SCIENCE, RISK AND PUBLIC POLICY:

OPs; GM Crops; BSE and MMR

A Comparative Study of the Use of Science in Policy-Making in Britain

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ABSTRACT

Over the past twenty years there has been much controversy and public anxiety over issues relating to environmental and health-related hazards. Many of these issues result from the modern state's enthusiasm for ever-increasing economic growth and strong support for the wealth-creating potential of new technologies. Yet some sections of society are concerned about science's potential for harm as well as its potential for good. The problem for governments is to work out how science can achieve the objective of developing wealth-creating technologies, and at the same time solve the problems for people and the environment that such technologies cause. The UK Government's use of scientific advice in many recent environmental and health-related issues raises serious questions about its success in striking the right balance between harnessing science for its benefits, and protecting the public from its potential harm.

The aims of this Thesis are to examine the role of science in policy-making in Britain and to evaluate how governments go about handling uncertain scientific knowledge in an age of public risk aversion and anxiety about the effects of technology on human health and the environment. The debate on this issue reveals a split between those who accept science in the service of government – the sound science approach; and those who would take a more precautionary stance, which entails that where there may be potential problems with a technology, a wider form of assessment than that carried out under the sound science approach should be carried out to ensure it is safe – the precautionary approach.

The theoretical basis for this Thesis will be organized around these two approaches to environmental policy-making: sound science and precautionary methodology. The Thesis constructs a theoretical framework for these respective approaches.

Research was carried out into four case studies, focusing on the way in which successive British Governments have used the advice of expert bodies to formulate policies on (1) organophosphates (OPs) in sheep dip; (2) the commercialization of GM crops; (3) the BSE crisis during the period 1985 – 1998; and (4) the MMR vaccine policy. I then analyze the case studies to see if there is a fit between them and my theoretical approaches. My conclusion is that, despite the Government's formal commitment to the precautionary approach, and some signs of adhering to a precautionary approach in some areas, sound science is still deeply embedded in the UK's statutory science advice system.

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Closer to home, I wish to express my thanks to my wife, Leny, whose encouragement and enthusiasm have supported me throughout my research and writing.

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ACRONYMS

ACP	Advisory Committee on Pesticides
ACNFP	Advisory Committee on Novel Foods and Processes
ACRE	Advisory Committee on Releases into the Environment
ACSP	Advisory Council on Scientific Policy
AEBC	Agricultural and Environmental Biotechnology Commission
ANDPB	Advisory Non-Departmental Public Bodies
AOEL	Accepted Operator Exposure Level
BBSRC	Biology and Biotechnology Scientific Research Council
BMA	British Medical Association
BMJ	British Medical Journal
BSE	Bovine Spongiform Encephalopathy
C4	Channel Four Television
CEC	Commission of the European Communities
CJD	Creutzfeldt-Jacob Disease
COPA	Control of Pesticides Act
COPR	Control of Pesticides Regulations
COSHH	Control of Substances Hazardous to Health
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CSM	Committee on the Safety of Medicines
CVL	Central Veterinary Laboratory (DEFRA)
DEFRA	Department for Environment, Food and Rural Affairs
DH	Department of Health
DOE	Department of the Environment
DTI	Department of Trade and Industry
EA	Environmental Agency

EEC	European Economic Communities
EFSA	European Food Safety Authority
EIA	Environmental Impact Assessment
EP	European Parliament
EPA	Environmental Protection Agency (USA)
FDA	Food and Drug Administration (USA)
FEPA	Food and Environment Protection Act (1985)
FOE	Friends of the Earth
FSA	Food Standards Agency
GM	Genetically Modified
GMO	Genetically Modified Organism
HEFC	Higher Education Funding Council
HPA	Health Protection Agency (UK)
HSE	Health and Safety Executive
ISIS	Institute for Science in Society
IOM	Institute of Occupational Medicine
JCVI	Joint Committee on Vaccination and Immunization
MAFF	Ministry of Agriculture, Food and Fisheries
MRC	Medical Research Council
MMR	Measles, Mumps and Rubella
NDPB	Non-Departmental Public Bodies
NFU	National Farmers Union
NGO	Non-Governmental Organisation
NOAH	National Office for Animal Health
NPU	Neuropathogenesis Unit (at the Institute for Animal Health)
OPIN	Organophosphate Information Network
OP	Organophosphates
OST	Office of Science and Technology

PAN	Pesticide Action Network
PABE	Public Perception of Agricultural Biotechnology
POST	Parliamentary Office of Science and Technology
PPE	Personal Protective Equipment
PRC	Pesticide Residue Committee
PSD	Pesticide Safety Directorate
QUANGO	Quasi-Autonomous Non-Governmental Organisation
RASE	Royal Agricultural Society of England
RCEP	Royal Commission on Environmental Pollution
RSPB	Royal Society for the Protection of Birds
SEA	Single European Act
SEAC	Spongiform Encephalopathy Advisory Committee
SARSS	Suspected Adverse Reactions Surveillance Scheme
SCRI	Scottish Crop Research Institute
USDA	United States Department of Agriculture
VPC	Veterinary Products Committee
VMD	Veterinary Medicines Directorate
WTO	World Trade Organisation

CHAPTER ONE

Introduction: Science and Society

Science has reached a point where imagination and technical capabilities of scientists are overtaking society's ability to evaluate and control the outcome. (Novotny 2003)

1.1. Background and Research Aims

1.1.1. BACKGROUND

Over the past twenty years, there have been many instances of controversy, and sometimes policy failure, over issues related to environmental hazards. During the 1980s, there was the long run saga of acid rain and whether or not it was destroying forests and poisoning lakes in Scandinavia; a crisis over salmonella in eggs; and a health scare over listeria in cheese. During the 1990s, there was a policy fiasco over bovine spongiform encephalopathy (BSE) in British cattle herds; alarm over the safety of radio masts and mobile phