symbolic indication of the Government's wish to show that they wanted the public to feel included in the decision-making over GM. The principal motivation for the enhanced consultation arises as a result of the contested harm of GM foods. Jones argues that: 'never before has there been a system of elaborate and expansive regulation based on hypothetical risks!' Jones calls for the freeing up of the regulation to facilitate the development of smaller companies, and this is an important issue because the biotech lobby is dominated by the large multinationals.³⁸⁸

³⁸⁷ Gaskell et al use the term watershed years to describe the years of GM regulation from 1999-2003. Gaskell et al 2003, op cit. passim.

³⁸⁸ Professor Jonathan Jones speaking on Radio 4 on 'You and Yours', 15/6/10.

The first phase of the regulation, from 1997 to 2002, is characterised by a large volume of regulatory output which was produced in a very piecemeal, inchoate and almost tentative way. I believe the regulatory purpose at this time was to increase public familiarisation with GM foods with the expectation that it would lead to social accommodation. However, it is apparent that this has not been the case and public opposition was quelled only by the de facto EU moratorium. The lack of any challenge at the time by the European Commission to the six Member States who initiated the moratorium is testament to the EU's recognition of the public mood. Clearly, the role of the media has been hugely influential and the data identified an unprecedented focus on the issue of GM foods resulting in a huge level of press coverage. It is interesting that the picture in 2005, when the Eurobarometer shows levels of opposition to GM foods to be similar to those in 1999, is very different from that in 1999 in terms of the media relationship to public attitudes. In 1999 there was a clear connection between the intense media coverage and opposition to GM foods. Yet in 2005 there is very low coverage given to GM foods and it is apparent from the low media coverage devoted to the BT10 and LL601 contamination cases that GM is no longer deemed a hot topic for the media. However, as already mentioned, the NGOs still consider it an important issue but appear to be failing to publicise beyond their core supporters. Labelling as a choice of regulatory approach has exacerbated the contested science debate by legitimising the issue, and the label in effect makes visible the contested science.

I argue that a thermostatic control effect is apparent in relation to the public opposed to GM foods. This plays out in the entrenchment of the opposition to GM foods where there is a definite bidirectional relationship between the regulators and the regulated. The deliberative circle (the entrenchment model) that I developed outlined this effect, whereby the regulatory response to public opposition towards GM foods legitimises the public opposition. In this way therefore it is evident that regulation has influenced those opposed to GM foods but not as a means to assuage public concerns. This is reinforced by the deepening product segregation and leads to calls for ever more stringent labelling regulations. In terms of the future interplay, one possibility is that the regulation is proceeding along this deterministic path to produce ever more stringent labelling requirements. I believe that opposition to GM foods will remain an issue, partly as a result of the impact of the labelling per se which highlights the product as being inferior to GM free.

When the survey data findings are stratified, it is clear that the anti-GM group are still a strong minority and the result of increased information and regulation on this section of the public has been to entrench their position. This group of people are the ones who are most vociferous in campaigning and it has been demonstrated in this chapter that this has been a successful campaign as the loudest voice has had a very marked influence over the regulation. The dominant force in the understanding of public opinion have been the NGOs. Tait stated in interview that:

‘In Europe the governments do listen to public opinion, but they are not very critical listeners, ...who shouts loudest tends to be taken as public opinion’.

This supports the idea of interchangeability between and across the different understandings of public opinion by the regulators and within the regulatory process.

The topic of GM foods makes for an enormously rich case-study of the relationship between public attitudes and regulation. They are not only a special case because of the attitudes held by the public but also because they have received special regulatory handling. It is evident that public attitudes towards GM foods have played an enormously influential part in the regulation of GM foods. The regulation is not driven by expert opinion on the level of risk posed but by public perception of the risks of GM foods. I contend that more than a one-way effect has been at work and that the regulation has additionally impacted upon public attitudes. However, the labelling of GM foods has not acted as a reassurance to those people opposed to GM foods. Whilst the two phases of the labelling regulation possess distinctive elements, there is a shared connective tissue running through the regulatory development suggestive of a strong teleological drive. The impression I gained from interviewing the regulators of GM foods is that the regulators are supportive of the opening up of the EU and UK markets to GM food products. However this would have to take place at EU level and it is argued that certain factors will stymie this, including the regulatory structures at national and EU levels and the powerful role of the NGOs.³⁸⁹

Therefore while it appears that there has been an attempt to assuage the demands of both the public and the biotech industry, the regulators have not found a clear direction, and I would assert that this has been a deliberate and not reactive policy move. The

³⁸⁹ See further: Pollack, Mark and Shaffer, Gregory, ‘When Cooperation Fails: The International Law and Politics of Genetically Modified Foods’. (2009, Oxford University Press)

labelling regulation is viewed by the regulators as provisional legislation implemented as a means to 'manage' fluctuating public moods insofar as it is anticipated that the regulation is a short-term fix. It might be that the regulators are currently gearing up for the next round of protest in the face of the animal feed shortage which will come in the form of increased pressure from the farming community. Whether a second wave of public protest would ensue is unclear but even if it does take place it is unlikely that it would be as heated as the protests of the late 1990s.

In the 1970s and 1980s when GM foods emerged as a new regulatory object, the response was to establish a plethora of regulatory and advisory bodies. Now the issue has been subsumed into the FSA, Defra and at a European level by EFSA. In terms of whether the regulation displays *sui generis* features, it is without doubt that this area of regulation receives special regulatory handling relative to other novel foods. In summary therefore while the regulatory oversight bodies are not distinctively genomics related, the umbrella of regulation to which GM foods are subjected is. Despite the impression I gained from the interviews that many of the regulators were frustrated by the special regulatory handling of GM foods, it is clear that regulation has not brought about resolution on this issue for the public. While the public may now be ambivalent or confused about GM foods, which is very different from the opposition of the past, there is no demand for the products. For this situation to change, the benefits of GM products, such as their potential to enhance the nutritional value and the shelf life, would have to be made explicit. The regulation of GM foods is underpinned by the regulatory science and the debate over contested harm. In contrast the next chapter reviews the regulation of prenatal testing and PGD which is underpinned by a contested benefit argument. The idea is that the regulation is driven by the need to enable or facilitate the development of the techniques in order to benefit people. Critically in both case-studies there is a great deal of common ground in that they are situated within highly contested debates surrounding their risks and benefits.

Durrant and Legge argue that the moratorium was a space in time which gave the Governments of the Member States the opportunity to increase public trust in their handling of GM foods.³⁹⁰ The Eurobarometer data shows that levels of public trust in

³⁹⁰ Durrant, Robert F. and Legge, Jerome S. 'Public Opinion, Risk Perceptions, and GM Food: Reassessing the calculus of Dissent among European Citizens', *European Union Politics*, Vol.6(2) pp.181-200, 2005 at p.197

the Government's ability to regulate on GM foods have risen since the late 1990s. This suggests that the public have placed their trust in Government to protect them from any perceived or actual harm associated with GM foods. However, while trust in Government may have increased, so it is argued have levels of uncertainty and confusion as to the risks posed by GM foods. This is a corollary of the contested science at the heart of the debate over GM. Division amongst expert opinion and scientific pluralism serve only to intensify public confusion. I contend that the very process of labelling the GM products is in itself recognition of the fact that the Government are sitting on the fence and will not state whether they deem these products to be safe. Importantly, the very presence of the authorisation process gives GM foods a level of legitimation in that the Government do not believe the products to be harmful. The label in effect makes visible the contested science.

According to the regulators interviewed, the issue of GM foods is set to return to the public and regulatory agenda due to the shortage of non-GM animal feed. Indeed, a regulator from the FSA commented in an interview for this thesis that while GM 'is not a ticking time bomb there are issues with the animal feed supply and there could be with food supply eventually as well as we are getting messages about this from the retailers'. She argues further that the retailers are calling on the FSA to provide more information and proactive communication about GM to the public because they believe GM is going to be an issue in terms of the supply chain. Interestingly she discusses the problem for retailers in being the first to 'stick their head above the parapet' vis a vis GM products. What is interesting is to speculate over whether the current labelling provisions combined with the most important problem on the public agenda being the current economic situation will mean that this is a non-issue. Indeed as has been argued here, it was the combination of many critical issues in 1999 which acted as the tinder box for the demonstrations and protests. GM has now become more of a 'boutique issue' in current politics and does not dominate the mainstay of public concerns.

Chapter 6

The Interaction between Public Opinion and the Regulation of Prenatal Testing and Preimplantation Genetic Diagnosis

6.0 Introduction

‘I think one of the things which is really interesting is the degree of interest in a procedure which is spectacularly rare’. (HFEA Member in interview, talking in relation to Preimplantation Genetic Diagnosis)

While this chapter relates to prenatal testing and diagnosis in addition to PGD, the above quote highlights the disproportionate allocation of regulatory resources to genetic technologies. By contrasting the way that PGD and prenatal testing are both regulated and perceived by the public it makes very clear that PGD has received a much higher level of attention by the media and the regulators than prenatal testing and this has been reflected in the number of public consultations. The focus of this chapter is to examine the interplay of regulation with public opinion in relation to prenatal and preimplantation genetic diagnosis. In doing this the chapter will address whether the regulatory approach has been appropriate in terms of appeasing the concerns of the public about prenatal testing and PGD. In the examination of the public opinion data it is important to assess whether the public are concerned over the use of genomics in this manner. I am also interested in the function and structure of the regulatory institutions, as a separate force to the regulation, in helping to make the public feel reassured about the application of these technologies. The principal IRA overseeing the regulation of PGD is also analysed in terms of the discretionary zone mentioned in chapter 3. While it is clear that PGD is given special regulatory handling, this is not the case for prenatal testing. In analysing the relationships between public opinion and regulation in this field, I will draw again on the five understandings of public opinion which were outlined in Chapter 2.

It is argued in this chapter that the speed of technological advances results in public opinion as an input into the regulatory process being in many instances redundant. To explain this further, it is not being argued that public opinion should *not* be included in regulatory decision-making, but rather that developments are taking place which the regulatory structures bend to meet, and that this is happening in an incremental way meaning that regulation is slowly evolving to the extent that the idea of public

consultation is not deemed relevant. However, there is the additional argument that another form of public opinion, that of the prospective parents, is making its view heard as a consequence of the demand for and take-up of the techniques now offered to them. Indeed it could be argued that the response of the regulators to the applications by parents – sometimes made via the fertility centres or through patient groups – is responsive to a public, but that this view of the public is very narrow. I will show that in contrast with the regulation of GM foods, the driver for regulating in this area has been to facilitate the application and development of the technology. The underlying regulatory ethos is that these technologies are beneficial to the public. However, public opinion does not show such a clear line of support and this mismatch between the regulatory approach and the public opinion data is analysed. It is argued that in terms of the different understandings of public opinion, the public opinion which the regulators are responding to is a combination of parental pressure, which may be voiced through interest groups, and the influence of clinicians who hold a very powerful position in health technology. Public concern does not arise from problems resulting from the form of the regulation which, while being permissive, is supported by a large volume of procedural safeguards. Concerns result from the controversial nature of the current uses of PGD and prenatal testing and the potential future developments.

In the introduction to the thesis, the provocative challenge set down by Sturgis et al was discussed; they claimed that their findings from the BSA survey were ‘a good deal more robust and representative of public preferences on these issues than can ever be produced by such exercises in public ‘consultation’’.³⁹¹ This claim will be examined in the chapter where the BSA survey data is compared to the data on public opinion commissioned and collected by the principal regulatory agency in this area of regulation: the Human Fertilisation and Embryology Authority (HFEA).

The chapter opens by defining the object of regulation by setting out the principal terms discussed and the differences between PGD and PGS. The range and availability of prenatal tests and applications of PGD are then examined which leads into a discussion of the clinical validity of procedures. The subsequent section of the chapter then gives

³⁹¹ Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, ‘Genomic Science: Emerging Public Opinion’, From Park, A., Curtice, J., Thomson, K., Bromley, C. and Phillips, M. (Eds) (2004), *British Social Attitudes – the 21st Report*, London: Sage at p. 121.

an overview of the regulation and the public opinion data is analysed in relation to prenatal testing and PGD. The case of prenatal sex selection is examined in terms of both the public opinion on this subject and the regulatory developments. Following this the application of PGD in cases of inherited cancer susceptibility and to HLA tissue-typing are examined in depth. The HFEA carried out public consultations on these two applications of PGD and the resultant findings are analysed with a view to the shaping of this data as an input into the regulatory process. The chapter includes an exploration of the numbers of elective abortions following a diagnosis of a serious mental or physical disability. I collated this data in order to establish whether there has been an increase in rates of such abortions in line with the increase in diagnostic techniques. This data ties in with my contention that a very forceful voice in both the development of prenatal testing and the regulation of PGD has been the parental views. The final section of the chapter deals with the regulators' understandings of prenatal testing and PGD. The chapter closes with some conclusions including the contention that public opinion in the cases of prenatal testing and PGD has been conflated with the views of the parents and the clinicians.

6.1 The Regulation of Prenatal Testing & Preimplantation Genetic Diagnosis

6.1.1 Defining the Object of Regulation

This section sets out the definitions of the principal terms under discussion, delimits the area of study and examines the range and scope of the techniques in practice in the UK. There are varied interlinked terms in prenatal testing and diagnosis and these include, inter alia: prenatal testing, prenatal screening, prenatal diagnosis (PND), preimplantation genetic diagnosis (PGD), preimplantation genetic screening (PGS) and non-invasive prenatal testing (NIPD). This area is problematic in that these terms are used to mean very specific things in some instances and yet in other contexts are used interchangeably. The distinction between prenatal testing and prenatal screening is difficult to make. The Human Genetics Commission defines prenatal screening as:

‘a public health service that offers pregnant women a test to see if the baby is at increased risk of having a particular disorder such as Down’s syndrome.’³⁹²

³⁹² Human Genetics Commission, ‘Making Babies: Reproductive Decisions and Genetic Technologies’ (2006).

Whereas the HGC definition for prenatal diagnosis is:

‘an individual procedure that aims to provide a diagnosis of a particular condition that the baby might have’.³⁹³

The distinction therefore hinges on whether the practice is offered widely or whether it is something tailored to meet an individual’s needs or demands. There is of course some crossover and they are very much interlinked.

Preimplantation genetic diagnosis (PGD) is a technique which was first undertaken in a clinical capacity in 1989. It takes place on embryos outside of the uterus in conjunction with in vitro fertilisation (IVF). It involves the analysis of one or two biopsied cells which have been taken from a 3-day old embryo with the intention of deselecting those embryos affected by serious genetic conditions. For the majority of cases, PGD is used when one or both parents are carriers of a serious genetic disorder which they do not wish to pass on to their offspring. It is argued that PGD reduces the distress faced by a woman or a couple in such circumstances who would otherwise undergo prenatal testing and choose to have an abortion in cases where the foetus was affected by the genetic condition. On the other hand, the discarding of embryos in PGD is controversial. While the case of deselecting embryos, or ‘negative’ selection has been outlined here as being the most common method for PGD application, it is important to note that ‘positive’ selection is an option and that embryos can be selected for specific conditions or attributes.

Returning to defining the key terms, there is a further distinction to be made between PGD and preimplantation genetic screening (PGS). It is generally understood that PGS is used to help couples with fertility problems in conjunction with genetic screening. PGS is carried out on embryos of infertile couples who are undergoing IVF with the goal of ruling out those embryos which have numerical chromosomal abnormalities, in the hope that this will increase the chances of embryo implantation and survival. PGS also termed as PGD-aneuploidy screening is defined by the European Society of Human Reproduction and Embryology (ESHRE) as ‘the detection of chromosomally

³⁹³ Human Genetics Commission, *ibid.*

normal embryos from sub-fertile patients'.³⁹⁴ PGS is interesting in that the motivation for the technique arises from a concern relating to increased maternal age, a history of recurrent IVF failures and/or repeated miscarriages. The couples involved are not seeking the treatment because they are aware of a genetic condition which they wish to screen against. Indeed the ESHRE states that they 'are parents with a normal karyotype',³⁹⁵ therefore a standard chromosomal complement. As the ESHRE comments there is some debate over what to call this technique in terms of whether it is screening, testing or diagnostic. An added blurring of any distinction between PGD and PGS is that there exists a correlation between maternal age and chromosomal abnormalities and further to this studies also show that more than half of recorded miscarriages are associated with chromosomal abnormalities.³⁹⁶ In other fields the distinction between PGD and PGS is made by referring to the former as 'high risk PGD' and the latter as 'low risk PGD'.³⁹⁷

6.1.2 The Range of Prenatal Testing and Preimplantation Genetic Diagnosis Techniques Available

(i) Prenatal Testing

Over a decade ago in 2000, Graham et al noted that less than one percent of British pregnant women received no form of prenatal testing.³⁹⁸ The UK Genetic Testing Network (UK GTN) hold a list of all the genetic tests licensed under the NHS. While it would be technically possible to carry out all of these prenatally it is not the case that

³⁹⁴ Harper, Joyce et al, 'What Next for Preimplantation Genetic Screening?' Human Reproduction, 2008, Vol.23, No.3, pp.478-480 at p.478. This document is classed by The European Society of Human Reproduction and Embryology (ESHRE) as an ESHRE PGD Consortium publication.

³⁹⁵ Harper, Joyce, 'Inside the PGD Consortium: Focus on Reproduction', A Review of the ESHRE PGD Consortium, January 2007 at http://www.eshre.com/binarydata.aspx?type=doc/Focus_article_jan07.pdf (last accessed 22 July 2009)

³⁹⁶ Soini, S. et al, 'The Interface between assisted reproductive technologies and genetics: Technical, Social, Ethical and Legal Issues', The European Journal of Human Genetics (2006) 14, pp.588-645 at p. 597.

³⁹⁷ ESHRE PGD Consortium, 'Best Practice Guidelines for Clinical preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS)', Human Reproduction, November 11, 2004, passim.

³⁹⁸ Graham, Wendy, Smith, Pat, Kamal, A., Fitzmaurice, A., Smith, NM., Hamilton, N., and Wyatt, Jeremy (2000) 'Randomised Controlled Trial Comparing Effectiveness of Touch Screen Systems with Leaflet for Providing Women with Information on Prenatal Tests', British Medical Journal, vol. 320, pp.155-60.

they are used on a routine basis. In practice there are a number of specific genetic conditions for which tests are routinely conducted under general public screening and these include trisomy 21 for Down's syndrome. However, if there is evidence of a family history of a genetic condition then the pregnant woman may be offered a relevant genetic test of which there are over 500 available.³⁹⁹ At present, it is not yet technically possible to carry out testing for a range of genetic conditions simultaneously. Jackson argues, however, that this will be feasible in the future and will 'undoubtedly promote universal screening for some of the more common genetic disorders'.⁴⁰⁰ Currently, the prenatal tests available range from the nuchal translucency test for Down's syndrome (which is carried out in conjunction with an ultrasound scan and the testing of maternal serum before the 14th week of pregnancy), chorion villus sampling (CVS), and amniocentesis. It should be noted that not all prenatal tests are genetic.

(ii) PGD

In contrast with prenatal testing, it cannot be stated strongly enough that both PGD and PGS are very rare procedures relative to the number of live births per annum. As established above, PND covers a wide range of tests and diagnoses to which all pregnant UK women are offered to varying degrees.⁴⁰¹ There are nine fertility centres in the UK which offer PGD and eight which offer PGS. Over fifty genetic conditions are now licensed for PGD and the Human Fertilisation and Embryology Authority (HFEA) provides an inventory of these on their website. However, the rarer conditions for which licenses exist are not listed in order to maintain patient anonymity.⁴⁰² The most recent figures available showing numbers of PGD and PGS cycles relate to 2005. In that year, 122 patients received PGD, which resulted in 17 live births. There were 166 patients who received PGS and this resulted in 42 live births. From this data it is

³⁹⁹ UK Genetic Testing Network, 'NHS Directory of Molecular Genetic Testing: A list of diseases for which tests are offered by UK GTN laboratories'.

⁴⁰⁰ Jackson, Emily 2001, op cit. at p. 125.

⁴⁰¹ With reference to Graham et al 2000, p.157, Jackson states that 'fewer than one percent of British pregnant women receive no prenatal tests', Jackson, Emily, 'Regulating Reproduction: Law, Technology and Autonomy' (Hart Publishing, 2001): Graham, Wendy, Smith, Pat, Kamal, A. et al, 'Randomised controlled trial comparing effectiveness of touch screen system with leaflet for providing women with information on prenatal tests', British Medical Journal, col.320 pp.155-160.

⁴⁰² http://www.hfea.gov.uk/docs/List_of_PGD_conditions.pdf (last accessed 23.08.11)

clear that a very small number of people seek out and receive such treatment and that the number of babies born following PGD and PGS is extremely low. The second observation of the data presented is that numbers of cases are increasing over time but this rise is not to a high level.

Figure 20: Data from the HFEA register showing numbers of PGD/PGS procedures (1999-2005)⁴⁰³

Year	PGD Patients	PGD Cycles	PGD Live Births	PGS Patients	PGS Cycles	PGS live Births	Total PGD/PGS Patients	Total PGD/PGS Cycles	Total PGD/PGS Live Births
1999	-	-	-	-	-	-	8	8	3
2000	-	-	-	-	-	-	64	66	9
2001	-	-	-	-	-	-	-	59	4
2002	-	-	-	-	-	-	120	128	22
2003	-	-	-	-	-	-	208	234	50
2004	84	95	17	164	190	25	246	285	42
2005	122	134	17	166	205	42	286	337	59

There are two significant features of this technology: the very rapid increase in the sophistication of the techniques and the ever enlarging diagnostic spread. In relation to the latter, the number of inherited diseases that could be tested in 2004 exceeded 40.⁴⁰⁴

⁴⁰³ Table 26 of the HFEA Register, p.95:

http://www.hfea.gov.uk/docs/Latest_long_term_data_analysis_report_91-06.pdf.pdf (last accessed 23.08.11) This data remains the most up to date and was published in 2008.

⁴⁰⁴ For more detail on the range of tests offered by UK fertility clinics cf:

http://www.bshg.org.uk/newsletter_135.pdf at p.7 (last accessed 28 August 2007)

6.1.3 Clinical utility and validity and parental decision-making

(i) Prenatal Testing

Screening for genetic conditions such as Down's syndrome was once restricted to pregnant women over 35 years old, but is now offered to nearly all pregnant women in the UK regardless of age. The test involves the nuchal translucency scan combined with a blood test, and if these show a higher risk in the pregnancy then the woman is offered amniocentesis. The techniques for prenatal screening are becoming ever more sophisticated and one of the most significant changes is the ability now to assess the probability of the actual risk of a chromosomal disorder as opposed to a woman's age-related risk. These technological advances have come about through the increased accuracy of blood testing and ultrasound technology which have enabled a more accurate identification of nuchal translucency or genetic markers.⁴⁰⁵

Jackson states that 'there are those who would argue that the accumulation of techniques to monitor foetal progress creates needless anxiety, wastes time and resources and does little to improve the proportion of healthy babies and reinforces the perception that every pregnancy must be subject to as much technological intervention as possible.' Jackson highlights the debatable discrepancy of offering prenatal diagnostic techniques such as ultrasound as a routine test for all pregnant women, when 98% of pregnant women receive 'normal' results.⁴⁰⁶ Interestingly there is no clear line given by the NHS on the purpose of the 18-20 week foetal scan. In Appendix 1 to the NHS Fetal Anomaly Screening Programme Standards, it states that:

'The understanding of the purpose of the scan is variable – from the woman's perspective it is a chance to see the baby and confirm normality rather than a screening test to look for abnormalities. From the clinical perspective it is considered to be a useful tool to identify problems and to allow the clinician to develop management pathways which are likely to optimise outcome. This dichotomy appears to have led to confusion over the purpose, limitations and benefits of the use of ultrasound screening.'⁴⁰⁷

⁴⁰⁵ Scott, Rosamund 2007 op cit. at p.176.

⁴⁰⁶ Jackson, Emily, 'Regulating Reproduction: Law, Technology and Autonomy', Hart Publishing 2001, at p. 122.

⁴⁰⁷ NHS, 'Foetal Anomaly Screening Programme 18 to 20 weeks Foetal Anomaly Scan: National Standards and Guidance for England', 2010.

This confusion over the purpose of the scan to detect, inter alia, genetic abnormalities, is borne out by Jorg's comments that:

'Although clinical validity and clinical utility are going to be important criteria in the decision making process of whether or not to offer and apply a genetic test, the development of standards and hence guidelines with the scientific community and health care providers of how to assess clinical validity and clinical utility are still in its infancy'.⁴⁰⁸

These comments need to be examined in terms of the regulatory structures discussed later in the chapter and in terms of whether the issues of clinical utility and validity are being taken seriously.

While prenatal tests may inform a couple that a foetus has a higher risk of a certain condition, or may give a more definitive result that a foetus will be born with a condition, it cannot generally state the extent or the severity of the condition or predict how it will impact a child's life or the level of treatability. Scott argues that there is a disconnection between the risk of a condition and the significance of harm which would potentially arise from a condition.⁴⁰⁹ In terms of public opinion on prenatal testing one has to consider the views of the millions of pregnant women who already receive such screening and assess the level of reassurance it may offer them. There is a wide debate on the decision-making processes of couples when they are given information that their future baby may be at risk of a certain genetic condition. Issues to consider include how the couples assess the information imparted to them by the clinicians and the different very qualitative ways in which parents will interpret the probability statistics that they are given. An important facet of this debate is to address whether it is appropriate to test a woman for a condition, for example, Down's Syndrome, if that woman has already stated that she will not terminate a pregnancy in any case. On the one hand one could argue that her awareness that there is an increased risk of her having a baby who has Down's Syndrome may give her some time to adjust to the knowledge of this. However, it is a risk calculation and it will give many women a level of anxiety during their pregnancy which may be unnecessary. Research shows that in the general

⁴⁰⁸ Schmidtke, Jorg, 'Clinical Validity and Utility of Genetic Testing – the Viewpoint of a Clinical Geneticist'. 2005 <http://www.eurogentest.org/web/files/public/unit3/CDBI.pdf> (last accessed 23/07/09)

⁴⁰⁹ Scott, Jackson 2007 op cit.

population, genetic disorders affect under three percent of neonates.⁴¹⁰ There are a number of procedural safeguards underpinning the application of prenatal testing and PGD, such as the system of informed consent, but while these issues are important they are not discussed here.

(ii) Preimplantation Genetic Diagnosis

Wyatt has stressed that the ‘take home baby rate’ following PGD is relatively low and may not be balanced by the high levels of psychological stress endured by couples undertaking the procedure.⁴¹¹ Added to this is a very pertinent comment made by a geneticist and member of the HGC who described how over the last decade she has spoken to hundreds of couples about PGD, and stressed that ‘for many people having learned what is involved they come to the decision not to proceed’.⁴¹² This is an important point and counters claims by some of the interest groups that once the technology is made available there will be immediate public demand for it.

Additionally, the costs of PGD are very high; for example the cost of a single cycle of PGD at Guy’s Hospital in 2010 was placed at £7,020 (this amount is exclusive of the charges for drugs).⁴¹³

6.1.4 The Regulatory Handling of Ethical Concerns

The principal issues which receive attention by ethicists and commentators in the arena of prenatal testing and PGD are: the case of discarded embryos; the status of the embryo in relation to selective abortion; ‘saviour siblings’; and the ‘designer baby’ arguments. These can be interlinked with the argument promoted by many clinicians that less harm is inflicted on the woman if she has PGD in comparison to prenatal testing and subsequent abortion. These ethical issues are concerns for members of the public and scenarios have been played out in media commentary. Related to the discussion of

⁴¹⁰ Skene, L., ‘Patient’s Rights or Families Responsibilities’, *Medical Law Review* 1998, vol.6, pp.1-41.

⁴¹¹ Wyatt cited in ‘Comparative European Approaches to Pre-implantation Genetic Diagnosis: Symposium Report’, 2007, BioCentre (Bell, Rachel, Editor) at p.18.

⁴¹² Frances Flinter, a clinician at Guy’s and St Thomas’ Hospital –comment noted at an HFEA consultation public event focussing on PGD of 26 January 2009.

⁴¹³ Giffard, David, ‘Commissioning Policy for Pre-implantation Genetic Diagnosis (PGD)’, NHS, East Midlands Specialised Commissioning Group, Report issued on 1/4/2011, <http://emscg.nhs.uk/Library/RevisedEMSCGPolicyforPGDv2.pdf> (last accessed on 26/8/11).

public opinion of prenatal testing and PGD is whether these issues have become 'normalised' as a result of increased familiarisation with them. Indeed it is difficult to separate the role of the regulation as a force for placating public concerns from the more gradual erosion of concern over the technologies arising from increased familiarisation with them. This process involves the very nebulous concepts of public confidence and public trust in genetic technologies. While the public have become very familiar with prenatal testing, PGD remains a technique which is used in such a small number of cases and is often portrayed by the media in highly emotive ways. For the regulators the balance is between facilitating the technologies to ensure that the public benefit and countering people's concerns over the ethical issues. In this chapter the drivers for regulators to change to accommodate new applications of PGD will be examined. Consumerism and the drivers of regulatory accommodation of new applications of PGD and PND are complex issues, and it is clear that some patient groups are very vocal and actively campaigning for such. On the other hand, it could be argued that these groups are responding to the science – for as the science develops and increasing number of genetic markers are identified this opens up options for new applications of PGD. Additionally, what is the role played by the clinicians and the fertility centres offering PGD? It is not clear that the adaptation of regulation to accommodate novel uses is parent-driven. Finally, there is the question of why some genetic conditions receive more publicity and more funding for research than others. Often this is not always a result of the numbers of people affected or the severity of the disease.

6.2 The Regulatory Approach to Prenatal Testing and Preimplantation Genetic Diagnosis

Knoppers and Isai describe the regulatory style adopted in the UK as a public ordering approach, characterised by a state-led framing of the use of biotechnologies which is permissive, incorporating a legislative approach with administrative oversight.⁴¹⁴ In essence, the regulatory issues have evolved in response to ethical concerns. The aim of the thesis is to examine public opinion in this arena in relation to the level of regulatory oversight and to attempt to determine whether the public find this appropriate. This raises two critical issues. The first is whether the public have knowledge of the

⁴¹⁴ Knoppers, Bartha M. and Isai, Rosario M. 'Regulatory Approaches to Reproductive Genetic Testing', *Human Reproduction*, Vol.19m No.12, pp.2695-2701, 2004

regulatory processes at work. The regulation is very piecemeal and is drawn from a wide range of sources. It is argued here that it is the presence of the regulatory institutions which is fundamentally significant in terms of assurance that prenatal testing and PGD are being appropriately regulated. The second issue is to question whether the public are really concerned about these issues. One could alternatively posit that it is the media, interest groups, influential politicians who through repeatedly telling us that the public are concerned have made this a reality. This will be examined in the next section of the chapter through the survey data and the HFEA's public consultation exercises.

6.2.1 The Regulation of Preimplantation Genetic Diagnosis

The regulatory framework for PGD is outlined in this section following which, the interaction between public opinion and regulation is broken down into 4 case-studies:

- (i) PGD as a novel regulatory object
- (ii) PGD and Sex Selection
- (iii) The Application of PGD for HLA Tissue Typing
- (iv) Lower Penetrance Inherited Cancer Conditions & PGD

The regulation governing the application and usage of PGD and PGS is found in the mandatory requirements: the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008), licence conditions, and HFEA Directions. These regulations work in conjunction with a number of HFEA Guidance notes. Finally there are relevant professional guidelines. Thus there exists a combination of substantive requirements and procedural safeguards in respect of PGD. There is no specific mention of PGD in the 1990 Act because the legislators did not anticipate the emergence of PGD and thus the HFEA have carved out the regulatory position on PGD acting on a case-by-case basis. The UK has adopted a public ordering, that is, a legislative top-down approach to the regulation of this area which rests on a pragmatic, permissive approach.⁴¹⁵ The regulation of PGD is set out in the HFEA 8th

⁴¹⁵ Knoppers, Bartha M. & Isai, Rosario M. 'Regulatory Approaches to Reproductive Genetic Testing', *Opinion, Human Reproduction*, Vol. 19, No.12, 2004, pp.2695-270, passim.

edition Code of Practice⁴¹⁶. The regulation of PGD is also directed by the ethical guidelines set out by UN and WHO. PGD is subject to the licensing procedures regulated by the HFEA and there are also a number of voluntary agreements of which the most significant are the ESHRE PGD Consortium's Best Practice Guidelines.⁴¹⁷ ESHRE justify the drafting of these guidelines on the grounds that there is a lack of common practice and regulation in this field relative to other domains of diagnostic testing. The guidelines list recommendations relating inter alia to: counselling, informed consent, treatment methods, patient inclusion criteria and clinical protocols.

Prior to the Human Fertilisation and Embryology Act 2008 which amends the Human Fertilisation and Embryology Act 1990, licences for PGD were examined as already stated on a case-by-case basis. The 2008 Act attempted to tidy up this by codification of the licensing arrangements for PGD, with the exemption of the 'saviour sibling' cases which will still be decided on a case-by-case basis.⁴¹⁸ This move has been criticised by Augst, the HFEA's acting Head of Policy who argues that greater legislative clarity comes at too high a price if the HFEA lose the interpretive flexibility of the regulation.⁴¹⁹ With regard to the interaction between the applicant couple and the regulation are the 2008 Act's amendments to the decision-making criteria. There are a number of grounds for consideration when the licensing committee are making a decision and prior to the 2008 Act one element of this was to take into account the family's perception of the genetic condition. While this is a hugely subjective issue to judge, it is significant in terms of the response of a regulator to individual families as opposed to a blanket regulatory approach. The most important element of introduction of the 2008 Act is that now all human embryos outside the body are subject to regulation.

⁴¹⁶ http://www.hfea.gov.uk/docs/8th_Code_of_Practice.pdf (last accessed 12 August 2011).

⁴¹⁷ European Society of Human Reproduction and Embryology (ESHRE) 'Best Practice Guidelines for Clinical Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS)', published on the ESHRE under the journal Human Reproduction on 11 November 2004.

⁴¹⁸ For further detail: see Schedule 2 of the Human Fertilisation and Embryology Act 2008.

⁴¹⁹ Augst, Charlotte, from a paper given at a workshop at University of Keele entitled 'The Human Fertilisation and Embryology Act 2008 - on 30 March 2009.

In terms of an application by parents for PGD the interpretation of the regulation by the regulators is commonly said to be in accordance with a pragmatic approach. There is a clinician's letter attached to the application but while this may include facts about the case that may incur an emotional response by the regulators, such as it being this couple's last chance, the nature of the letter is not sentimental. Of course this pertains to a discussion of how the regulation is interpreted and not thus how regulation and public opinion interact, but in the course of the regulation in practice the relationship between the regulation, regulators and public opinion is still a critical factor, for regulation evolves, and in this area of technology, the techniques are evolving also.

6.2.2 The Regulation of Prenatal Testing

'...doctors have enormous discretion in relation to what you can test prenatally. There is not a list of conditions, no law which says you can or can't do anything, so in a sense PND practice is to say you do anything you like!' (HFEA Member in interview)

While there is no specific legislation covering prenatal testing and PND, there is a wealth of regulations, codes and guidance notes. Principally, the regulation draws from codes and guidance which oversee the procedural safeguards which include:

- (i) Safeguards relating to patients' rights (informed consent, counselling, confidentiality) and;
- (ii) Safeguards relating to civil status, oversight and licensing mechanisms (which in turn provide the list of licensed tests available on the UK Genetic Test Network).

Additionally, the Abortion Act 1967 (amended by the Human Fertilisation and Embryology Act 1990), sets out the legal grounds for a selective abortion in the case of a genetic condition being diagnosed. It should be stressed that at the heart of these layers of regulation and having a great influence over the outcome is the role of medical discretion.

The procedural safeguards outlined above are drawn inter alia from the Department of Health, the NHS, the Care Quality Commission, the UK National Screening Society, and Royal College of Obstetricians and Gynaecologists' (RCOG) guidelines. The specific standards overseeing the prenatal testing procedures are many and varied but are overarched by the NHS Constitution and the National Minimum Standards Regulations 2002. These regulations are generic in their scope. For more focussed

guidance one would turn to the UK National Screening Committee's 'Foetal Anomaly Screening Programme: Screening for Down's Syndrome' and the National Standards issued on the Foetal Anomaly Screening Programme.⁴²⁰

In turning to the Abortion Act 1967 as amended by the HFE Act 1990, the most relevant section relates to the interpretation of 'seriously handicapped' under section 1(d). The RCOG states in relation to this section that:

'...a strict definition is impractical because we do not have sufficiently advanced diagnostic techniques to detect malformations accurately all of the time and it is not always possible to predict the 'seriousness' of the outcome (in terms of the long-term physical, intellectual or social disability on the child and the effects on the family). The RCOG believes that the interpretation of 'serious abnormality' should be based upon individual discussion agreed between the parents and the mother's doctor'.⁴²¹

It is apparent that a feature of the regulation of both PGD and PND is the issue of discretion over regulatory interpretation. It has been shown to be a useful tool in these cases as it allows the regulator (or in this instance the clinician) to come to a decision which is tailored to the needs of the individual. The regulation has been drafted with a level of discretion given to interpretation, leaving this in the hands of the regulator or clinician. What does this mean for the interaction between regulation and public opinion?

⁴²⁰ Department of Health, 'Independent Health Care National Minimum Standards Regulations' 2002. Statutory Instrument 2002, No. 2375, 'The NHS (Functions of Strategic Health Authorities & Primary Care Trusts & Administrative Arrangements) (England) Regulations 2002. UK NSC, 'Foetal Anomaly Screening Programme: Screening for Down's Syndrome: UK NSC Policy Recommendations 2007-2010: Model of Best Practice. NHS Foetal Anomaly Screening Programme 18 – 20 weeks Foetal Anomaly Scan: National Standards and Guidance for England 2010. Care Quality Commission: A New System of Registration: The Scope of Registration', March 2010.

⁴²¹ Royal College of Obstetricians & Gynaecologists, July 2008, at <http://www.rcog.org.uk/what-we-do/campaigning-and-opinions/briefings-and-qas/human-fertilisation-and-embryology-bill/abort> (last accessed 21 September 2009).

6.3 Public Opinion

This section of the chapter contrasts the findings of different sources of public opinion data collected in relation to prenatal testing and PGD. This data is reviewed in relation to the five understandings of public opinion and these are listed again here as an aide-memoire:

- (i) Public opinion is an aggregation of individual opinions
- (ii) Public opinion is a reflection of the majority beliefs
- (iii) Public opinion is a channelling of the public voice by interest groups
- (iv) Public opinion is a fiction – it is a rhetorical construct
- (v) Public opinion is what the media and elite tell us public opinion is.

The research carried out for the thesis shows that when regulators talk of public opinion, they are most often referring to the findings of public engagement exercises commissioned by their own institutions. This begs the question of what the value is of the collection of survey data by for instance, academics, which was the case with the cache of genomics questions in the BSA survey. It is argued that the public consultations are dominated by stakeholders who are invited to participate by the HFEA or HGC. This stands in strong contrast to the self-selection method adopted by the GM nation? debate and yet neither has produced data which is representative of public opinion. It is contended however that the different routes adopted have led to very similar committee profiles and the resulting public opinion data should be called stakeholder opinion. The views of parents and in particular applicant couples for PGD are influential in the evolution of the regulation in this field. Indeed it is argued here that it is the views of parents affected by serious genetic diseases, either alone or represented by interest groups, that are being responded to by regulators. Again it is a case of listening to those who speak loudest and perhaps dominate public engagement exercises. The influence of the clinicians should not however be underestimated in prenatal testing and PGD. The chapter now turns to analyse the public opinion data by dividing the analysis into the following five areas:

1. Public Opinion of PGD & PND
2. Public Opinion of Sex Selection
3. Public Opinion of PGD for Inherited Cancer Susceptibility
4. Public Opinion of HLA Tissue-Typing Typing ('Saviour Siblings')

5. The Influence and Views of the Parent in PND and PGD

The table below illustrates a very brief chronological overview of the data points and the principal regulatory developments.

Figure 21: Regulatory developments, IRA public consultations and BSA survey data entry-points

Year	PGD Regulation	BSA data point	Consultation
1998		5 questions on Prenatal diagnosis	
1999	PGD 'interim policy' issued by the HFEA & the Advisory Committee on Genetic Testing (ACGT)		HFEA/Advisory Committee on Genetic Testing (ACGT) commission Public Consultation
2000		In 2000 there are 4 questions on PGD (n=2,267) plus the same 5 PND questions as in 1998	PGD - HFEA 31/3/00
2001	HFEA & HGC, 'Outcome of the Public Consultation on PGD', 18 June 2001 (The Outcome Report)		
2003	2002-2003 HFEA Review of sex selection regulation and the HFEA commissioned a MORI poll on sex selection.	Genetic test questions which may relate to PGD – one question re. sex selection and one relating to HLA Tissue Typing	
2004			HGC – Choosing the Future consultation
2005-2006	HFEA Decision on PGD for lower penetrance cancer conditions		HFEA Public Consultation on lower penetrance inherited cancer conditions (November 2005 – April 2006) 'Choices & Boundaries'
2008	The Human Fertilisation and Embryology Act 2008		HFEA Consultation in 2009 following the Revisions to HFE Act in preparation for the 8 th Code of Conduct

6.3.1 Public Opinion of Prenatal Testing and Preimplantation Genetic Diagnosis

The data contrasted in this section is the BSA survey, which has data on prenatal testing in 1998 and 2000 and PGD in 2003, and the results of the public consultations carried out by the HFEA and ACGT in 1999. In 1998 and 2000, the BSA survey asked:

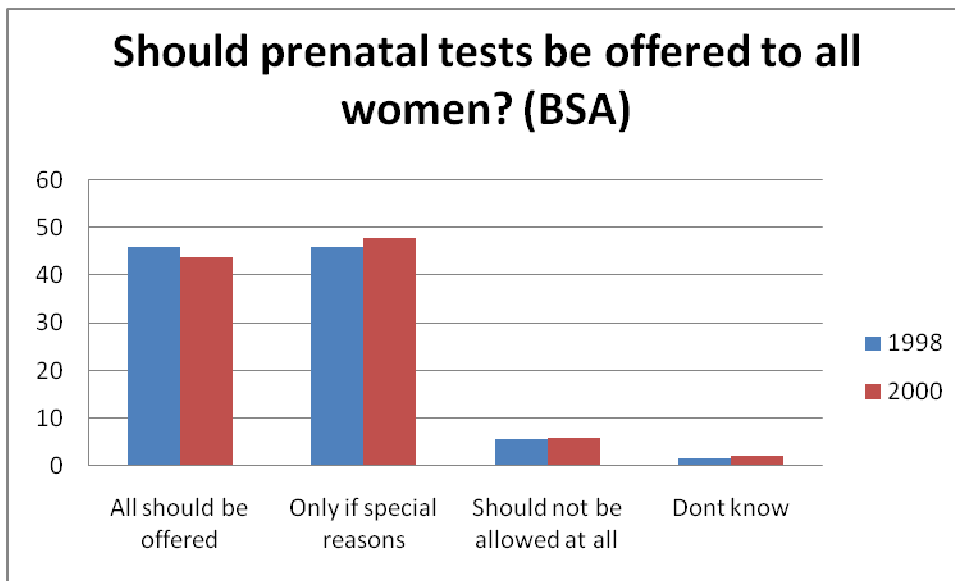
‘Genetic tests can [also] be taken from unborn babies while still in the womb, to show if the child is likely to be born with a serious medical condition, but such tests carry some risks.

Which of the statements on this card comes closest to your view:

1. All pregnant women should be offered such tests.
2. Only women where there is a special reason should be offered such tests.
3. Such tests should not be allowed at all.⁴²²

The responses to this question are shown below.

Figure 22: Should prenatal tests be offered to all women (BSA survey)



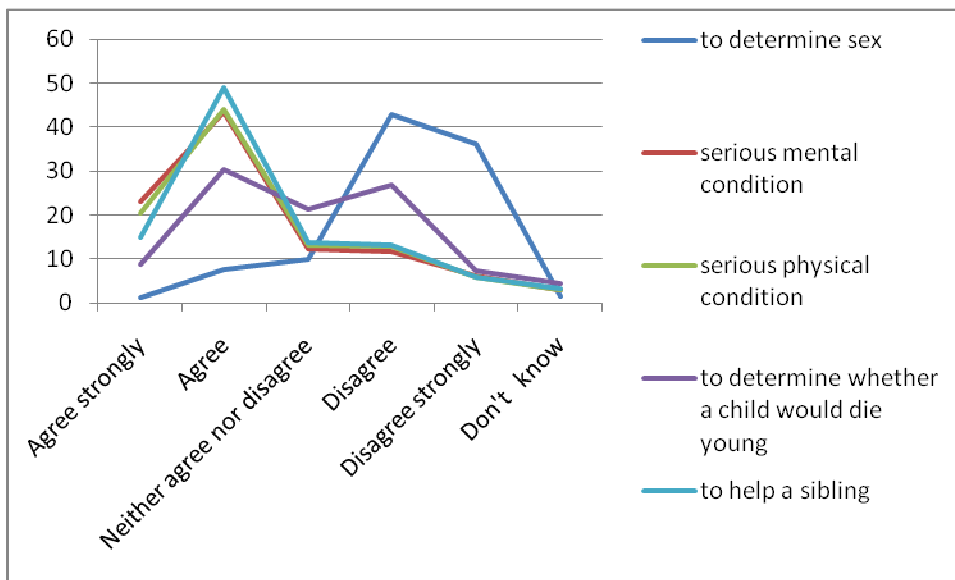
This shows little variation in response over the two years, which is to be expected since this question was only asked in two years with just a two year gap. The most noticeable feature of the results is that there is an approximate but very clear split between those respondents who agree that prenatal testing should be offered to everyone and those

⁴²² Q.735, **1998**, versions B&C, (pregtest), 2000, Q.688 – sample sizes: in 1998 n=2,111 and in 2000, n=2,267.

who believe that it should only be offered if there are ‘special reasons’. There are very few survey respondents who felt that the testing should be prohibited.

The graph below illustrates the responses in the BSA survey in 2003 to the question: ‘Do you agree with genetic tests to help decide whether to have a child with...a serious mental condition, a serious physical condition, the same types of body tissues needed to treat a sibling who was seriously ill, a condition that means the child would die in their 20s or 30s, that is one sex rather than another’. It is noteworthy that the wording of this question is not explicit as to whether it refers to prenatal testing or PGD, but it seems to suggest that it relates to the use of PGD. This is a critical failing of the BSA survey and undermines the data findings.

Figure 23: Public opinion of prenatal genetic testing (BSA 2003)



These results have the interesting feature of reviewing the attitudes to the different uses of prenatal testing and diagnosis. The graph highlights very clearly the contrasting views of the survey respondents to the different uses of prenatal diagnosis techniques. It is evident from this data that in the cases of diagnosing whether a baby has a serious mental or physical condition or is a tissue match for a sibling, the majority of survey respondents were in agreement that this was acceptable. However, the response is very different in the cases of determining the sex of the foetus and in the case of a foetus which has a condition which would mean that the child would not live beyond young adulthood. These two cases are discussed in more depth below with reference to the regulation governing the application of PGD in such circumstances.

6.3.2 The Regulation & Public Opinion of Prenatal Sex Selection

(i) The Regulatory Issues

The regulation in relation to sex selection makes a clear division between sex selection for medical grounds and selection for social grounds. Approximately 200 genetic conditions have been identified which only affect males. This is a very different rationale for sex selection than that related to the concept of 'family balancing' or social selection. Data collected by the HFEA shows that as a general trend in the UK there is little public preference for one sex over another in terms of children. However the same HFEA data additionally showed that in ethnic populations there was a 'disproportionately high percentage' of people with a social preference for male offspring.⁴²³

In the case of medical justification for sex selection this is permitted under the Human Fertilisation and Embryology Act 1990 (as amended by the HFE Act 2008) where a woman 'risks having a child with a life-threatening disease'⁴²⁴. The issue of sex selection using PGD for social reasons was not subject to any regulation until the HFEA's 6th Code of Practice which was published in 2003. Under the Human Fertilisation and Embryology Act 1990, a treatment licence issued by the HFEA can authorise an activity only if it is deemed by the Authority to be 'necessary or desirable for the purposes of providing treatment services'.⁴²⁵ In addition to the split between the medical and social purposes of sex selection, the regulation was unclear and inchoate until the 2003 Code due to the differences in the regulatory treatment of sperm sorting techniques and PGD. Sex selection for social reasons was not explicitly prohibited until the very significant inclusion in the HFE Act 2008 which placed it clearly in the statute. This finally tidies up the HFEA and governmental position on this issue. In 1998 the World Health Organisation proposed a number of ethical guidelines in relation to medical genetics which included the following:

⁴²³ HFEA, 'Sex Selection: Options for Regulation: A Report on the HFEA's 2002-03 Review of Sex Selection including a Discussion of Legislative and Regulatory Options.' Para. 26.

⁴²⁴ Human Fertilisation and Embryology Act 1990, Schedule 2, para. 3(2)(e)

⁴²⁵ HFE Act 1990 Rel. para?

‘prenatal diagnosis is carried out only to give parents and physicians information about the health of the foetus. The use of prenatal diagnosis for paternity testing, except in cases of rape or incest, or for gender selection, apart from sex-linked disorders, is not acceptable’.⁴²⁶

These guidelines are categorically prohibiting sex-selection beyond the therapeutic de-selection of a foetus with a sex-linked chromosomal condition.

(ii) Public Opinion of the Use of PGD for Sex Selection

‘The thing about sex selection – it was decisive – the public was overwhelmingly and adamantly against it...and as such it would be perverse of the regulator to go against it’.
(Member of the HFEA in interview)

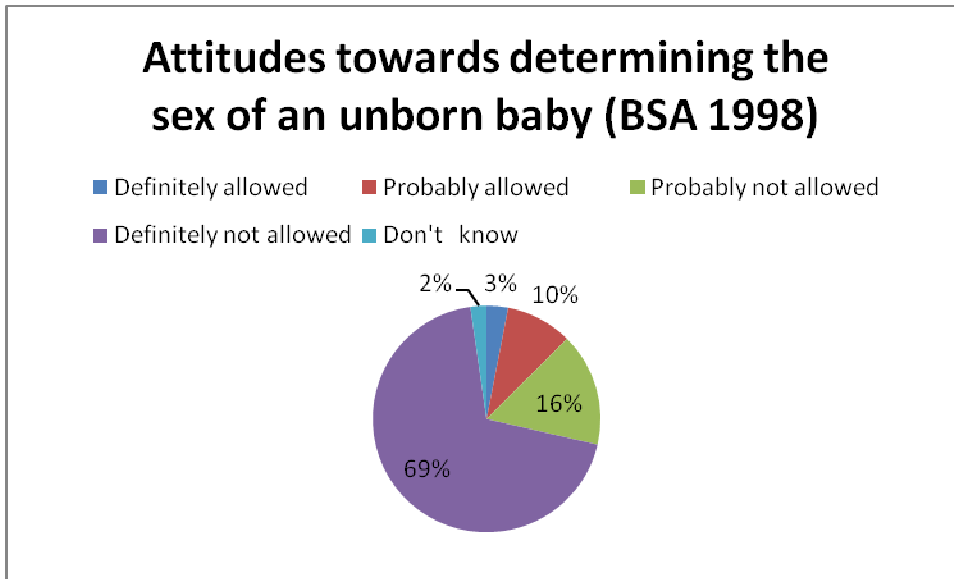
In terms of establishing levels of public opinion on the question of sex selection, we will first turn to the BSA data and following this examine the steps taken by the HFEA to determine public opinion. Unfortunately the BSA survey data does not provide us with a great deal of detailed data and there are no questions which probe the respondents in terms of whether their views differ in relation to the selection of a specific sex for medical or social reasons. Despite such limitations in scope, the BSA survey data has a large sample size and is robust in terms of its collection and while the results are crude they are the results of best endeavours and rank highly in terms of survey data per se. There is one further problem however in that the BSA survey data relating to sex selection for the years 1998, 2000 and 2003 is unfortunately hindered by a confusingly worded survey question:

‘Suppose it was discovered that a person’s genes could be changed. Taking your answers from this card, do you think this should be allowed or not allowed to make a person...determine the sex of an unborn baby?’⁴²⁷

⁴²⁶ World Health Organisation, Proposed International Guidelines on ethical issues in medical genetics and genetics services. Geneva: WHO, 1998.

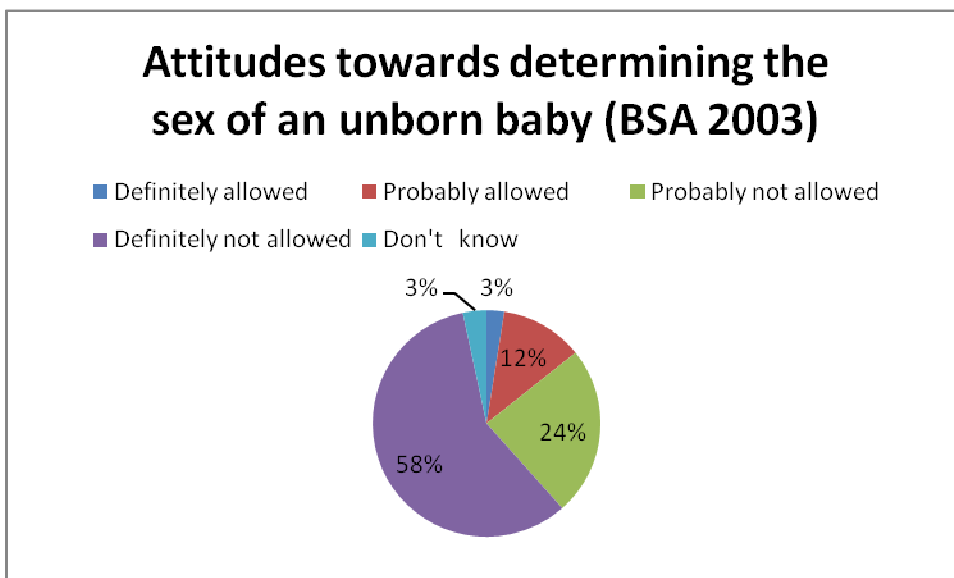
⁴²⁷ British Social Attitude Survey 1998, question 756, 2000, question 708 and 2003, question 805.

Figure 24: Attitudes towards determining the sex of an unborn baby (BSA 1998)



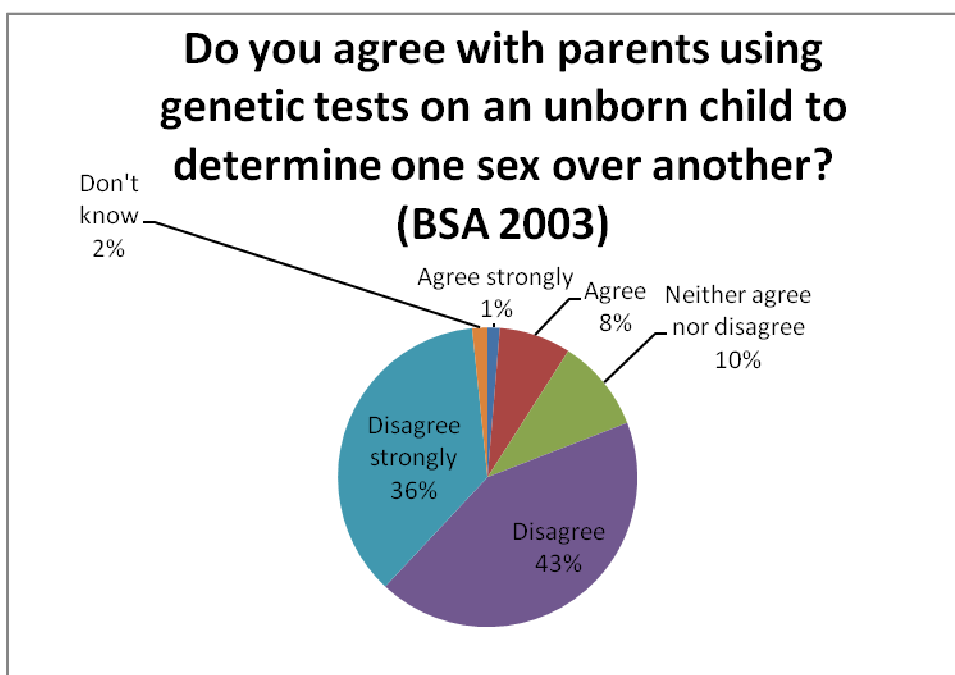
The data for 2000 is not shown here as there is very little change in response across the five years from 1998-2003. The respondents who consider that the proposed intervention should not be allowed reduce slightly over the years from 69% in 1998 to 58% in 2003 and while this is indicative of a softening to sex selection, it still shows the majority of respondents to be very much opposed to prenatal sex selection.

Figure 25: Attitudes towards determining the sex of an unborn baby (BSA 2003)



In 2003 a more clearly worded question was also added for which the results are shown in the pie-chart.⁴²⁸ This final chart shows a clear and overwhelming opposition to sex selection of an unborn child. The combination of the survey questions show that while the respondents are very happy for the sex of an unborn child to be identified but strongly against a technique which will select one sex over another. The data limitations have been outlined above but in terms of a match between public opinion data and regulation, the limitation which is most obvious is that the survey questions did not discriminate between sex selection on medical as opposed to social grounds, yet this is how the regulation is determined.

Figure 26: Attitudes towards prenatal testing for sex selection (BSA 2003)



(iii) HFEA Public Consultations

The HFEA conducted two consultations on sex selection in 1993 and 2003. As already stated, regulation pertaining to the use of sex selection for social reasons did not exist until the 6th Code of Conduct in 2003. It is interesting that sex selection was the focus for the first public consultation on PGD conducted by the HFEA. This consultation involved a written consultation document, of which 2000 copies were disseminated

⁴²⁸ British Social Attitude Survey 2003, question 796: 'Do you agree or disagree with parents using such tests [genetic tests carried out on an unborn child] to help them decide whether or not to have a child that is one sex rather than another?'

resulting in 165 responses. In addition to this in 2003, the HFEA commissioned a MORI poll on the issue of sex selection with a sample size of 2,165. These people were interviewed face-to-face across Britain in 198 different locations in the period from 9th to 14th January 2003. Significantly, the findings of the poll show that 68% of the respondents think that regulation on this issue would be a good idea. In terms of understandings of the term 'sex selection', only one in five respondents knew that this related to the choice of a baby's sex with 47% not understanding what this meant. A very large majority, 69%, of respondents, disagree that prospective parents should have the right to choose the sex of their child. This consultation had an additional component of a focus group analysis. The consultation findings were published in the HFEA's report, 'Sex Selection: Choice and Responsibility in Human Reproduction'.

In both the HFEA consultations, the respondents are opposed to sex selection for social reasons: 67% opposed in 1993 and 2003. In the 2003 MORI poll, 65% agree with the use of sex selection for medical reasons while 67% oppose it for family balancing purposes and 79% disagree with it being permitted for other non-medical reasons. Following the 1993 consultation, the HFEA state that:

'the view of the Authority on sex selection for social reasons is strongly supported by the public who responded to our consultation exercise'.⁴²⁹

It is interesting to posit the MORI poll result that 69% of respondents disagree with sex selection against the BSA survey data of the same year which found that 79% disagreed with sex selection.

While the BSA survey has been criticised for not making a distinction between social and medical grounds for sex selection, the MORI poll commissioned by the HFEA did address this and made a distinction in the questions between attitudes towards social and medical use of PGD for sex selection. The data shows that 65% agreed with the use of PGD for sex selection on medical grounds and only 18% agreed with PGD for sex selection on the grounds of 'family balancing', with 8% agreeing and 79% disagreeing

⁴²⁹ Correspondence from Prof. Colin Campbell, Chairman, HFEA to Tom Sackville, Health Minister, p.2 of letter dated 15 July 1993.

with the use of PGD for sex selection in the case of other non-medical reasons such as social and cultural reasons.⁴³⁰

In terms of public opinion, it would seem unlikely that there would be a shift of feeling in favour of sex selection for social reasons; however it may be that the regulatory arena is being neglected as the technology outpaces it. There have been rapid technological changes in the fields of PND and PGD and things have moved on radically from the sex selection techniques available in 1993 such as sperm sorting. The field of prenatal genetic testing is to be radically affected by the introduction of non-invasive prenatal tests (NIPD). A NIPD test for sex selection is now available and can be purchased by pregnant women and simply involves testing the maternal blood. This test can be carried out on a woman from seven weeks into a pregnancy and it is said to be 95% accurate. It is already in use at Great Ormond Street Hospital where it is argued that it is useful for medical grounds to detect male foetuses in cases where there is a family history of serious genetic disorder. In such cases, there is a clinical advantage to gaining this knowledge as early as possible, as an earlier stage termination involves less clinical risk. The risk is however that from these uses of NIPD for sex selection, the test will become publicly available and pregnant women would be able to use the test in their own homes and may seek a selective abortion if the sex is not to their liking. By omitting that they have conducted a NIPD, the pregnant woman may argue alternative grounds for an abortion. Such technological advances are difficult for the regulators to keep apace of and arguably make the regulation redundant. It can be proposed that public opinion in such circumstances is playing out in a different way in that there is consumption and demand for a test which arguably could be classed as an indicator of approval and acceptance by the public. This is in strong contrast to the polls and survey data which shows that the public disapprove of sex selection on non-medical grounds.

⁴³⁰ HFEA, 'Sex Selection – A Public Consultation: Research Study Conducted for the Human Fertilisation and Embryology Authority', January 2003, MORI poll question 5, sample=1,123.

6.3.3 The Regulation & Public Opinion of the Application of PGD for Inherited Cancer Susceptibility

In 2005, the HFEA chose to review its licensing position in relation to the use of PGD for lower penetrance inherited cancers for breast and bowel. Prior to this the majority of the conditions licensed by the HFEA were fully penetrant which means that once a specific gene is found to be present, the condition will develop. Interestingly the push for a public consultation on the licensing of lower penetrance conditions at this time, in late 2005 was stated by the HFEA as being a response to ‘several PGD centres [which had] expressed an interest in applying to us to carry out PGD for breast cancer’. Further to this, the HFEA had not received an application for the use of PGD in this way at the time of the consultation.⁴³¹ The HFEA launched a public consultation, entitled ‘Choices and Boundaries’ in November 2005 which was concluded in January 2006. There were two dimensions to the consultation: a written discussion document which was issued in November 2005 and left open for responses until January 2006 and a public meeting in December 2005. The discussion document is an interesting approach and it sets out to outline the regulation of PGD, it defines penetrance, and includes a couple of true scenarios from women with familial experience of cancer. Following this the proposals to extend licensing of PGD to lower penetrance inherited cancer are delineated. The respondents were invited to read this information and to answer six very lengthy questions.⁴³² The conditions under discussion differed from those licensed beforehand in three respects: they were conditions of a lower penetrance (40-80%), they were later onset conditions (often affecting people in their 30s or 40s), and the conditions were in some cases treatable.

The written consultation document received only 284 responses and notably 56% of these responses were from school pupils.⁴³³ 109 people attended the public meeting and while there was a wider cross section of the public at this meeting, 24% were

⁴³¹ http://www.hfea.gov.uk/docs/Choices_and_boundaries_Report_2006_summary.pdf (last accessed on 28th September 2011) at page 5. Additional research showed that there were two PGD centres that had made enquiries about this, see further: Ethics and Law Committee (02-06)-2, 2006.

⁴³² HFEA ‘Choices and Boundaries: Should People be able to Select Embryos Free from an Inherited Susceptibility to Cancer’, <http://www.hfea.gov.uk/516.html> (last accessed on 28th September 2011).

⁴³³ http://www.hfea.gov.uk/docs/Choices_and_boundaries_Report_2006_summary.pdf at p.6.

academics, 12% IVF clinicians or scientists and 8% were patients or from patient-groups. It is fair to describe the meeting attendants as stakeholders rather than the public. In contrast, the make-up of the written respondents was described in the HFEA report as ‘a significant majority were school pupils and interested non-affiliated members of the public’.⁴³⁴ However, it was on the back of the findings from this meeting and the written responses that the HFEA produced the decision. The HFEA states repeatedly throughout the consultation document that it welcomes the views of the public and wants to hear the views of patients and carers.⁴³⁵ It is also stated in the document that the purpose of the discussion document is ‘to gather the views of the public to inform licensing decisions and help the Authority decide....’, and ‘[T]hese views will help the Authority to decide if PGD should be used to detect lower penetrance cancer susceptibility....’⁴³⁶ The report produced by the HFEA on the consultation is a very qualitative document which has quotes from the respondents scattered throughout, yet this qualitative approach is to the detriment of any indication of how many people felt one way or another in relation to the questions asked. All responses are formatted in the phrasing of: ‘Some people felt....’ and ‘A number of people said that...’. However, a breakdown of the findings can be found in a document produced by the HFEA’s Ethics and Law Committee who noted that ‘if people do not accept the current use of PGD, it was difficult for them to respond to specific questions about its wider use’.⁴³⁷ It is important to review to what extent the findings of the consultation fed into the HFEA decision to allow licenses for PGD for lower penetrance conditions including inherited cancers.⁴³⁸ It was found that the majority of respondents to the written document felt that PGD had already crossed the boundary whereas at the public meeting, nobody expressed this view. As a final word on this consultation it is noteworthy that the HFEA states in the Choices and Boundaries Report that:

⁴³⁴ http://www.hfea.gov.uk/docs/The_Authority_decision_Choices_and_boundaries.pdf at p.6.

⁴³⁵ http://www.hfea.gov.uk/docs/Choices_and_Boundaries.pdf p.2-3 and passim.

⁴³⁶ http://www.hfea.gov.uk/docs/Choices_and_Boundaries.pdf at p.2-3 and p.11.

⁴³⁷ The HFEA’s Ethics and Law Committee: Berry, Katy ‘PGD for inherited cancer susceptibility’, ELC (02-06)2, 2006. The HFEA is explicit in its assumption that people are in favour of PGD –see further: http://www.hfea.gov.uk/docs/Choices_and_boundaries_Report_2006_summary.pdf at p.7.

⁴³⁸ http://www.hfea.gov.uk/docs/The_Authority_decision_Choices_and_boundaries.pdf

‘The lack of an overall consensus is probably unsurprising as it is almost impossible to achieve compromise or consensus on issues where the views of respondents and society in general are so polarised and this highlights the difficult environment in which the HFEA has to make decisions’.⁴³⁹

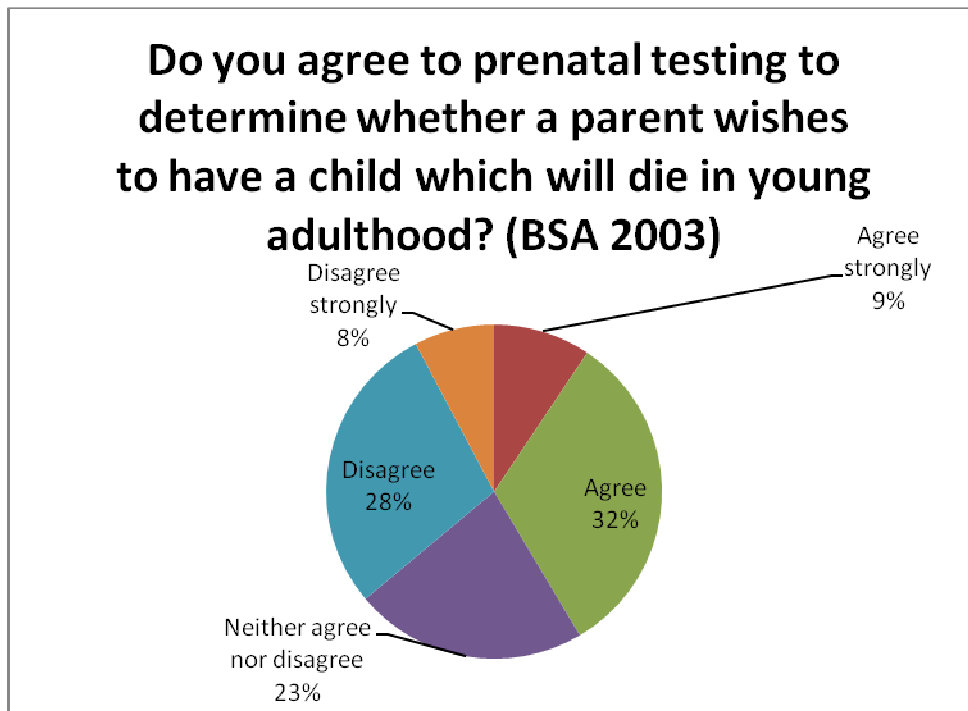
The following question was asked in the BSA survey of 2003:

‘Genetic tests can be carried out on an unborn child. Do you agree or disagree with parents using such tests to help them decide whether or not to have a child that has a condition that means it would live in good health but would then die in its 20s or 30s?’

The chart below shows the responses, and one of the interesting features of the results is how great the deviation of response is from the responses to the other uses of PGD (see figure 27 in relation to a serious mental genetic condition). While the BSA survey respondents were in favour of the use of PGD to deselect a serious physical and mental genetic condition, when it comes to using PGD to deselect an embryo where the child would die in early adulthood opinion is very different, with far fewer numbers of people in favour of the technique for these purposes. It is this case which shows the least response by the regulators to public opinion, if the Choices and Boundaries Report or the BSA survey are to be understood to be public opinion. It is therefore argued that the regulators decided to respond to the very vocal parents and interest groups who attended the public meeting of the Choices and Boundary review.

⁴³⁹ http://www.hfea.gov.uk/docs/Choices_and_boundaries_Report_2006_summary.pdf at p.14.

Figure 27: Attitudes towards prenatal testing to determine whether a child will die in young adulthood



6.3.4 The Regulation & Public Opinion of the Application of PGD for HLA Tissue Typing ('Saviour Siblings')⁴⁴⁰

'Trying to define what is scientifically allowable based on primary legislation doesn't make any sense. In the long term it'll be unwieldy and people will constantly be pushing at the boundaries of that and parliament will have to go through this process again' (Dr Minger, Director Kings Stem Cell Biology Laboratory, with reference to the draft Amendments to the HFE Act).⁴⁴¹

One application of PGD is to use it as a means to select foetuses which have a tissue matched with an existing sibling thus providing the potential to use the cord blood and bone marrow to help an existing sibling suffering from a genetic condition such as Fanconi anaemia. The term 'saviour sibling' was coined by the media for such cases. It is argued here in terms of the relationship between public opinion and regulation that the driving force behind these cases has been the push for them by a very small number of parents. The issue came to public attention through widespread media attention when the Hashmi family applied to the HFEA for a licence to carry out HLA tissue

⁴⁴⁰ HLA stands for Histocompatibility Leukocyte Antigen

⁴⁴¹ The Guardian 1 August 2007

typing using PGD. Zain Hashmi suffered from the blood disorder beta thalassaemia major, and he needed stem cell transplantation in order to recover. Unfortunately, Zain's siblings were not compatible for a tissue match and Mrs Hashmi had one abortion following parental tests which showed that the foetus was not a match either. A subsequent pregnancy produced a healthy baby but s/he was not compatible. It was following these events that the Hashmis looked into HLA tissue typing PGD, a new procedure which had not been authorised by the HFEA. While PGD as part of the IVF procedure was not novel, tissue typing had not before been undertaken in conjunction with PGD.

The HFEA issued an interim policy on preimplantation tissue typing in November 2001 permitting a restrictive policy which allowed the procedure only in cases where PGD was already necessary in order to avoid disability in the future child. Thus PGD was not permitted on the grounds of HLA tissue-typing alone. This is known as 'selection in two stages' and is a critical hinge for the ethical debate in this area as it is generally a corollary of the argument that PGD solely for tissue-typing is unethical due to instrumentalisation of the embryo.⁴⁴² The HFEA Licence Committee made the decision to issue a licence to CARE Nottingham for the treatment of Mr and Mrs Hashmi in February 2002 in accordance with the 'selection in two stages' policy. The Hashmis case was given a high level of media and legal attention at the point when, following the second cycle of treatment, an interest group sought a judicial review against the HFEA's decision to allow this procedure. Comment on Reproductive Ethics (CORE) argued that the HFEA had acted ultra vires in making the decision regarding HLA tissue typing. The Court of Appeal found in favour of the HFEA⁴⁴³.

There was a further pushing of the HFEA's stance in the form of a second application for HLA-tissue typing from the Whittaker family. This case deviates from the Hashmis and tested the HFEA's position on the two-stage test in that there was no need for PGD

⁴⁴² There are a number of conditions to the issue of such licenses which include: the particular genetic disorder must be severe or life-threatening; the embryo itself must be at risk of this disorder; all other treatment possibilities must be exhausted; the intended recipient must not be the parent; the intention is to use the cord blood; the parents would receive counselling; the family would be encouraged to participate in follow-up studies; no embryo would be genetically modified in order to provide a tissue match.

⁴⁴³ Quintavalle, R. (on the application of) v Human Fertilisation and Embryology Authority [2003] EWCA Civ 667 (May 16 2003)

except for the purpose of the tissue-typing. Charlie Whittaker suffered from Diamond Blackfan anaemia for which there is currently no known genetic marker. The HFEA retained their regulatory position and the Whittaker's application was refused in July 2002. Subsequently, the Whittakers travelled to the USA for the treatment.

Whether it was as a consequence of what Brownsword calls 'determined purchasers' putting great pressure upon the regulators, the HFEA policy did undertake a radical shift in July 2004 following a review of policy in this area. This involved the HFEA relaxing its policy on HLA tissue typing to remove the two-stage process and to permit cases where PGD was not necessary except for the tissue typing. In September 2004, the Fletcher family benefited from this new decision and their application for a licence relating to their son, who also suffered from Diamond Blackfan anaemia, was granted. Little has been noted in the literature of the fact that this decision by the HFEA goes against the International Bioethics Committee guidance which supports the two-stage process.⁴⁴⁴

With reference to the attention cycle literature discussed in Chapter 4, the origins of this shift in regulation are critical. In the words of Professor Emily Jackson, Member of the HFEA's Ethics & Legal Committee, the change came about because 'this is what the public want'. Jackson contends that 'the decision was made on the grounds that the law is not in the business of promoting moral virtue but is there to prevent harm and thus by permitting this technique, there is reduced harm as the child survives and there is reduced parental grief'.⁴⁴⁵ Emily Jackson bases her opinion upon the results of the HFEA's public consultation exercise on PGD. In the HFEA's consultations it is clear that there is a need to reflect the views of two very distinct publics: one that will promote an individual's right to personal autonomy (for example in this case, the parents pushing for HLA tissue typing) and the 'public citizen' who will generally present a less emotive opinion because the regulation has no direct effect on his/her life at that time.

⁴⁴⁴ UNESCO, *Report of the IBC on preimplantation genetic diagnosis and germ-line intervention: SHS-EST/02/CIB-9/2*, United Nations Educational, Scientific, and Cultural Organization, Geneva (April 24, 2003).

⁴⁴⁵ Professor Emily Jackson, Deputy Chair, Ethics and Law Committee, HFEA quoted from a presentation I attended at the Genethics Club, London, July 2007.

The 2004 Review of the regulation relating to saviour siblings involved some limited public consultation which was contracted out to Opinion Leader Research who conducted a series of six workshops with members of the public. Each of these six groups was made up of 6-8 individuals. It was found that the participants were 'broadly in favour' of tissue typing and that there was 'cautious approval' for the process. The areas of concern centred on the seriousness of the genetic condition and there were greater reservations about the use of the procedure to produce a bone marrow donor. However the HFEA report states that these concerns 'tended to diminish in the light of more information about the procedure provided by the invited experts'.⁴⁴⁶ The limitation of any analysis of the HFEA report is that it is very spare in its detail of the workshop data. The number of participants was very small and evidently benefits from presenting the HFEA findings in a light fashioned to suit their own outcomes. While the latter comment is unsubstantiated, it is noteworthy that the report states that 'the Authority concluded that research into public opinion formation had been extremely helpful'.⁴⁴⁷ From a series of workshops involving a maximum of 48 people, the term 'public opinion' is used.

It is interesting to review the role of the HFEA which is a regulatory authority often called a model for other jurisdictions, indeed it is described by Knoppers et al as 'probably the best model of effective oversight and licensing'.⁴⁴⁸ Yet significantly, the HFEA chose to adopt this regulatory line in divergence with the International Bioethics Committee guidance on saviour sibling cases. The institutional dynamics of the HFEA as a channel for public opinion is also a very pertinent factor in these cases. As Stimson contends in his discussion of dynamic representation it is essentially a question of how closely coupled the institutional policy is with public opinion. Stimson states that:

⁴⁴⁶ HFEA Report on Preimplantation Tissue Typing at para. 33, http://www.hfea.gov.uk/docs/PolicyReview_PreimplantationTissueReport.pdf (last accessed on 26th September 2011).

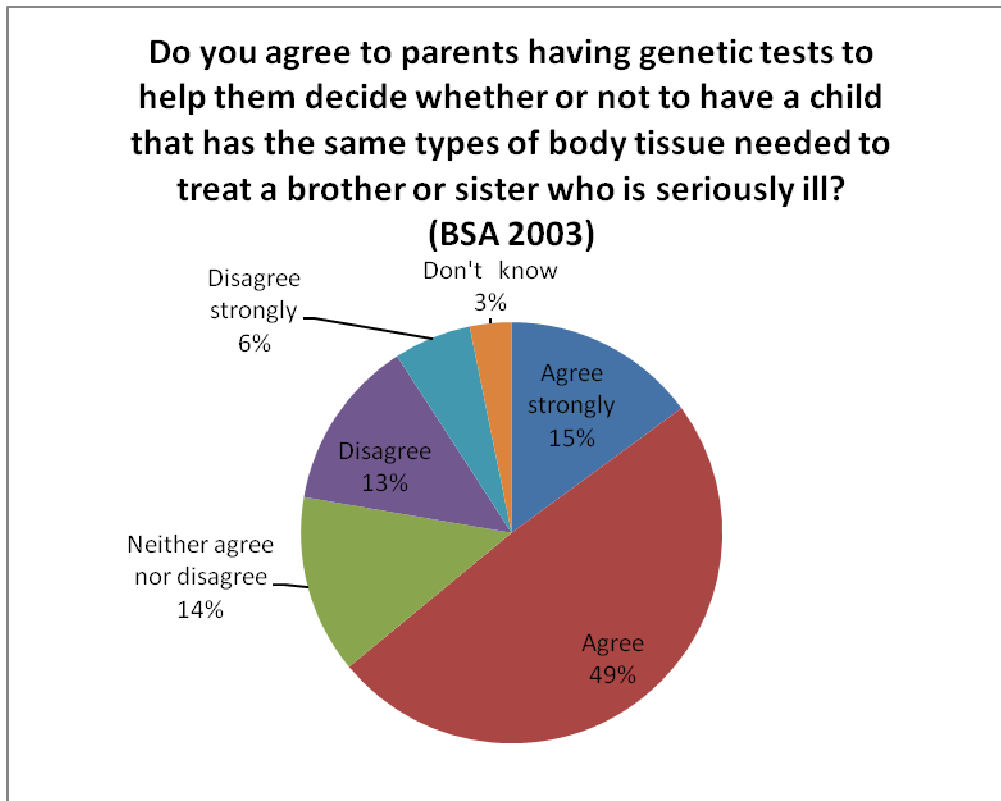
⁴⁴⁷ HFEA Report, op cit. at para.33.

⁴⁴⁸ Knoppers, B.M. and Isai, R.M., 'Regulatory Approaches to Reproductive Genetic Testing', Human Reproduction Volume 19, No.12, pp.2695-2701, 2004 at p. 2700.

‘A closely coupled system would have a relatively short institutional memory in the sense that policy will incorporate recent (as opposed to long prior) shifts in public opinion’.⁴⁴⁹

The BSA Survey data from 2003 is shown in the pie-chart below. The critical finding from this is that there is a very strong response in favour of saviour siblings.

Figure 28: Attitudes towards prenatal genetic tests for tissue typing (BSA 2003)



Steve Webb MP conducted an on-line survey from his constituents prior to the House of Commons free vote on saviour siblings which was part of the Human Fertilisation and Embryology bill now enacted as the Human Fertilisation and Embryology Act 2008. In this survey it was found that 56% of the respondents were in favour and 39% against the amendments to the HFE 1990 Act specifically relating saviour siblings. These amendments included: extending the treatment to ‘serious’ as well as ‘life-threatening’ conditions, and extending the scope of the treatment from the use of stem cells from the umbilical cord blood only to allow the possibility of treatment using other types of tissue and cells from the sibling – although not permitting the transplantation of whole

⁴⁴⁹ Stimson, James A. 1991, ‘Public Opinion in America: Moods, Cycles and Swings.’ (Bolder Colorado: Westview Press).

organs. As McLean highlights the HFE Act 2008 was significant in increasing the 'lawfulness of the creation of so-called 'saviour siblings' because prior to this there was no statute in place from which the HFEA could determine regulatory policy.

Where are the public here? In terms of locating public opinion in this area, it is evident that there was no public backlash to the Hashmi case. Equally, the results from the BSA survey in 2003 and (while less robust and representative) the results of Steve Webb's survey,⁴⁵⁰ both show that while this is potentially a controversial issue, the general consensus is in favour. Evidently however there are some very strong oppositional views which are stressed by the interests groups, including CORE the pro-life charity, LIFE and GeneWatch, but which have not had an impact on the direction of the regulation.

6.4 Prenatal Diagnosis and Selective Termination: The Parents' Voice as Public Opinion?

It is interesting to question the weight, if any, that should be given to a pregnant woman and prospective parent's view surrounding a positive test result which pertains to a higher than average risk of a genetic condition. Issues such as the clinical advice and support are critical at this stage in terms of the prospective parent's knowledge of the degree of risk and the seriousness of such a condition for a child and future adult. In relation to the concept of public opinion it is often the views of the affected prospective parents which are referred to as an alternative sample to that of the 'general' public which are randomly selected. In responding to a survey question relating to this issue, where would one put oneself - in the position of the parents or as a member of the public for whom this has never been an issue? In respect of how a survey respondent situates him or herself, the framing of the survey question is crucial.

Under the current legislation a number of reasons are specified for which an abortion may be undertaken.⁴⁵¹ The relevant section in the context of this study are those abortions which are carried out under section 1(d) of the Abortion Act 1967 which permits an abortion in cases where 'there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously

⁴⁵⁰ <http://www.stevewebb.org.uk/savioursiblings.html> sample size=1228 people

⁴⁵¹ The Abortion Act 1967 as amended by section 37 of the Human and Embryology Act 1990

handicapped'. The statutory requirements need to be viewed in association with the social justifications given in a decision to terminate a pregnancy where such serious handicap is perceived. In such cases the principal reasons cited are the disruption to the family that the birth of a child with serious handicap would cause and the lack of a decent quality of life for the unborn child. The medical authorities will also refer to the cost-effectiveness of the prenatal testing and therapeutic abortion in relation to the costs of medically supporting children and adults with serious genetic conditions.

I wish to focus here on the question of whether there is evidence of a correlation between the increased number of prenatal genetic tests available and the number of abortions on the grounds of genetic conditions. There has been a strong push for prenatal testing and diagnosis to be rolled out and offered across the board to pregnant women. Indeed the Advisory Committee on Genetic Testing (ACGT, now subsumed into the Human Genetics Commission) proposed in 2000 that screening tests for all serious genetic conditions should be offered to pregnant women.⁴⁵²

6.4.1 Is there a correlation between increased prenatal genetic diagnosis and elective abortion rates for serious mental and/or physical genetic conditions?

Abortion statistics are collected annually by the National Statistics Online (ONS) database. For the purposes of this study I examined the data inputs for each year and have extracted the numbers of abortions carried out under section 1(d) of the Abortion Act 1967. These statistics can be sub-divided further into either chromosomal abnormalities and/or for Down's Syndrome. I have collated the data and supplied percentages of the number of abortions carried out under section 1(d) as a percentage of the total, and the percentage of abortions relating to chromosomal and Down's syndrome in relation to the total number of abortions under section 1(d) of the Abortion Act 1967.

⁴⁵² Advisory Committee on Genetic Testing, 'Prenatal Genetic Testing: Report for Consultation', London: Human Genetics Commission, 2000.

Table 29: Legal abortions under section 1(d) of the Abortion Act 1967

Year	Total legal abortions	Total legal abortions under section 1(d)	Number of abortions carried out under section 1(d) as a % of total of all legal abortions	Number of abortions carried out on the grounds of a chromosomal abnormality	Chromosomal as a % of total number of abortions under section 1(d)	Number of abortions on grounds of Down's Syndrome	Down's Syndrome as % of total ground number of abortions under section 1(d)
1995	163638	1828	1.12	468	25.6	283	15.5
1996	177495	1929	1.08	561	29.1	303	15.7
1997	179746	1853	1.03	580	31.3	316	17.1
1998	177871	1903	1.07	578	30.4	339	17.8
1999	173701	1902	1.09	613	32.2	333	17.5
2000	175542	1927	1.09	637	33.1	353	18.3
2001	176364	1822	1.03	615	33.8	358	19.6
2002	175900	2008	1.14	732	36.5	389	19.4
2003	181606	2077	1.14	731	35.3	401	19.3
2004	185414	2018	1.08	749	37.1	430	21.3
2005	186400	2053	1.1	776	37.8	429	20.9
2006	193700	2172	1.12	797	36.7	448	20.6
2007	205598	2074	1.01	778	37.5	437	21.1

My aim is to ascertain whether the increased number of prenatal tests has led to increased abortions under section 1(d) the Abortion Act. In 1999, the screening test for Down's Syndrome was offered to 70% of pregnant women who were deemed to be at risk of the disease (risk was highly related to the over-35 mother group at this time). By 2001, this figure was 80%.⁴⁵³ It is argued here that there exists a general acceptance by both the public and clinicians of the informative role of screening, for example, to show that a foetus has a higher risk of being born with Down's Syndrome, yet this isn't the case for the operative part, for example, the decision to have a selective abortion on the grounds that the foetus has a severe genetic condition. From 1995 to 2007, it is evident

⁴⁵³ Harker, Rachel, 'Statistics on Abortion', (House of Commons Library, 2009)

that there has been a significant rise in the number of abortions on the grounds of the foetus having Down's syndrome. Allied to this finding is that, of the abortions carried out under section 1(d) of the Abortion Act, the percentage for Down's syndrome has risen from being 15.5 % of the total number to 21.1% over the years 1995-2007. This correlates with the increase in prenatal genetic diagnosis taking place over this period.

There is research into the gap between what people say in surveys and their actions. A study was undertaken by Corral-Verdugo in the late 1990s in relation to people's recycling habits which highlighted a gap between their competencies and their beliefs.⁴⁵⁴ Relating this study to these statistics on abortion and the responses given in, inter alia, the BSA survey, there is an argument to be made that there is a relationship between the increase in diagnoses of Down's Syndrome that has led to an increase in abortions of foetuses with this condition. However, it is notable that the percentage of cases of abortions under section 1(d) of the Abortion Act has not increased over the period measured – in 1995 abortions in this section accounted for 1.12% of total abortions and in 2007, this figure was 1.01. This would therefore suggest that, while diagnosis of serious genetic conditions in prenatal testing is increasing, with the exception of Down's Syndrome there is no indication of an increase in selective abortions arising from this.

6.5 The regulators' views of public opinion

The public opinion data has been explored and it is interesting to enrich these findings with the comments of the regulators as an insight into their views on public opinion. A member of the HFEA commented on the problematic nature of public consultations by stating that:

'one of the interesting things about consultation is that you get so few responses...it's not the best way of gaining a view of what the public think, you only get a tiny slice of the public'.

A second Member of the HFEA stated that it was 'hard to say' whether the HFEA's consultations were an effective measurement of public opinion and she commented further that in relation to the responses to consultations: 'what have we gained by asking

⁴⁵⁴ Corral-Verdugo, Victor, 'Dual Realities of Conservation Behaviour: Self-Reports versus Observations of Re-use and Recycling Behaviour', *Journal of Environmental Psychology*, Volume 17 (Issue 2), June 1997, pp.135-145.

a question which 30 people respond to?’ The regulators interviewed for this thesis included members of the HFEA, the HGC, a clinical geneticist who was a Member of the HFEA and the Director of the Genetic Interest Group (GiG). GiG is an umbrella group for approximately 140 member organisations which range from large NGOs such as Cancer Research UK to smaller interest groups. In the first instance it is important to view the role Mr Kent, Director of GiG plays, as GiG is a hugely influential interest group in this field. With reference to partiality and being a member of the HGC while also chairing GiG, Mr Kent’s observes that:

‘...as a member of the HGC, I am not there as Director of GiG, I am there as an individual appointed in my own right and that is a useful fiction, of course it is a fiction because they could have appointed me as a representative from the top of the Clapham omnibus but I think it is probable that I was asked to join because of the perspective I could give being Director of GiG.....’

In the course of the interviews and from researching the make-up of the regulatory bodies, two issues emerge vis a vis regulators and partiality. Firstly, we see this concept of a ‘useful fiction’ and the idea that individuals have been appointed as non-partisan yet will inevitably maintain their own personal agenda. Secondly, regarding partiality on a regulatory body, it is noteworthy that there is a very high ratio of Members of the HFEA who are geneticists. For instance, of the eighteen Members of the HFEA, half are involved in clinical genetics. This last point is not in itself a criticism of the running of the regulatory body, for there is clearly a need to involve clinical members in order to gain a full understanding of the issues being discussed and it is evidently not wise to ignore sources of specialist knowledge. It will, however, impact upon regulatory decision-making and may have implications for the recourse of the regulators to public opinion. Will a regulator prefer to determine a case in view of the specialist knowledge over what is perhaps deemed the uniformed view of the public? As Mr Kent succinctly comments in relation to the partiality of regulators: ‘there clearly is a feed through, you don’t leave your GiG hat at the door of the HGC meeting’.

All of the interviewees were asked whether they believed that the level of responsiveness of regulators to public opinion has altered over time, and there was a consensus that public engagement had increased over the last decade which is evidently a related but different matter. However, as a member of the HFEA highlighted, the presumption in favour of consultation may be partly attributed to compliance with the

Cabinet Office Code of Practice on consultation.⁴⁵⁵ Mr Kent believes that ‘there’s been a fairly steady and growing recognition of the importance of listening to the end-users’. Of course, the end-users in this case are a select group in relation to PGD, and while they are a much larger number in relation to prenatal testing, they would not unanimously be regarded as ‘the public’. While this noticeable increase in public engagement has occurred, levels of responsiveness are less predictable. Although a member of the HFEA stated that ‘one example where public opinion was absolutely decisive was sex selection’, this is not the case for all the public consultations in this field. The same member additionally commented that it would not be appropriate to consult on every single genetic condition as ‘that wouldn’t make sense’. However, a further Member of the HFEA pertinently commented that ‘there’s a need to gauge what the regulators are doing...which is broadly kept in line with what individuals think is ok’, which suggests that this regulator believes that the regulation is responsive to public opinion.

The regulators interviewed were quite open about discarding uninformed responses, as one regulator observes:

‘There are ways of consulting that are really meaningful but they take a great deal of effort, the public find some things more interesting at certain times...we have to consult but we do sometimes get some really terrible responses’ (HFEA Member).

There was also agreement that knowledge of PGD among the general public had not increased over the last 5-10 years. Contradictorily, however, one HFEA member discussed the influence of a television programme which portrayed very emotively a family looking into the application of HLA tissue typing. This interviewee mentioned that a shift occurred upon airing and that there was a noticeable impact on both the representation of such issues by the press and the views of the general public, which became more favourable towards the issue. This contradiction may suggest a difference of definition between being informed about and being more familiar with PGD.

Interviewee 2, also a Member of the HFEA, opined that the press often misrepresent PGD by placing articles ‘that say a child with a squint will get it’. She went on to comment that ‘I mean if someone in Eastenders went and had PGD it would be a great!’

⁴⁵⁵ HM Government, Code of Practice on Consultation, 2008, www.berr.gov.uk/bre (last accessed 8/8/11)

In this thesis it is argued that in the capture of public opinion by regulators there is something akin to ‘imaginary public opinion’ taking place in that regulators and politicians alike will often discuss the public mood, the public opinion etc. but without acknowledging any data or evidence to back up this portrayal of the public opinion to which they allude. While the interviewees were asked whether they pick up signals from people they meet, this was played down by them and they all wished to argue that they were more interested in robust public opinion data. What is happening here? With regard to understandings of public opinion used by regulators, one interviewee comments that ‘it is not possible to take every belief factor into account all the time so you have to do your best to distil out what is seen as broad consensus and you know if you asked me what that meant I couldn’t tell you...it becomes very complex.’ In the course of the interviews, the regulators switched between many different understandings of public opinion: in some cases discussing members of the public, parents who utilise PGD, the media (generally the press but some mention of television), survey data, and findings from HFEA and HGC consultations.

I discussed with the interviewees the findings from the BSA data which show that there is a less positive response to the application of PGD relative to that for prenatal testing. This is of note because many consultants voice the view that PGD is far less invasive than prenatal treatments which may result in a selective abortion and as such should be preferred. When these two points were raised in the interview, it is interesting that two of the interviewees asked what the source of the data was and questioned its value. Interviewee 2, a Member of the HFEA commented that she would ‘question the survey and whether it was an educated response....people who’ve been through prenatal testing to that level....well, it’s just horrific’.

A Member of the HFEA who was actively involved in the Choices and Boundaries Review argued that despite it having been set up with the intention of being a public debate, it failed. The interviewee stated that the people who attended included members of CORE⁴⁵⁶, family groups who suffered from severe genetic diseases, school children and professionals. In this regard, the interviewee commented ‘there were very few people who came off the streets because they thought it would be a jolly interesting debate’. The debate itself, the interviewee argued, was dominated by the groups of

⁴⁵⁶ Comment on Reproductive Ethics (CORE)

families who had severe genetic diseases who spoke about their experiences in a very moving and emotive manner and argued strongly that everything possible should be done to avoid certain genetic conditions. As a consequence the interviewee concluded that the members of CORE who are known to vociferously attack genetic testing and PGD ‘hardly said a word’. To this effect the interviewee felt that a genuine debate did not take place.

In questions of balancing the wishes of the select group of patients/users of the technology with the views of the population as a whole, where should the regulator stand? It is very difficult not to keep returning to the normative question about how responsive to public opinion the regulator should be. At a wider level some criticism was levelled against the HFEA in a 2005 House of Commons Report which suggested that it was active beyond its discretionary powers and mandate. The Commons Select Committee stated that: ‘the current regulatory model, which provides the HFEA with a large amount of policymaking flexibility, should be replaced with a system which devolves clinical decision-making and technical standards down to patients and professionals’.⁴⁵⁷ How this is best achieved is a knotty issue however, as it suggests the need for a fairly permissive regulatory framework.

To summarise the interviewees, it is necessary to stress that the regulators spoken to all believed that public opinion data was a valuable input into the regulatory process, it was the degree to which its inclusion was taken that was up for question. While the limitations of with the data were discussed, it is evident that the IRAs and the individual regulators are undertaking a ‘best endeavours approach’ and are keen to have up-to-date, robust data. Although it should be noted that a member of the HFEA was of the opinion that public consultation is something you can have too much of, and she holds that ‘there are areas where I don’t think the public has a very strong view’.⁴⁵⁸

⁴⁵⁷ House of Commons, ‘Human Reproductive Technologies and the Law: Fifth Report: Session 2004-2005, Volume 1 (London: House of Commons Science and Technology Select Committee), HG7 1, available at www.publications.parliament.uk/pa/cm200405/cmsctech/491/491.pdf at p.169.

⁴⁵⁸ Member of the HFEA, Interviewee 1.

6.6 Conclusions

Public confidence and support can be derived from familiarity with the object being regulated but equally the regulation per se can shape public opinion and lead to public acceptance. However as a caveat to this, it is generally in reference to strict or prohibitive regulation that much is made of the correlation between regulation and public acceptance, for example, in relation to the stringent regulation of embryo research in the UK.

There are factors that make public opinion, or reference to public opinion by the regulators irrelevant. Some of these factors relate to public understanding or knowledge of the techniques in practice, such as levels of clinical utility and the fact that genetic consultants argue that the distress (both physical and emotional) of prenatal testing in conjunction with a selected termination far outweighs that of undergoing PGD. If the public are unaware of such issues then it becomes a normative issue as to who should be driving the direction of the regulation.

In terms of public opinion, it is argued here that the most clearly heard voices in the case of PGD are the clinicians. Prenatal testing is interesting in contrast as it has attracted very low levels of public interest and as such has not been the subject of public consultation, whereas there have been several large scale public consultations on various applications of PGD which singles it out as being subject to special regulatory handling. It is not clear whether the higher prominence of PGD results from its special handling or from the movements of the HFEA in capturing the regulatory space and proving their legitimacy.

The decision to prohibit the use of PGD for sex selection on social grounds is a very clear response to public opinion as understood to be the aggregation of individual opinions. The views highlighted in the survey support this regulatory stance. However in the use of PGD for cases of lower penetrance diseases, the regulators have taken their own regulatory decision. It may be that the regulators believe this to be in the best interests of the public by responding to the interest groups. A further factor has been the increased sophistication of the lobbying by NGOs and their increased access to formal channels of decision-making, such as the role played by the Director of GiG as a member of the HGC. It is often the case that those outside of the formal channels are deemed to be the public – so the increased access of interest groups to the formal

channels has in some way shifted the perception of them so that they are no longer representatives of the public.

The influence of the clinicians is very pervasive in the regulation of PGD and prenatal testing. With reference to PGD, as mentioned above, a high number of the members of both the HFEA and the HGC are clinical geneticists. I attended a meeting which was described as a public consultation on the provisions for PGD in the 8th Code of Practice in 2009⁴⁵⁹ and was overwhelmed by the number of clinical geneticists. The meeting was not what I was expecting in that apart from a very small number of representatives of interest groups, it was HFEA members and clinicians. I later requested a list of all those who had attended this ‘public’ meeting and was told that this information was not available under the Data Protection Act! This does not give the impression of transparency in relation to consultation exercises.

It should be asked whether PGD merits all this attention when the numbers of cases are so rare. While it is the case that many of the applications of PGD are controversial, the rapid developments in the range of tests carried out prenatally should surely merit more attention? I contend that the role of the HFEA has been paramount in the attention received by PGD and its subsequent special regulatory handling relative to prenatal testing. What will be interesting to follow in the future will be the advancement of non-invasive prenatal diagnosis, the ease with which these tests can be purchased on the internet, and the impact of NIPD on PGD and prenatal testing.

⁴⁵⁹ The HFEA meeting took place in London on 26th January 2009.

Chapter 7

Thesis Conclusions

7.0 Introduction

This thesis has focused on the interactions of regulation and public opinion by tracking the relationships between these two variables in relation to GM foods and prenatal testing and PGD. In the course of this research some interesting insights have emerged about the ways that regulation impacts on public opinion, and equally how public opinion feeds into the regulatory process. It is reiterated here that despite the significance of this field of study not only to academics but also to regulators and politicians, these interactions have been neglected in social science research. The reasons why this field has not been researched widely may be a consequence of the challenging nature of the subject matter, which arises from the difficulty of mapping the correlations between regulation and public opinion. The dynamics at play are often difficult to draw out when a multitude of factors are involved.

The central premise driving this thesis is that there needs to be a questioning of the rhetoric surrounding the elevated role given to public opinion by the regulators in the regulation of genomics. This questioning concerns what the input is, whether the rationale behind the rhetoric is justified, and whether it is all just rhetoric or whether in practice public opinion is playing an important role in shaping the regulation of genomics. One of the principal reasons given for the enhanced role of public opinion in the regulation of genomics has been that this area is rife with ethical and controversial issues which give cause for public concern. An additional question was therefore added to the study, asking what the capacity of the regulation is to alleviate public concern.

It is in the response to these questions that the original contribution of this thesis to the field of socio-legal studies and political science is made. The contribution of the thesis is three fold: it has a novel methodology, a challenging and novel subject of analysis, and presents original findings.

Methodological originality is derived from the novel application of mixed-methods in conjunction with the analysis of various sources of public opinion data. The methodological approach will be evaluated later in this chapter.

The second and principal means by which this thesis offers an original contribution relates to the subject matter of the research. While the role of public opinion in the regulation of genomics has received a great deal of attention from academics, the specific interactions have not. Additionally, the models of opinion-responsiveness have not been applied to this sector. The thesis offers a unique and nuanced level of description and analysis to this field. The role played by regulation and the IRAs on public opinion of genomics has not been covered by the existing literature. In undertaking this thesis the analysis of the diverse data sources has given a richness and depth to the study.

The third area of original contribution is the research findings. While a privileged role is given to public opinion in the regulation of genomics in the policy making rhetoric, it is argued that this is not carried through to practice for two reasons: firstly, the data is not representative, and secondly, the understanding of the public is more clearly that of stakeholders. Seven areas are highlighted below which draw out the various dynamics and interactions between the two variables of regulation and public opinion. These issues have been at the heart of the thesis and are:

1. understandings of public opinion in the regulation of genomics
2. the role of regulation in the alleviation of public concerns over genomics
3. the representativeness of the public opinion data used in the regulatory process
4. the use of public opinion as a means to boost IRA credibility and increase regulatory share
5. the privileged role given to public opinion in the regulation of genomics
6. the regulators' views on public opinion
7. special regulatory handling and the idiosyncrasies of the regulation of genomics

In this chapter, these seven areas are discussed in terms of the research findings, following which the methodology is evaluated to draw out its merits and limitations. This leads into a discussion of lessons learned from this research in terms of application to other areas of novel technology, and a final section on possibilities for further research prompted by this study.

7.1 Understandings of Public Opinion in the Regulation of Genomics

There is a very powerful normative pressure upon regulators to not only refer to public opinion but to respond to it in the course of regulatory decision-making. Appropriate or effective levels of responsiveness to public opinion are not the focus of this thesis, but what is central is who, if anyone, the regulators are responding to, in terms of who is represented by the public opinion data. Throughout the thesis it has been established that there is a substantial and fundamental difference between the measured impact of what is called ‘public opinion’ on the direction of the regulation and the ways that public opinion is used rhetorically by regulators in discussion. The underlying issue which has been analysed in this thesis is that while the regulators discuss public opinion, they cross cut and interchange between different meanings of public opinion. In some instances they are discussing the public opinion data which has resulted from a consultation process and in others they are referring to the views of stakeholders. A particularly interesting finding that emerged from the interview data was that they all agreed that public opinion data is not representative of public opinion. However, paradoxically, while these regulators deem public opinion data to be unrepresentative they agree that it retains a prominent role as an input into regulatory decision-making.

In the thesis the various understandings and definitions of public opinion have been ring-fenced into five groups and this has assisted the analysis and been a useful heuristic device. However, in conclusion it appears that one either opts for Zaller’s belief that public opinion simply does not exist, or holds the view that public opinion evades capture. The regulatory process demands that regulators and regulatory agencies continue to strive for robust data on public opinion, but it is critical that regulators acknowledge that there is no alethic truth that equates to public opinion. What remains however, is for regulators and academics alike to find working definitions and understandings relating to the public opinion data used which denotes what such data represents. Within the regulatory process, the many and varied representations of public

opinion will continue to co-exist as a result of NGO lobbying, elite and stakeholder views, survey data and consultation exercises, not ignoring the huge role played by the media. The thesis has made clear that it is not a case of only analysing the relationship between public opinion and regulation: a third variable has been at play – that of public opinion data.

In contrasting the two case-studies, it has been argued here that the perceived role of the regulation has played a part in the weighting given to public opinion. While the regulatory rhetoric is that regulation is responsive to public opinion, it is argued here that due to the nature of the public opinion data used, it is more apparent that regulators are acting in response to the principal stakeholders. For GM foods this means balancing the demands of the suppliers of GM produce, the retailers and the anti-GM NGOs. With reference to prenatal genetic diagnosis and prenatal testing, the response is to the clinicians, and the applicant couples. In neither case, therefore, is it an aggregation of individuals or the majority view that is prominent in the decision-making process.

Regulation has the capacity to facilitate, to enable, to prohibit and to protect people from risk, which is interesting in terms of the two case-studies. The role of regulation in GM foods is very complex, and while it may be may first appear as a system designed to protect people from the perceived risks of GM foods, it may be more realistic to see the regulation in this arena as a mechanism to enable the companies producing GM foods to survive in the EU, while the label gives the consumer a choice through information. The lack of scientific unanimity surrounding the safety of GM foods will remain a hindrance to regulatory resolution in this field. As regards the second case-study, prenatal testing and PGD, the regulation sets out to enable individuals to be able to benefit from these technologies. As has been argued in the preceding chapter however, the regulation of prenatal testing and PGD is driven by the clinicians, the applicant parents and NGOs. Indeed many regulators, members of the HFEA and HGC are also clinicians. It has been argued here that this blurring of the regulatory role, in conjunction with increased access to regulatory processes by NGOs, while not amounting to a high level of regulatory capture, should lead regulators to re-evaluate their understandings of what constitutes the public. The public have moved into the policy rooms and often public consultations and public meetings are stakeholder only affairs. As the public consultation processes outlined showed, whether

by self-selection of participants or invited participants, the resulting committee structures are very similar. As a regulator from the FSA commented:

‘actually reaching out to Joe Bloggs I don’t think it really sort of happens to be honest we’ve got individuals who take a vested interests in GM and they come to consultations but the general public aren’t involved in those sort of consultations’.

The number of stakeholders has grown as a corollary of the enhanced recourse to public consultation and this has had two impacts: firstly, these stakeholders are often conflated with the public; and secondly, there is the illusion that there is a public beyond the debates, one which is often alluded to but which is not defined.

7.2 The Role of Regulation in Alleviation of Public Concerns over Genomics

There is no question that regulation has an impact on public opinion and this effect is linked to public trust in regulatory institutions and to the regulation per se. Three interconnected factors are at play in the capacity of regulation to alleviate public concerns over genomics and these are:

- (i) The regulations
- (ii) The regulatory structure – the IRAs
- (iii) The nature of the inclusion of public opinion in the regulatory process

These three factors are connected to the level of responsiveness of the regulators to public concern, but it is argued here that in the cases discussed in this thesis, the existence of these factors alone has an impact regardless of the level of responsiveness to the public opinion input. Thus the public feel that there is a level of protection provided by the regulations regardless of their knowledge of the detail of the regulation. Likewise, there is a level of surety derived from knowing that there exists an IRA which is responsible for a regulatory object. Finally, the assumption that public opinion is taken into account in the regulatory process provides assurance that democratic principles are being upheld. Interestingly, whether the findings of a public consultation are responded to by the regulatory stance or whether the participants of the consultation were all stakeholders does not detract from the capacity to reassure the public.

In the UK the regulation has balanced a permissive style which facilitates the availability of products derived from genomics with necessary and tightly governed oversight safeguards. This policy has engendered a level of trust in some of the

products and imbued them with an authority which runs along the lines that ‘it must be safe because it’s in the shops’ or ‘it’s a procedure offered to me in the hospital’.

However, the correlation between the regulation and the alleviation of public concern is not as straightforward as the case of GM foods illustrates. In the analysis in Chapter 5, it was a useful heuristic to stratify the public and to identify and highlight the different effects of regulation on groups of the public. In very general terms the most evident trend arising from the BSA survey data in relation to GM foods was the very dramatic rise in the numbers of respondents who said that they neither agreed nor disagreed with the statements on GM foods. It was purported in Chapter 5 that this related finding was a response to the lack of scientific unanimity surrounding the issue of risks posed by GM foods and it is argued that the labelling regime has helped to engender uncertainty.

The second principal finding relating to the BSA survey data was the smaller increase in size over time of those who were pro-GM foods. With reference to the entrenchment model a narrative is outlined in Chapter 5 which relates to those people who are opposed to GM foods and whose opposition has become more entrenched as a result of the regulation. The entrenchment model is supported by the BSA survey and Eurobarometer data showing that the more knowledge someone has on GM foods the more likely they are to be anti-GM. The opponents to GM have reduced by a small amount according to the BSA survey data, although the Eurobarometer data shows that the opposition levels remain high. Pertinently, groups opposed to GM are the most vociferous in campaigning and undoubtedly have the loudest voice, giving them a strong influence. It has been shown that the regulation has been highly responsive to this group. The argument that familiarisation with a product leads to increased support or reduced opposition ties in with the deficit model. However, according to the survey data, the opposite effect has been shown to have occurred.

Turning to the second case study, the role of the IRA in helping maintain public trust is critical, and the Government’s proposal to abolish the HFEA and transfer its duties together with those of the HTA to the Care Quality Commission (CQC) has met some strong opposition, not least in the press. The *New Statesman* maintained that: ‘Without a distinct, visible body to oversee reproductive ethics, scientists in the field stand to lose public trust’.⁴⁶⁰

⁴⁶⁰ The *New Statesman* quoted by Baroness Deech 2011, *ibid*.

This comment adds weight to the argument that regulatory institutions act in an overarching capacity, providing the authority to engender trust in the activities they oversee and to those, such as the scientists, who undertake the activities. The following further comment by *The Guardian* in relation to the proposed abolition of the HFEA provides an interesting slant on both public opinion and how the HFEA behave. It states:

‘The abolition of the HFEA will leave a major policy vacuum in biotech ethics. Without intervention it’ll be filled by the *Daily Mail*’.⁴⁶¹

While it is very clear that public concern over prenatal tests and the use of PGD are not on a par with the concerns surrounding GM foods, there is a level of controversy and ethical debate about the use of PGD particularly. The challenge arises in the separation of the role of regulation as a force for placating public concerns from the more gradual erosion of concern over the technologies which has occurred in response to increased familiarisation with them. The role of familiarisation contrasts strongly in this context with the way it has played out in GM foods.

Interconnected with the influence of familiarisation on public understanding and public opinion in relation to novel technologies are the nature and the pitch of the regulation. The regulatory ethos of GM food regulation is centred on the debate over the contested harm whereas prenatal testing and PGD regulation is focussed on harnessing the contested benefits. Despite the different focuses of the regulation, the oversight mechanisms are designed to achieve the same outcomes: to facilitate the products or techniques in conjunction with protecting the public from harm. The capacity of strict regulation to result in high levels of public trust is discussed earlier in the thesis with reference to the work of Lofstedt. The impact of strict and prohibitive regulation was very clearly played out when the moratorium was placed upon GM foods. The public opinion data shows that the public were placated by the moratorium on GM foods. The moratorium engendered a level of trust in the IRAs and regulation per se as a means of protection from the risks posed by GM foods, perceived or otherwise. The moratorium on GM is viewed here as a shrewd development by regulators in that it gave them time

⁴⁶¹ The Guardian quoted from a speech by Baroness Deech in the Public Bodies Bill (HL) Amendment 7 on HFEA and HTA, 5th September 2011 at http://www.appg-popdevrh.org.uk/Parli_News/lords/2011%20lords/Deech%20Debate%20Public%20Bodies%20Bill-hfea%20and%20hta%2009-05-11.htm (Last accessed 26th October 2011).

to gain public trust while additionally allowing a rethink on the appropriate means to reintroduce GM foods in the future and as such respond to the commercial sector pushing for this to happen. Following the moratorium the regulators chose to reintroduce GM products in conjunction with labelling regulation, thus responding both to the concerns of the public and to the producers and suppliers of GM products.

A common thread linking the case-studies is uncertainty surrounding these novel techniques and products. There exists conflict over the potential benefits and risks posed by GM foods and prenatal testing and PGD. This uncertainty and lack of consensus is central to the regulatory style. It can be argued that while both case-studies are subject to special regulatory handling, the regulation of GM foods has been treated in a very different way to the handling of other novel foods and this has simply been because of the technology used to produce the products. In the case of PGD, the special regulatory treatment pertains to the disproportionate amount of regulatory activity and resources that have been devoted to it relative to the number of people who benefit from it. This last point is not normative in that while it is disproportionate it can be seen to be justified. As regards prenatal testing, the regulatory field is very different in that there are no specific regulations but a system of generic procedural safeguards and licensing regulations.

7.3 The Representativeness of the Public Opinion Data used in the Regulatory Process

While varied sources of public opinion data have been analysed throughout the thesis, there has been a greater role devoted to survey data as it has been used as a comparator against which the public opinion data collected by the IRAs can be analysed. As with all sources of data, survey data is limited in what it can represent and the limitations of this data have been outlined in earlier chapters. While survey data will evidently never be representative of public opinion, it is argued here that the majority of the limitations of survey data arise from the failure to adequately establish the purpose behind the collection of the data at the outset of the research process. As a consequence, survey data is often inchoate and inconsistent; the questions change their wording over time reducing the opportunity for longitudinal study and evaluation of whether public opinion is changing as a result of regulation. Further limitations arise as a consequence of the ad hoc funding provision which may be subject to the political salience of a topic.

With reference to the various sources of public opinion data, I return to the claim made by Sturgis et al in relation to the genomics questions in the BSA survey that:

‘While we make no claims to having fostered a public dialogue by administering the questions in this survey, we believe that our findings are a good deal more robust and representative of public preferences on these issues than can ever be produced by such exercises in public ‘consultation’’.⁴⁶²

In accordance with the findings of the thesis, it has been shown that the participants in the public consultations are stakeholders with a vested interest in the object under discussion. Survey data and especially the BSA survey which has a sample that is representative and large is undoubtedly more representative of the general public than the consultations. This raises the question again as to why IRAs prefer to conduct public consultations rather than carry out surveys or look at data collected, for example, by Eurobarometer or the BSA survey.

There was agreement amongst the regulators interviewed that they do not have the time to keep up with the latest public opinion data and they rely on the external relations teams of their respective IRAs to both keep abreast of this data and to summarise data findings. Importantly the data often is not in a form which is readily digestible by the regulatory process. One of the most important elements gleaned from the interview data was the ‘representative paradox’. When asked whether the public opinion data was representative, they would say it was not, and that it had limitations. However, when asked about the value of their own institution’s public opinion data collection exercises, these were not only deemed of extreme importance, they were held as being indicative of the public mood.

In the interviews, I introduced the findings of the BSA survey to initiate a response from the interviewees. The data introduced pertained to each of the case-studies as related to the regulator being interviewed. Two of the interviewees were highly critical of the BSA survey data findings, before asking the source. The pertinent point is that later in the interviews the interviewees introduced data that they felt happy with and presented it as being representative.

⁴⁶² Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, ‘Genomic Science: Emerging Public Opinion’, From Park, A., Curtice, J., Thomson, K., Bromley, C. and Phillips, M. (Eds) (2004), *British Social Attitudes – the 21st Report*, London: Sage at p. 121.

7.4 The use of public opinion as a means to boost IRA credibility and increase regulatory share

Regulatory lacunae are a common feature in the regulation of areas of fast developing science and technology. An interesting focus is to ask how the IRAs and the regulators have capitalised on these gaps in the regulation of genomics. This activity is in addition to the other feature demonstrated by the IRAs, debated throughout this thesis, which is the role given to the public opinion input in the regulatory decision making process. As a procedural input, public opinion has been given an enhanced role in this field, but it is the quantifiable level of the input which has been put to the test in the course of this thesis. In terms of the ways it has been used as an input, differentiation is required between the rhetorical discussion of the need to respond to public opinion and the substantive role that it has played. There is additionally the question of responsiveness of the regulator to public opinion. It has been argued in this thesis that firstly, reference to public opinion increases credibility and gives legitimacy to decision-making and, secondly, it can be viewed as a means to remove the IRA from full responsibility for the decisions made, which is useful in areas of controversial science and technology.

Public opinion has an enhanced role in the domain of genomics as a result of a number of factors which were outlined in earlier chapters. However in addition to the arguments made for the inclusion of public opinion in the regulatory process, there has been a noticeable carving out of the regulatory space by IRAs in the field of genomics. While competing for regulatory space is not a novel activity, what makes it noteworthy is that the ethical controversies surrounding genomics have facilitated these expansionist tendencies.

Rothstein argues that:

‘[c]ontemporary preoccupations with risk are driven less by a changing distribution of real, or imagined, ills in society, than by a changing distribution of ills in governance’.⁴⁶³

Rothstein talks in terms of regulators having to justify their aims as a result of the increased systems of scrutiny and transparency that they are subject to. Rothstein argues that a response to this has been for regulators to reframe regulatory objects in

⁴⁶³ Rothstein, Henry, ‘The Institutional Origins of Risk: A New Agenda for Risk Research’, *Health Risk and Society*, September 2006; 8(3): pp. 215-221, at page 215.

terms of risk.⁴⁶⁴ As has been discussed, the risks posed by GM foods are contested, and while the regulation is nominally risk based, these risks are not measurable, which creates problems for the regulators. However, regulators are compelled to justify their aims and the enhanced role and reference given to public opinion as a rhetorical aid for regulators has been one recourse in the case of genomics. The concept of risk colonisation which is developed by Rothstein also serves to broaden this discussion about the use of public opinion in regulation, in that it may help account for why rare procedures such as PGD receive disproportionate amounts of regulatory attention and political salience.

The HFEA has been very actively seeking to carve out a regulatory space which denotes a level of authority and this is seen in the number of consultations being commissioned by the HFEA on different applications of PGD, whereas prenatal genetic testing, which falls outside of the HFEA's remit has not received the same attention. The regulators of GM foods interviewed from EFSA and the FSA were largely opposed to any further role being given to public opinion and felt that the authorisation process was adequate. The official from Defra showed a greater understanding that whatever the regulators may believe, the role of public opinion cannot be ignored as the events of the late 1990s demonstrated. While it appears contradictory, I believe that the IRAs of GM foods routinely use public opinion to further the credibility of their regulatory stance.

7.5 The privileged role given to public opinion in the regulation of genomics

Figure 3 from Chapter 4 supports the argument of this thesis that the public opinion input in the regulation of genomics has been given a privileged or enhanced role.

Figure 3 outlined the normative arguments given in the field of genomics for a greater reference to public opinion and also listed the substantive responses identified in this thesis to these normative arguments. Rhetorically, public opinion has been given a privileged role in regulatory decision-making in genomics, relative to other spheres of regulation, yet in practice the research shows that public opinion data may not be representative of the public opinion and that the collection of public opinion data is not a prerequisite for responsive regulation. A distinction was made in the thesis between

⁴⁶⁴ Rothstein, Henry, 2006, *ibid.* at p.217.

the rhetoric surrounding public opinion inclusion and the nature of the role played by public opinion in the evolution of the regulatory field.

One conclusion from this thesis is that there has been a significant enhancement of the role given to public opinion in the regulation of genomics. In analysing the reasons for this, it is important to differentiate between the rhetorical use of the term ‘public opinion’ and the cases where there is evidence that public opinion data has been a significant contributor to regulatory decision-making. It is salient to note that due to the discretion offered to the IRA in the interpretation and use of the public opinion input, it is exceedingly difficult to quantify the actual input of the public opinion data.

Additionally, there is no reference in committee notes and regulatory documentation to the cases where public opinion data had been reviewed and where it was deemed more appropriate by the regulators to follow a course which did not respond to it. Regulators will often choose to act in the public interest, which may be a very different stance to responding to public opinion and has overtones of paternalism.

The level of political salience and media attention devoted to an issue is often no indication of the relative harm or risk posed. IRAs are extremely sophisticated in the use and manipulation of the media to enhance their own regulatory status through, for instance, press releases and media and external relations. While this is true, regulators are not responsible for the return of GM food to the political agenda, and it is stressed here that it is not the wish of the author to malign the role of the regulator. The regulators interviewed came across as genuinely interested in the pursuance of regulation which meets the needs of society.

7.6 The regulators’ views of public opinion

To summarise the interviewees, it is necessary to stress that although the regulators spoken to all believed that public opinion data was a valuable input into the regulatory process, the degree to which they took it into account by regulators was questionable. While limitations with the data were discussed, it is evident that the IRAs and the individual regulators are undertaking a ‘best endeavours approach’ and are keen to have up-to-date, robust data. The exception to this was a Member of the HFEA who was of the opinion that public consultation is something you can have too much of, and she

held that ‘there are areas where I don’t think the public has a very strong view’.⁴⁶⁵ In the course of the interviews the regulators gave the impression that they felt that they generally know what the public mood is. This was not made explicit and they would clearly disagree if asked this directly, but when asked whether they had ever been surprised by the results of a consultation, only one interviewee answered that she had been and that related to only one specific case.

One interesting finding from the interviews was the way that the regulators moved from one understanding of public opinion to another, crossing and interchanging throughout the interview. This fluidity and interchangeability of understandings of public opinion is however problematic in that when the regulators argue that they are responding to the public, it is not clear whether they mean the stakeholders, the most influential interest group, or the clinicians or scientists. As already stated in earlier chapters, there was strong agreement across the regulators interviewed that there has been a significant increase in consultation and recourse to public opinion. Implicit in this is the idea that the regulators are more responsive than previously, yet the findings of this thesis do not show this to be so straightforward.

In Chapter 4, the idea was posited of regulatory decision-making being carried out in response to different sources of evidence which needed to be deliberated over. An official from the FSA interviewed in the course of this research contended that the public opinion was viewed in this light as another piece of evidence to be taken into consideration; although she did not allude to its ranking against the other pieces of evidence involved in the process. Regulatory decision-making is not however, a case of deliberating between different sources of empirical data; as Majone highlights, values and opinions count for a great deal. Majone identifies the problems entailed in unregulated discussion which he argues would result in ‘unending dispute’.⁴⁶⁶ It is for this reason that one cannot criticise too harshly the efforts of the regulatory institutions as it is necessary for them to delimit the deliberation.

⁴⁶⁵ Member of the HFEA, Interviewee 1.

⁴⁶⁶ Majone, Giandomenico, (1998) ‘Evidence, Argument and Persuasion in the Policy Process’, Yale University

7.7 Special regulatory handling and the idiosyncrasies of the regulation of genomics

The case-studies have highlighted some interesting commonalities across the regulation of genomics which would suggest that the regulations can be grouped in relation to the process from which the products and techniques originate. This is in contrast to the perspective of regulation by product which is more prevalent in the USA. In relation to GM foods, the product is regulated within the same IRA that oversees the regulation of novel foods, the special regulatory handling arises from the huge umbrella of regulation it sits under. The contrast between the regulatory handling of prenatal testing and PGD was very revealing in that PGD has received a great deal of attention from the media, the regulators and the politicians alike. Prenatal testing however has been regulated in the same fashion as other medical techniques with little regard for any emergent ethical issues.

7.8 Evaluation of the Methodological Approach

The methodology adopted in this thesis needed to facilitate the research in two ways. Firstly, it needed to respond to the challenging ambition of the research, namely, to analyse the interaction and impact upon each other of regulation and public opinion. While regulation and the accompanying documents relating to consultations can be easily accessed for analysis, the identification of correlations is less easy. The second challenge was that of assessing the various sources and forms of public opinion data taken to be an input into the regulatory process, and further to use them against each other to see whether they resulted in similar findings. Evidently a mixed methods approach was an appropriate choice in responding to these challenges as it meant that the quantitative data in the form of survey data could be analysed in addition to the consultation and regulatory documents. The interview data added a very important layer of richness to the study and while it is by no means representative of regulators, the fact that very senior officials were interviewed lends the data a level of import as these are the regulators ‘calling the shots’.

(i) Situating in a Socio-legal Studies Context

The interdisciplinary nature of the study combined with the situating of the research within the socio-legal literature has benefited the study in offering novel perspectives on the findings. The focus of the study was very challenging for the reason that correlation can often incorrectly be conflated with causation. The findings here are therefore nuanced and subtle while equally opening up a field of rich research. Adopting a socio-legal stance has aided the research by allowing the exploration of the gap between the black letter of the regulation and the role denoted to public opinion in the regulatory and policy documentation as well as an analysis of the reality of the interactions between these two variables.

The choice of genomics as a case-study has been very appropriate for this study as it is an area where public opinion is deemed central to the regulatory approach. Genomics additionally encompasses a variety of products, processes and techniques enabling a wider study to ensue. The very novelty surrounding the regulatory treatment of the products derived from genomics has been illuminating in terms of the roles of the principal IRAs and the impact of the regulation on public mood. The choice to conduct a comparative study using the two case-studies of GM foods and Prenatal testing and PGD as representatives of green and red biotechnology has led to a more substantial thesis being produced than would have been possible had an analysis of the interplay between public opinion and regulation been limited to one case. The choice of a comparative case-study approach has meant that common features which link the cases are highlighted, giving a greater support to the argument that the regulation of genomics can be considered a discrete area than is suggested by the wide range of products encompassed under the term.

(ii) The Survey Data

An evaluation of the methodological approach used in this thesis must acknowledge the limitations of the data that arise from the nature of the survey data, as discussed earlier in the thesis. If one could conduct a meta-review of survey data in a bounded time-frame in relation to each of the case-studies then evidently a far superior study would ensue.

(iii) The Elite Interviews

One problem which arose in relation to the qualitative research was that of finding regulators who were willing to be interviewed and agreed to a time which they stuck to. These issues arose as a consequence of my status as a PhD student and due to the fact that the regulators, as with the majority of prospective elite interviewees, are busy people.⁴⁶⁷ As an interesting aside, one regulator I approached who worked in the GM Team at Defra responded to my interview request by stating quite rudely that he had nothing to do with the public as the team were all scientists. I later interviewed a more senior member of the same Defra GM team who was extraordinarily helpful and who couldn't stress more how important public opinion was in making regulatory decisions!

7.9 Are there lessons that can be learned from the regulation of genomics that will help Regulators in other novel technologies?

Both the literature and the regulators interviewed often discuss the idea that the GM story will lead to lessons being learned by policy makers and regulators who will in the future respond with greater sensitivity to public anxiety. It is argued that things have changed, the levels of consultation are higher, and the sophistication of the consultation and surveys conducted have improved over the last couple of decades. The recommendations for regulators following this study are to continue with public consultations on the grounds that the stakeholders need to be consulted. However, robust survey data also is needed as it is a more representative indicator of the opinions of the general public. The combination of these different sources of data will give the regulators knowledge of a wider breadth of opinion. A further recommendation is that this data is used with a greater awareness of its limitations in representing the public opinion.

It would be inappropriate to apply the findings of this thesis as a whole to the field of the regulation of genomics, because while this field originates from a common ground which does imbue it with some similarities, the regulatory set-up is very product orientated. The connections which unite the techniques and products resulting from

⁴⁶⁷ Stephens, Neil discusses the problems surrounding interviewing elites in 'Collecting Data from Elites and Ultra Elites: Telephone and Face-to-Face Interviews with Macroeconomists', *Qualitative Research*, vol. 7(2), 2007 pp.203-216.

genomics are the enhanced role played by public opinion, public concerns and anxieties, and the regulatory lacunae resulting from the fast developing technology.

While transparency of processes is a prerequisite for a smoothly run democratic state, it is not wholly a case of increasing transparency in order for the gap to be highlighted between public opinion data as a procedural input and public opinion as it is used in regulatory debate. To achieve this, regulatory regimes need to become more deeply involved in the interpretation and discussion of the procedures. Central to an improvement in the workings of the interaction between public opinion and regulation, is a recognition of the limitations of public opinion data per se and a less reverent view of this data as justification for a particular regulatory stance.

Genomics has some very idiosyncratic features which lead to its special political handling. The most pertinent of these are the associated ethical dilemmas and the speed of technological development which often mean the regulators are responding to situations rather than forward planning. Regulatory lacunae arise as it is exceedingly difficult for regulators to anticipate products or techniques which will develop and need to be regulated. This is at the heart of the issue when it comes to public concern however, and one recommendation of this thesis is that regulators should formalise relationships with scientists and attempt to anticipate areas of regulation which will require attention in order to be effective in the light of novel product developments. In support of anticipatory governance, Guston argues that regulators should turn from precaution which ‘connotes acting to avoid predicted and uncertain hazards’ to anticipation which ‘denotes building the capacity to respond to unpredicted and unpredictable risks’.⁴⁶⁸ This may be a means to reassure the public through regulatory oversight. This concept of regulators developing forecasting skills is not unrealistic; science and industry develop products for decades in advance of them being put into the public domain. Equally it is not argued here that the only concern of the public is safety, since there are evident ethical concerns and through some higher level of regulatory foresight the debates surrounding new techniques could be discussed at an earlier stage meaning that whether to permit or to prohibit such an activity could be decided in advance.

⁴⁶⁸ Guston, David H. ‘Innovation Policy: Not Just a Jumbo Shrimp’, *Nature Commentary*, Vol. 454, August 2008 at p.940.

7.10 Further Research Openings

This research approach could be broadened to study the interactions between regulation and public opinion in other novel technologies such as nanotechnology or synthetic biology where the regulatory set up is still very formative and the public awareness of the products arising from these technologies is very low. This would give insights into how the regulators are using the ‘public opinion input’ in these areas of novel technology. One could also analyse the levels of public concern regarding these new products and techniques as well as the regulators handling of and response to such anxieties. Alternatively, the current focus could be deepened and analysed with additional and more recent sources of public opinion data as a meta review. Finally the research could be taken in new directions, for example it would be fascinating to analyse the role of the social scientist in the midst of the interplay between regulation and public opinion.

7.11 A Final Comment on Regulatory Resolution

The idea that regulation has the capacity to bring about public ease or to placate public unrest and anxiety has to some level been borne out in this thesis. While the case-studies analysed are each idiosyncratic, it is the case of GM foods which commentators persistently return to because there is a lack of policy resolution and a level of frustration about this amongst the regulators. This thesis has shown that regulation has helped to reduce levels of public concern but it has not resolved the issue in either the minds of the suppliers of GM products, the public or the regulators. In summary therefore the science has imbued the regulatory projection: there will not be regulatory resolution until the contested harm of GM foods is resolved and the contested benefits of prenatal testing and PGD are established. It may be that resolution is not achievable.

This thesis has shown that the public opinion model which has become common place in the regulation of genomics does not work. The idea that the public can be placated by the incorporation of public opinion into the regulatory process has limited success. One reason has been that the findings of some of the IRAs’ consultations have been based on stakeholder views. A further reason is the confusion caused by the conflation between public opinion and the public interest. As Feintuck argues public interest is an

‘empty vessel’ for the regulators to fill.⁴⁶⁹ The regulatory system does not provide an adequate framework for areas which are controversial or where harm and benefits are contested. This thesis helps to explain the limitations of the public opinion model and in doing so offers understandings of the regulatory system and the role played by public opinion in the regulation of genomics. It is for this reason that I suggest that the gauge which regulators refer to as ‘public opinion’ should for reasons of transparency be called ‘public opinion data’. Public opinion data is defined as the results of formal attempts to measure opinion. Such a move would reflect its value in the process but simultaneously indicate that such data has inherent limitations. This would increase transparency in the regulatory system.

⁴⁶⁹ Feintuck, Mike (2004), *op cit.* at p.108

Appendix 1

Information/Consent Form for Research Interviews

Title of Research Project

The Role of Public Opinion in the Regulation of Genomics in the UK

Details of Project

The research aims to establish whether there is any evidence of a two-way relationship between the regulation of and public attitudes to genomics. As such both the responsiveness of the regulation to public attitudes and whether the regulation plays a role in changing public attitudes to the technologies will be analysed. The case studies being researched are GM foods and prenatal testing including pre-implantation genetic diagnosis (PGD).

You have been asked to take part in this research as you work for one of the regulatory bodies which I am studying and I am interested in your thoughts about the role of public opinion and regulation in the field in which you work. It is anticipated that the interview will last approximately one hour.

Contact Details

For further information about the research or your interview data, please contact:

Kate Getliffe, University of Exeter, Egenis, Byrne House, St Germans Road, Exeter EX4 4PJ , Email: ksg203@exeter.ac.uk

If you have concerns/questions about the research you would like to discuss with someone independent of it, please contact:

Professor Oliver James, Politics Department, University of Exeter,

Email: O.James@exeter.ac.uk

Confidentiality

Interview data and transcripts will be held in confidence. They will not be used other than for the purposes described above and third parties will not be allowed access to them (except in the case of legal subpoena). However, if you request it, you will be supplied with a copy of *your* interview transcript so that you can comment on and edit it as you see fit (please give your email below).

Anonymity

Would you prefer your interview information to be held and used on an anonymous basis, with no mention of your name? (Note that I still need to refer to the Institution/Organisation you work for or represent).

PLEASE CIRCLE

YES / NO

IF YES

Pseudonym to be used :.....

Institution/ Organisation:.....

IF NO

Name of interviewee:.....

Signature:

Email/phone:.....

Institution/ Organisation:.....

Consent

I voluntarily agree to participate and to the use of my data for the purposes specified above. I can withdraw consent at any time by contacting the interviewer.

TICK HERE:

Interviewee signature.....

Date.....

Interviewer signature.....

Date.....

Appendix 2

Interview Schedule

Opening question

1. I wondered if you would be able to tell me a bit about your work. - What does being a member of [relevant IRA] entail?

Core Questions

2. My research examines the role of public opinion in the regulatory process and I wonder how responsive you feel regulators are to public opinion? What weight do you feel is given to the views of the public?
3. Public opinion is a pretty vague concept - how do you think it is generally defined by regulators and policy makers?
4. Expert opinion - What do you think is the role of expert opinion, e.g. from clinicians? Should it at times outweigh the views of the public?
5. This also relates to the role of the regulator and the question of the level of autonomy of the [principal IRA] to make decisions within its mandate and whether it should devolve clinical decision-making and technical standards down to patients and professionals /Scientists (in the case of GM foods)
6. What do you think about the idea of alignment of PGD with prenatal diagnosis? Do you think they should be regulated on the same basis and do you feel it is currently in line? [not a relevant question for GM foods]
7. Do you feel that the public have a greater understanding of [insert case-study] now than say ten years ago?
8. Why do you say this? What grounds are there for this?
9. Is it important that the individuals consulted as representatives of the public can produce an informed opinion? I note for example in the [example of one of a specific consultation and the levels of knowledge displayed] - Is the opinion of an informed public more significant?
10. In general terms, do you think that the findings of consultation exercises representative of public opinion?
11. (if no,) Why then, do you think the results retain their significance in the regulatory process?

12. Do you think that regulation has the capacity to shape public opinion? (if yes, how does it do this?)
13. Can you tell me about the [relevant IRA] consultation processes? – Do you feel these consultation processes are an effective measurement of public opinion? –is the data produced representative of public opinion?
14. Do you feel that survey data is useful?
15. Have you been involved personally in any consultation exercises? Could you tell me about the experience?
16. What role do the media play in influencing your view of the public opinion on an issue? Are you influenced by newspaper reports on public opinion?
17. When you are out socially, e.g. At non-work parties etc., and you chat about your work – do peoples’ responses have any bearing on your understandings or ideas of what the public think?
18. Beyond accountability and issues of democracy, do you feel that recognition of the public opinion and responsiveness to it improves regulatory output?
19. Do you feel that public opinion is given a greater weighting in the determination of policy in the application of genetic technologies relative to other technologies?

Wrapping up

20. I was just wondering whether there is anyone who you could recommend who would be useful for me to interview, maybe someone who deals with public consultations?
21. Is there anything that you would like to add? Is there any question that you think I should have asked but didn’t?

Bibliography

- Advisory Committee on Genetic Testing, 'Prenatal Genetic Testing: Report for Consultation', London: Human Genetics Commission, 2000.
- Aubert, Vilhelm, (Ed) 'Sociology of Law; Selected Readings' (1969, Penguin Books Ltd)
- Augoustinos, Martha, Crabb, Shona, and LeCouteur, Amanda, 'Representations of genomics in the UK; media, interest groups and government texts', July 2005 (unpublished).
- Ayres, Ian and Braithwaite, John, (1992) 'Responsive Regulation: Transcending the Deregulation Debate', Oxford University Press
- Baldwin, Robert & Cave, Martin, 'Understanding Regulation: Theory, Strategy and Practice' (Oxford University Press, 1999)
- Baldwin, Robert, 'Rules and Government', (Oxford University Press, 1995)
- Baldwin, Robert, Scott, Colin & Hood, Christopher, 'A Reader on Regulation', (Oxford University Press, 1998)
- Barling, David, 'Regulating GM Foods in the 1980s and 1990s', in Smith, David F. and Phillips, Jim (Eds), 'Food, Science, Policy and Regulation in the Twentieth Century: International and Comparative Perspectives', (London: Routledge, 2000)
- Barnes, Barry, (1995) 'The Elements of Social Theory', UCL Press
- Bate, Roger, 'The European Union's Confused Position on GM Food', Economic Affairs, Vol.23, No.1, (March, 2003)
- Bateson, P.P.G. in Science and Technology Select Committee publication of March 2000 cited in The Independent, 25 March 2000.
- Baumgartner, F., C. Green-Pedersen, et al. (2006). "Comparative studies of policy agendas." *Journal of European Public Policy* 13(7): 959-974.
- Baumgartner, Frank R. & Jones, Bryan D. 'Agendas and Instability in American Politics', (University of Chicago Press 1993)
- Beck, Ulrich. 'Risk Society: Towards a New Modernity' (London: Sage 1992 trans. M. Ritter).
- Beck, Ulrich 'Ecological Politics in an Age of Risk' (London: Polity Press 1992, trans. A.Weisz).
- Benjamin, R. B. (2005). "Public culture and public understanding of genetics: a focus group study." *Public Understanding of Science* 14(1): 47-65.
- Bennett, S. E. (2005). "Silent voices: Public opinion and political participation in America." *Public Opinion Quarterly* 69(3): 463-467.

Bennett, W. L. (2002). "Constructing public opinion: How political elites do what they like and why we seem to go along with it." *Public Opinion Quarterly* 66(2): 312-314.

Berinsky, A. J. (2006). "American Public Opinion in the 1930s and 1940s - The analysis of quota-controlled sample survey data." *Public Opinion Quarterly* 70(4): 499-529.

Bernstein M.H. 'Regulating Business by Independent Commission', (Princeton University Press, 1955) cited in James, Oliver 'Regulation inside Government: Public Interest Justifications and Regulatory Failures', *Public Administration*, Vol.78, No.2, (2000) pp.327-342.

Bertrand, Marianne & Mullainathan, Sendhil, 'Do People Mean What They Say? Implications for Subjective Survey Data.' Mimeo, University of Chicago, 2000.

Best, S. J. (1999). "The sampling problem in measuring policy mood: An alternative solution." *Journal of Politics* 61(3): 721-740.

Bell, Rachel (Editor) (2007) 'Comparative European Approaches to Pre-implantation Genetic Diagnosis: Symposium Report', BioCentre

Bier, V.M. 'On the State of the Art: Risk Communication to the Public', *Reliability Engineering and System Safety*, 71, 2001 pp.139-150.

Birch, A. H., 'Representative and Responsible Government: An Essay on the British Constitution', (Unwin Brothers Limited 1964)

Bishop, G. (1999). "Public opinion." *Public Opinion Quarterly* 63(4): 628-630.

Black, Julia (2002) 'Critical Reflections on Regulation', LSE Paper, CARR.

Black, Julia 'Regulation as Facilitation: Negotiating the Genetic Revolution', *Modern Law Review*, 1998 61(5), 621-60

Black, Julia, (2009) 'Legitimacy and the Competition for Regulatory Share', LSE Working Paper 14/2009

Blair, A. 'Science Matters', Speech to the Royal Society, 10 April 2002 cited in Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris, Shepherd, Richard, 'Genomic Science: Emerging Public Opinion', from Park, A., Curtice, J., Thompson, K., Bromley, C. and Phillips, M. (Eds) (2004) *British Social Attitudes - the 21st Report*. (London: Sage)

Blumer, Herbert, 'Public Opinion and Public Opinion Polling', *American Sociological Review*, Vol. 13, No. 5, (Oct. 1948), pp.542-549.

Bodiguel, Luc and Cardwell, Michael, (2010), 'The Regulation of Genetically Modified Organisms: Comparative Approaches' Oxford University Press

Bohman, J. & Rehg, W. (Eds) 'Deliberative Democracy: Essays on Reason and Politics (MIT: Cambridge, MA. 1997)

- Bourdieu, Pierre, 'Public Opinion Does Not Exist', in Armand Matterlart and Seth Siegerlaub, eds, 'Communication and Class Struggle' (New York: International General, 1979) pp.124-130
- Bourdieu, Pierre, 'Understanding', in Bourdieu et al 'The Weight of the World: Social Suffering in Contemporary Society' Stanford University Press, 1999.
- Braithwaite, John, 'Rewards and Regulation', *Journal of Law and Society*, Vol.29, No.1, March 2002, pp.12-26
- Brannen, Julia, 'Mixed Methods Research: A Discussion Paper', ESRC National Centre for Research Methods, NCRM/005
- Brewer, M. D. (2005). "Tides of consent: How public opinion shapes American politics." *Public Opinion Quarterly* 69(4): 632-634.
- Brommage, D I, 'Prenatal Diagnosis and Selective Abortion: A Result of the Cultural Turn', *Medical Humanities*, 2006, vol.32, pp.38-42
- Brown, M. B. (2007). "Can technologies represent their publics?" *Technology in Society* 29(3): 327-338.
- Brownsword, Roger, 'Code, Control and Choice: Why East is East and West is West', *Legal Studies*, Vol.25, No.1, March 2005
- Brownsword, Roger, Cornish, William R. and Llewelyn, Margaret, 'Law and Human Genetics: Regulating a Revolution'. (Hart 1998)
- Bucchi, Massimiano, 'Can genetics help us rethink communication? Public communication of science as a double helix', *New Genetics and Society*, Vol.23, No.3, December 2004, pp.269-270.
- Burstein, P. (2003). "The impact of public opinion on public policy: A review and an agenda." *Political Research Quarterly* 56(1): 29-40.
- Calvert, Jane, 'Goodbye Blue Skies? The Concept of 'Basic Research' and its Role in a Changing Funding Environment' DPhil, 2002 (Unpublished).
- Capano, Giliberto & Howlett, Michael, 'The Determinants of Policy Change: Advancing the Debate', ECPR Workshop, Helsinki 2007.
- Carson, Lisa and Lee, Robert, 'Consumer Sovereignty and the Regulatory History of the European Market for Genetically Modified Foods' *Environmental Law Review*, Vol.7(3) (2005), pp.173-194.
- Claassen, R. L. and B. Highton (2006). "Does policy debate reduce information effects in public opinion? Analyzing the evolution of public opinion on health care." *Journal of Politics* 68(2): 410-420.

- Cobb, Roger W. & Ross, Marc Howard (1997), 'Cultural Strategies of Agenda Denial' University of Kansas Press
- Coglianese, Cary, 'Empirical Analysis and Administrative Law', University of Illinois Law Review, (2002) Vol.4, pp.1111-1137
- Condit, Celeste, 'What is 'public opinion' about genetics? Nature Reviews, Genetics, vol.2, Oct. 2001, pp.811-815
- Cook, F. L., J. Barabas, et al. (2002). "Invoking public opinion - Policy elites and social security." *Public Opinion Quarterly* 66(2): 235-264.
- Cook, Guy, Robbins, Peter T. & Pieri, Elisa, 'Words of Mass Destruction: British Newspaper Coverage of the Genetically Modified Food Debate, Expert and Non-Expert Reactions', *Public Understanding of Science*, Vol. 15, No. 1, 5-29 (2006)
- Corral-Verdugo, Victor, 'Dual Realities of Conservation Behaviour: Self-Reports versus Observations of Re-use and Recycling Behaviour', *Journal of Environmental Psychology*, Volume 17 (Issue 2), June 1997, pp.135-145.
- Cotterrell, Roger, 'Subverting Orthodoxy, Making Law Central: A View of Sociolegal Studies', *Journal of Law and Society*, Volume 29, No.4, December 2002, pp.632-644.
- Cresswell, J.W., Plano Clark, V.L., Guttman, M., Hanson, W. 'Advanced Mixed Methods Research Design' in Tashakkori, A. and Teddlie, C. (Eds), 'Handbook on Mixed Methods in the Behaviour and Social Sciences', Thousand Oaks, Calif: Sage Publications, 2003, pp. 209-240
- Cutler, F. (1999). "Jeremy Bentham and the public opinion tribunal." *Public Opinion Quarterly* 63(3): 321-346.
- Dahl, Robert A. 'Democracy and its Critics', (Yale University Press, 1989)
- Dahl, Robert A., 'A Democratic Dilemma: System Effectiveness versus Citizen Participation', *Political Science Quarterly*, Vol. 109, No.1, (Spring 1994), pp.23-34.
- Dexter, L.A., 'Elite and Specialised Interviewing' 2006, Essex ECPR Press.
- Dicey, A.V. 'Legislation, Law and Public Opinion in England' (1905) in Aubert, Wilhelm, (Ed) 'Sociology of Law; Selected Readings', (1969, Penguin Books Ltd)
- Doern, G. Bruce & Wilks, Stephen, 'Changing Regulatory Institutions in Britain and North America', (University of Toronto Press, 1998).
- Doern, G. Bruce (Ed) (2007), 'Innovation, Science, Environment: Canadian Policies and Performance, 2007-2008', McGill University Press
- Doern, G. Bruce and Johnson, Robert, (Eds) (2006) 'Rules, Riles, Rules, Rules: Multilevel Regulatory Governance', University of Toronto Press

- Durrant, Robert F. & Legge, Jerome S. 'Public Opinions, Risk Perceptions and Genetically Modified Food Regulatory Policy: Reassessing the calculus of Dissent among European Citizens', *European Union Politics*, Vol, 6(2), 2005, pp.181-200.
- Edna, E. (2007). "Editorial: Of publics and science." *Public Understanding of Science* 16(1): 5-6.
- Eisinger, R. M. (2005). "The illusion of public opinion: Fact and art fact in American public opinion polls." *Journal of Politics* 67(3): 955-957.
- European Commission: Framework 6, Project number 518435, 'Do European Consumers buy GM Foods?' (Consumer choice) Kings College London, 2008.
- European Society of Human Reproduction and Embryology (ESHRE) 'Best Practice Guidelines for Clinical Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS), published on the ESHRE in Human Reproduction on 11 November 2004.
- Feintuck, Mike, 'The 'Public Interest' in Regulation', (Oxford University Press, 2004)
- Fessler, James W. & Kettl, Donald F. 'The Politics of the Administrative Process' (2nd Edition) Chatham House Publishers, Inc. 1996.
- Fishkin, James S. 'Democracy and Deliberation: New Directions for Democratic Reform', (Yale University Press, 1991).
- Foucault M. (1991) 'Governmentality' in Faubion, James D. (Ed), 'Power: The Essential Works 3'
- Frewer, L., Miles, S., and Marsh, R. 'The GM Foods Controversy. A Test of the social Amplification of risk Model', *Risk Analysis*, 22: pp. 713-723, 2002.
- Friant-Perrot, Marine, 'The European Union Regulatory Regime for Genetically Modified Organisms and its Integration into Community Food Law and Policy', Chapter 4 in Bodiguel, Luc and Cardwell, Micheal, 'The Regulation of Genetically Modified Organisms: Comparative Approaches', Oxford University Press, 2010.
- Fukuyama, Frances, 'Our Posthuman Future: Consequences of the Biotechnology Revolution', (Profile Books Ltd. 2002).
- Gaskell, George, Allum, Nick & Stares, Sally, 'Europeans and Biotechnology in 2002' (2nd Edition; 21/03/03) A report to the EC Directorate General for Research from the project 'Life Sciences in European Society' QLG7-CT-1999-00286.
- Gaskell, George, Allum, Nick and Stares, Sally, 'Europeans and Biotechnology in 2002' Eurobarometer 58.0, A Report to the EC Directorate General for Research from the project 'Life Sciences in European Society', QLG7-CT-1999-00286 (2nd Edition: March 21st 2003); Gaskell, George, Stares, Sally, Allansdottir, Agnes, Allum, Nick, Corchero, Cristina, Fishler, Claude, Hampel, Jurgen, Jackson, Jonathan, Kronberger, Nicole, Mejlgaard, Niels, Revielta, Gemma, Shreiner, Camilla, Torgersen, Helge and Wagner, Wolfgang, 'Europeans and Biotechnology in 2005: Patterns and Trends; Final

Report on Eurobarometer 64.3' A Report to the European Commission's Directorate-General for Research. (July 2006)

Gaskell, George, Allum, Nick, Bauer, Martin, Jackson, Jonathan, Howard, Susan, Lindsey, Nicola 'Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002', Life Sciences in European Society Report: London School of Economics and Political Science, 2003 at p.2; Gaskell, George, Allum, Nick & Stares, Sally, 'Europeans and Biotechnology in 2002' (2nd Edition; 21/03/03) A report to the EC Directorate General for Research from the project 'Life Sciences in European Society' QLG7-CT-1999-00286; Sturgis, Patrick, Cooper, Helen & Fife-Shaw, Chris, 'Attitudes to Biotechnology: estimating the opinions of a better informed public', New Genetics & Society, Vol.24, No.1, April 2005.

Gaskell, George, Allum, Nick, Bauer, Martin, Jackson, Jonathan, Howard, Susan, Lindsey, Nicola 'Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002', Life Sciences in European Society Report: London School of Economics and Political Science, 2003.

Gaskell, George, Stares, Sally, Allansdottir, Agnes, Allum, Nick, Castro, Paula, Esmer, Yilmaz, Fischler, Claude, Jackson, Jonathan, Kronberger, Nicole, Hampel, Jurgen, Mejlgaard, Niels, Quitanilha, Alex, Rammer, Andu, Reveulta, Gemma, Stoneman, Paul, Torgersen, Helge, Wagner, Wolfgang, 'Europeans and Biotechnology 2010: Winds of Change', European Commission, DGR 2010

Gene, R., H.-J. Tom, et al. (2005). "Difficulties in evaluating public engagement initiatives: reflections on an evaluation of the UK GM Nation? public debate about transgenic crops." *Public Understanding of Science* 14(4): 331-352.

George, G., E. Toby Ten, et al. (2005). "Imagining nanotechnology: cultural support for technological innovation in Europe and the United States." *Public Understanding of Science* 14(1): 81-90.

Giffard, David, 'Commissioning Policy for Pre-implantation Genetic Diagnosis (PGD)', NHS, East Midlands Specialised Commissioning Group, Report issued on 1/4/2011, <http://emscg.nhs.uk/Library/RevisedEMSCGPolicyforPGDv2.pdf> (last accessed on 26/8/11).

Giliberto, C. (2003). "Administrative Traditions and Policy Change: When Policy Paradigms Matter. The Case of Italian Administrative Reform During the 1990s." *Public Administration* 81(4): 781-801.

Glynn, Carroll J., Herbst, Susan, O'Keefe, Garrett J. & Shapiro, Robert Y. 'Public Opinion' Westview Press, 1999.

Glynn, Carroll J., Herbst, Susan, O'Keefe, Garrett J., Shapiro, Robert Y. 'Public Opinion' (2nd Edition, Westview Press, 2004).

Graham, Wendy, Smith, Pat, Kamal, A., Fitzmaurice, A., Smith, NM., Hamilton, N., and Wyatt, Jeremy (2000) 'Randomised Controlled Trial Comparing Effectiveness of Touch Screen Systems with Leaflet for Providing Women with Information on Prenatal Tests', *British Medical Journal*, vol. 320, pp.155-60.

- Gray, V., D. Lowery, et al. (2004). "Public opinion, public policy, and organized interests in the American states." *Political Research Quarterly* 57(3): 411-420.
- Greif, Karen Faye and Merz, Jon Frederik, 'Current Controversies in the Biological Sciences: Case Studies of Policy Challenges from New Technologies (2007, MIT)
- Gunningham, and Grabosky, (1998) 'Smart Regulation' Clarendon Press, Oxford
- Guston, David H. 'Innovation Policy: Not Just a Jumbo Shrimp', *Nature* vol. 454(21) August 2008, pp.940-941.
- Guy, C., T. R. Peter, et al. (2006). "'Words of mass destruction": British newspaper coverage of the genetically modified food debate, expert and non-expert reactions." *Public Understanding of Science* 15(1): 5-29.
- Habermas, Jurgen 'The Future of Human Nature' (Polity Press, 2003)
- Hagendijk, Rob and Irwin, Alan, 'Public Deliberation and Governance: Engaging with Science and Technology in Contemporary Europe', *Minerva* (2006), 44, pp.167-184
- Hansen, Kirsten, 'Does Autonomy Count In Favour Of Labelling Genetically Modified Food?' *Journal of Agricultural and Environmental Ethics*, 17, (2004), pp.76-76.
- Harker, Rachael, 'Statistics on Abortion', House of Commons Library, 2009
- Harper, Joyce et al, 'What Next for Preimplantation Genetic Screening?' *Human Reproduction*, 2008, Vol.23, No.3, pp.478-480 at p.478. This document is classed by The European Society of Human Reproduction and Embryology (ESHRE) as an ESHRE PGD Consortium publication.
- Harper, Joyce, 'Inside the PGD Consortium: Focus on Reproduction', A Review of the ESHRE PGD Consortium, January 2007 at http://www.eshre.com/binarydata.aspx?type=doc/Focus_article_jan07.pdf (last accessed 22 July 2009)
- Hawkins, Keith, 'Troubles Galore and GM Food too!', *The Grocer*, 25th January 2008.
- Helm, Dieter, 'Regulatory Reform, Capture and the Regulatory Burden', *Oxford Review of Economic Policy*, 2006, Vol. 22, No.2.
- Henry, G. T. and C. S. Gordon (2001). "Tracking issue attention - Specifying the dynamics of the public agenda." *Public Opinion Quarterly* 65(2): 157-177.
- Hill, Alison & Michael, Mike, 'Engineering Acceptance: Representations of 'The Public' in Debates on Biotechnology', Chpt. 12 in Wheale, von Schomberd & Glasner (Editors), 'The Social Management of Genetic Engineering'(Ashgate Publishing Ltd. 1998)
- HM Government, Code of Practice on Consultation, 2008, www.berr.gov.uk/br
- Hood, Christopher, 'The Blame Game: Spin, Bureaucracy and Self-preservation in Government', (2011) Princeton University Press.

- Hood, Christopher, Rothstein, Henry & Baldwin, Robert, 'The Government of Risk: Understanding Risk Regulation Regimes' (Oxford university Press, 2001)
- Hood, Christopher, Rothstein, Henry, Baldwin, Robert, 'The Government of Risk: Understanding Risk Regulation Regimes', (Oxford University Press, 2004)
- Horkheimer, Eclipse of Reason: 1947: 2004:7 in 'Tailoring Biotechnologies', vol.3(1)
- House of Commons, 'Human Reproductive Technologies and the Law: Fifth Report: Session 2004-2005, Volume 1 (London: House of Commons Science and Technology Select Committee), HG7 1
- House of Lords Select Committee on the European Communities, 'EC Regulation of Genetic Modification in Agriculture', Session 1998-99, 2nd Report
- Howard, L. and A. M. Pablo (2005). "Is there a Science of the Processes Underlying Health and Illness Behaviors? A Comment on Maes and Karoly." *Applied Psychology: An International Review* 54(2): 255-266.
- Howlett, Michael and Ramesh, M. 'Studying Public Policy: Policy Cycles and Policy Subsystems', (2003, Oxford University Press) 2nd Edition
- Hughes, Stephen & Bryant, John, 'GM Crops and Food: a Scientific Perspective', in Bryant, John, Baggott la Velle, Linda & Searle, John (Editors), *Bioethics for Scientists*, (2002, John Wiley & Sons Ltd.)
- Human Fertilisation and Embryology Authority , 'Sex Selection: Options for Regulation: A Report on the HFEA's 2002-03 Review of Sex Selection including a Discussion of Legislative and Regulatory Options'.
- Human Fertilisation and Embryology Authority 'Choices and Boundaries: Should People be able to Select Embryos Free from an Inherited Susceptibility to Cancer', <http://www.hfea.gov.uk/516.html> (last accessed on 28th September 2011).
- Human Fertilisation and Embryology Authority Report on Preimplantation Tissue Typing, http://www.hfea.gov.uk/docs/PolicyReview_PreimplantationTissueReport.pdf (last accessed on 26th September 2011).
- Human Fertilisation and Embryology Authority, 'Sex Selection – A Public Consultation: Research Study Conducted for the Human Fertilisation and Embryology Authority', January 2003.
- Human Genetics Commission (HGC) 2001 'Public Attitudes to Human Genetic Information. People's Panel Quantitative Study (London: HGC)
- Human Genetics Commission, 'Making Babies: Reproductive Decisions and Genetic Technologies' (2006).
- Hume, Essays, vol.1, Essay 4 cited in Dicey, A.V. (1905) 'Law and Public Opinion in England', chpt.7 in Aubert, Vilhelm (Ed), 'Sociology of Law; Selected Readings', (1969, Penguin Books Ltd.)
- Hutter, Bridget M. (2006) 'The Role of Non-State Actors in Regulation', CARR discussion paper no.37.

- Imig, Douglas R. and Tarrow, Sidney, G. (Eds), 'Contentious Europeans: Protest and Politics in an Emerging Polity', 2001, Roman and Littlefield Publishers, Inc.
- Irwin, Alan, 'The Politics of Talk: Coming to Terms with the 'New' Scientific Governance', *Social Studies of Science* 36/2 (April 2006) pp.299-320
- Jackman, S. and P. M. Sniderman (2006). "The limits of deliberative discussion: A model of everyday political arguments." *Journal of Politics* 68(2): 272-283.
- Jackson, Emily, 'Regulating Reproduction: Law, Technology and Autonomy', Hart Publishing 2001.
- Jallinoja, Piia, Aro, Arja, 'Knowledge about Genes and Heredity among Finns' *New Genetics and Society*, Vol.18, No.1, 1999.
- James, Oliver (2000), 'Regulation inside Government: Public Interest Justification and Regulatory Failures', *Public Administration*, Vol.78 (2) pp.327-343
- Jan, G., H. Lucien, et al. (2006). "Trust in governance and the acceptance of genetically modified food in the Netherlands." *Public Understanding of Science* 15(1): 103-112.
- Jasanoff, Sheila, 'Designs on Nature: Science and Democracy in Europe and the United States' (Princeton University Press, 2005)
- Jasanoff, Sheila, 'Product, Process, or Programme: three cultures and the regulation of biotechnology', Chapter 15 in Bauer, Martin, 'Resistance to New Technology: Nuclear Power, IT and Biotechnology', (Cambridge University Press, 1995) at p.311.
- Jennings, Will, and John, Peter, 'Error Correction in Public Policy: Public Opinion and Policy Agendas in the UK 1959-2001, ESRC and LSE paper
- Jones, Bryan D. & Baumgartner, Frank R. 'The Politics of Attention: How Government Prioritizes Problems' (University of Chicago Press, 2005)
- Jordana, Jacinct and Levi-Faur, David, (Eds) (2004) 'The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance' Edward Elgar Publishing Limited
- Kasperson, R.E. 'The Social Amplification of Risk: Progress in Developing an integrative framework of risk' in Krimsky, S. and Golding, D. (Eds) 'Social Theories of Risk', (Westport, CT: Praeger, 1992) at p.182 cited by Murdock, Graham, Petts, Judith and Horlick-Jones, Tom, in 'After Amplification: Rethinking the Role of the Media in Risk Communication', Chpt. 7 in Pidgeon, Nick, Kasperson, Roger E, and Slovic, Paul, 'The Social Amplification of Risk', (Cambridge University Press, 2003)
- Keller, Evelyn Fox & Lloyd, E.A. (Eds) 'Keywords in Evolutionary Biology', (Cambridge MA: Harvard University Press, 1992)
- Keller, Evelyn Fox, 'The Century of the Gene' (First Harvard University Press, 2002)

- Kelly, Susan, E. 'Qualitative Interviewing Techniques and Styles', Chapter 16 in Bourgeault, Ivy, Dingwall, Robert and de Vries, Raymond (Editors) 'The Sage Handbook of Qualitative Methods in Health Research' 2010.
- Kingdon, John W. (2003) 'Agendas, Alternatives, and Public Policies' (Second Edition) Addison-Wesley Educational Publishers Inc.
- Knoppers, Bartha M. & Isai, Rosario M. 'Regulatory Approaches to Reproductive Genetic Testing', *Opinion, Human Reproduction*, Vol. 19, No.12, 2004, pp.2695-270.
- Kosicki, G. M. (2006). "Setting the agenda: The mass media and public opinion." *Public Opinion Quarterly* 70(1): 124-127.
- Lang, K. (1999). "Reading public opinion: How political actors view the democratic process." *Public Opinion Quarterly* 63(3): 437-439.
- Latour, Bruno, 'We have never been Modern', (Cambridge: Harvard university Press, 1993)
- Lee, Eun Sul and Forthofer, Ronald N., (2006) 'Analysing Complex Survey Data' (2nd Edition), Sage
- Lee, Maria, 'EU Environmental Law' (Hart, 2005)
- Lee, R. F., Andrew (Editors) (2004). "The Food Standards Agency: Making a Difference?" *The Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) Working Paper Series No. 21.*
- Lee, R., Thankappan, Samantha, Flynn, Andrew (Editors) (2004). "The Battle for the Consumers: Building Relationships in a New Phase of Contested Accountability in the UK Food Chain'." *The Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) Working Paper Series No.17.*
- Leonie, A. M., K. Nicholas, et al. (2007). "Mass media framing of biotechnology news." *Public Understanding of Science* 16(2): 183-203.
- Lezaun, Javier & Soneryd, Linda, 'Government by Elicitation: Engaging Stakeholders or Listening to the Idiots?' *CARR Discussion Paper No: 34, May 2006*
- Lichtenstein, C. 'GM Debate: Dispelling myths' *Heredity, Nature* 2004, 92 pp.135-138
- Lofstedt, Ragnar E. 2007 'The Impact of the Cox-2 Inhibitor Issue on Perceptions of the Pharmaceutical Industry: Content Analysis and Communication Implications', *Journal of Health Communication* vol. 12, pp.471-491
- Luhmann, N. 'Familiarity, Confidence, Trust: Problems and Alternatives' in 'Trust: Making and Breaking Cooperative Relations', Gambetta, D., (Ed), 2000
- Lustig, B. Andrews, Brody, Baruch A. and McKenny, Gerald P. (Eds), 'Altering Nature: Concepts of 'Nature' and the 'Natural' in Biotechnology Debates, 2008, Springer.

- Lyall, Catherine and Tait, Joyce, (2005) 'New Modes of Governance: Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment', Aldershot, Ashgate
- MacMaolain, Caoimhin, 'The New Genetically Modified Food Labelling Requirements: Finally a Lasting Solution', *European Law Review* 2003, 28(6), pp.865-879.
- MacKenzie, Robin 'From Sanctity to Screening: Genetic Disabilities, Risk and Rhetorical Strategies in Wrongful Birth and Wrongful Conception Cases', *Feminist Legal Studies* 7, 1999, pp.175-191.
- Majone, Giandomenico, (1998) 'Evidence, Argument and Persuasion in the Policy Process', Yale University
- Majone, Giandomenico, 'The New European Agencies: Regulation by Information', *Journal of European Public Policy* 4:2 June 1997, pp.262-275
- Mark, F., S. Bruce, et al. (2005). "What do individuals in different science groups within a life sciences organization think about genetic modification?" *Public Understanding of Science* 14(3): 317-326.
- Martin, Paul, 'From Eugenics to Therapeutics: The Impact of Opposition on the development of Gene Therapy in the USA', Chpt. 8 in Wheale, Peter, von Schomberg, René & Glasner, Peter (Eds), 'The Social Management of Genetic Engineering' (Ashgate Publishing Ltd., 1998)
- Martin, Sam and Tait, Joyce, 'Attitudes of Selected Public Groups in the UK to biotechnology', in Durant, John (Ed), 'Biotechnology in Public: A Review of Recent Research', (Science Museum, 1992)
- Martin, W. B. (2007). "The public career of the 'gene' - trends in public sentiments from 1946 to 2002." *New Genetics and Society* 26(1): 29-45.
- Marton, K. (2006). 'Studies in public opinion: Attitudes, nonattitudes, measurement error, and change' *Public Opinion Quarterly* 70(1): 130-132.
- Mayer, Sue and Stirling, Andy, 'GM crops: good or bad?' *EMBO Reports* (2004) 5, pp.1021-1024.
- McLean, Iain, 'The History of Regulation in United Kingdom: Three Case Studies in Search of a Theory', Chpt. 3 in Jordana & Levi-Faur 2004
- Mendelshon, Mattheew, (2003) 'A Public Opinion Perspective on Regulation', Smart Regulation Paper
- Milewa, Timothy, (1999) 'Public Opinion and regulation of the new genetics: a Critical Review', Public Health Genetics Unit paper
- Miller, J.D., (1983) 'Scientific Literacy: a conceptual and empirical review', *Daedalus*, 112, pp.29-48.
- Millstone, Erik, 'Analysing Biotechnology's Traumas', *New Genetics and Society*, Vol.19, No.2, (2000) pp.117-132

Mittra, James (2007). "Marginalising 'eugenic anxiety' through a rhetoric of 'liberal choice': a critique of the House of Commons Select Committee Report on reproductive technologies." *New Genetics and Society* 26(2): 159-179.

Morgan, Bronwen & Yeung, Karen, 'An Introduction to Law and to Regulation: Text and Materials' (Cambridge University Press 2007)

Moss, Lenny, 2003 'What Genes Can't Do'. (Cambridge, MA: Bradford Books/MIT Press)

Noelle – Neumann, Elisabeth, 'Public Opinion and the Classical Tradition: A Re-evaluation', *Public Opinion Quarterly*, 1979 pp. 143-157.

Norton Wise, M. 'Thoughts on the Politicisation of Science through Commercialisation', *Social Research* vol. 73: No.4, Winter 2006

Ogus, Anthony, 'W(h)ither the economic theory of regulation? What economic theory of regulation? Chpt.2 in Jordana, Jacinct & Levi-Faur, David (Eds), 'The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance' (Edward Elgar Publishing Limited, 2004).

O'Keefe, G. J. (2001). "The anatomy of public opinion." *Public Opinion Quarterly* 65(3): 425-427.

Oliver, Dawn, (1999) 'Common Values and the Public-Private Divide', Butterworths

Page, Benjamin I. & Shapiro, Robert Y. 'Effects of Public Opinion on Policy', *The American Political Science Review*, Vol. 77, No. 1 (March 1983), pp.175-190

Pal, Leslie A. & Maxwell, Judith, 'Assessing the Public Interest in the 21st Century: A Framework', Paper prepared for the External Advisory Group on Smart Regulation, (2003)

Park, Alison, Curtice, John, Thompson, Katarina, Phillips, Miranda, Johnson, Mark, (2007) 'British Social Attitudes: The 23rd Report: Perspectives on a Changing Society', Sage

Pestre, D. 'Science, Political Power and the State' in Krige, J. and Pestre, D. (eds), 'Science in the Twentieth Century', (Amsterdam, Harwood, 1997)

Peter, J. (2006). "Explaining policy change: the impact of the media, public opinion and political violence on urban budgets in England1." *Journal of European Public Policy* 13(7): 1053-1068.

Peter, J. and M. Helen (2003). "Policy punctuations in the UK: fluctuations and equilibria in central government expenditure since 1951." *Public Administration* 81(3): 411-432.

Pidgeon, Nick, Kasperson, Roger E. and Slovic, Paul, (Eds), 'The Social Amplification of Risk, (Cambridge University Press, 2003)

- Poortinga, Wouter and Pigeon, Nick F. 'Trust in Risk Regulation: Cause or consequence of the Acceptability of GM Food?' *Risk Analysis*, Vol.25, No.1, 2005.
- Powell, A., O'Malley, M., Müller-Wille, S., Calvert, J.& Dupre, J., 'Disciplinary Baptisms', (February 2007) (unpublished)
- Prosser, Tony, 'Regulation and Social Solidarity', *Journal of Law & Society*, Vol. 33, No.3, September 2006, pp. 364-387
- Reynolds, Larry and Szerszynski, Bronislaw, 'Representing GM Nation?' (report published as part of the EU funded project PAGANINI (Participatory Governance and Institutional Innovation))
- Robert, F. (2007). "The political economy of 'normative power' Europe: EU environmental leadership in international biotechnology regulation." *Journal of European Public Policy* 14(4): 507-526.
- Rothstein, Henry, 'The Institutional Origins of Risk: A New Agenda for Risk Research', *Health Risk and Society*, September 2006; 8(3): pp. 215-221.
- Rowe, Gene & Frewer, Lynn J. (2005) 'A Typology of Public Engagement Mechanisms' *Science, Technology & Human Values* 30, pp.251
- Salter, Brian & Jones, Mavis, 'Human Genetic Technologies, European Governance and the Politics of Bioethics', *Nature Reviews Genetics* 3, 808-814 (2002)
- Sara Binzer, H. and K. Robert (2005). "Responsive Government? Public Opinion and Government Policy Preferences in Britain and Denmark." *Political Studies* 53(2): 379-402.
- Schmidtke, Jorg, 'Clinical Validity and Utility of Genetic Testing – the Viewpoint of a Clinical Geneticist'. 2005 <http://www.eurogentest.org/web/files/public/unit3/CDBI.pdf> (last accessed 23/07/09)
- Schuman, H. (1998). "The public opinion process: How the people speak." *Public Opinion Quarterly* 62(3): 431-433.
- Scott, Colin 'Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance' *Journal of Law and Society*, Volume 29, Number 1, March 2002, pp.56-76.
- Scott, Colin, 'Rethinking regulatory governance for the age of biotechnology' chpt. 2 in
- Scott, Rosamund 'Choosing between possible lives: Law and ethics of prenatal and preimplantation genetic diagnosis', (Hart Publishing 2007)
- Selznick, Philip, 'Law in Context' Revisited', *Journal of Law and Society*, Volume 30, Number 2, June 2003, pp.177-186
- Skene, L., 'Patient's Rights or Families Responsibilities', *Medical Law Review* 1998, vol.6, pp.1-41.

Smith, E., Marsden, Terry & Flynn, Andrew (2004). "Regulating Food Risks: Rebuilding Confidence in Europe's Food?." *Environment and Planning C: Government and Policy* 22: 543-567.

Smith, M. 'Novel Foods Create Novel Dilemmas for Trade Partners', *The Financial Times*, 22, June 1998, p.7.

Soini, S. et al, 'The Interface between assisted reproductive technologies and genetics: Technical, Social, Ethical and Legal Issues', *The European Journal of Human Genetics* (2006) 14, pp.588-645

Somsen, Han (Ed), (2007) 'The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents', Edward Elgar 2007

Soroka, Stuart N. & Wlezien, Christopher, 'Opinion-Policy Dynamics: Public Preferences and Public Expenditure in the United Kingdom' *B.J.Pol.S.* 35, 2005, pp.665-689

Stake, Robert E. (1995) 'The Art of Case Study Research'. Thousand Oaks, CA: Sage

Steel, Daniel, 'Social Mechanisms and Causal Inference', *Philosophy of Social Sciences*, Vol. 34, No.1, March 2004, pp.55-78

Steele, Jenny, 'Participation and Deliberation in Environmental Law: Exploration a Problem-solving Approach', *Oxford Journal of Legal Studies*, Vol.21, No.3 (2001) pp.415-442

Stephens, Neil, 'Collecting Data from Elites and Ultra Elites: Telephone and Face-to-Face Interviews with Macroeconomists', *Qualitative Research*, vol. 7(2), 2007 pp.203-216.

Stringer, Joan K. & Richardson, J.J. 'Managing the Political Agenda: Problem Definition and Policy Making in Britain' *Parliamentary Affairs* vol.23, 1980 pp.23-39

Sturgis, Patrick and Allum, Nick, 'A Literature Review of Research Conducted on Public Interest, Knowledge and Attitudes to Biomedical Science', August 2006, The Wellcome Trust.

Sturgis, Patrick, Cooper, Helen & Fife-Shaw, Chris, 'Attitudes to biotechnology: estimating the opinions of a better informed public', *New Genetics & Society*, Vol. 24, No.1, April 2005 pp.31- 56

Sturgis, Patrick, Cooper, Helen, Fife-Shaw, Chris & Shepherd, Richard, 'Genomic Science: Emerging Public Opinion' from Park, A., Curtice, J., Thompson, K., and Phillips, M. (Eds) (2004) *British Social Attitudes – the 21st Report*, London: Sage.

Tait, Joyce and Martin, Sam, 'Attitudes of Selected Public Groups in the UK to biotechnology' in Durant, John (Editor), 'Biotechnology in Public: A Review of Recent Research', Science Museum, 1992

Tait, Joyce, 'Upstream Engagement and the Governance of Science: The Shadow of the Genetically Modified Crops Experience in Europe', *Science and Society*, EMBO Reports, Vol. 10, 2009.

- Tait, Joyce, 'Who's afraid of biotechnology: How can we sensibly regulate biotechnology', *New Scientist*, 27 June 1992.
- Taylor-Gooby, Peter and Zinn, Jens, (2006) 'Risk in Social Science', Oxford University Press
- Tee, R.-H. and P. Nick (2007). "Moving engagement "upstream"? Nanotechnologies and the Royal Society and Royal Academy of Engineering's inquiry." *Public Understanding of Science* 16(3): 345-364.
- Thatcher, Mark and Stone Sweet, Alec, (Editors) (2003) 'The Politics of Delegation', Frank Cass and Company
- Tilly, Charles, 'Speaking Your Mind Without Elections, Surveys or Social Movements', *Public Opinion Quarterly* Vol.47, pp.461-478
- UNESCO, Report of the International Bioethics Committee on preimplantation genetic diagnosis and germ-line intervention: SHS-EST/02/CIB-9/2, United Nations Educational, Scientific, and Cultural Organization, Geneva (April 24, 2003).
- Voss, Georgina, 'Report to the Human Genetics Commission on Public Attitudes to the Uses of Human Genetics Information' September 2000.
- Waltz, Emily, 'Battlefield', *Nature* Vol.461, 3 September 2009.
- Webster & Nelis 1999, 'Regulating the gene: from genetic consumption to regulatory trust', *Health, Risk and Society*, Vol.1, No.3
- Weighardt, F. (2006) 'GMO Labelling Thresholds Impractical and Unscientific', *National Biotechnology*, January 24(1)
- Weiss, R., 'Giant US food corporations and biotech industry are terrified of mandatory labels on GE food', *Washington Post*, 15 August 1999, p.17
- Wickham, Gary and Pavlich, George, (Eds) (2001) 'Rethinking Law, Society and Governance: Foucault's Bequest', Hart Publishing
- Wiener, J. B. (2004). "The regulation of technology, and the technology of regulation." *Technology in Society* 26(2): 483-500.
- Winner, Langdon, 1980 'Do Artifacts have Politics', Chpt. 1 in MacKenzie, Donald & Wajcman, Judy, 'The Social Shaping of Technology' (2nd Edition) (Open University Press, 1999)
- Wlezien, C. (2004). "Patterns of representation: Dynamics of public preferences and policy." *Journal of Politics* 66(1): 1-24.
- Wlezien, Christopher, 'On the Salience of Political Issues: The Problem with 'Most Important Problem' Electoral Studies, Vol.24, Issue 4, December 2005, pp.555-579.

Wolpert, L. 'The Public's Belief about Biology', *Biochemical Society Transactions* (2007) 35, pp.37-40.

World Health Organisation, *Proposed International Guidelines on ethical issues in medical genetics and genetics services*. Geneva: WHO, 1998.

Wynne, Brian, Chapter 1 of Irwin, Alan & Wynne, Brian (Editors) 'Misunderstanding Science?: The Public Reconstruction of Science and Technology', Cambridge University Press 1996.

Zaller, John R. 'The Nature and Origins of Mass Opinion', (Cambridge University Press, 1992)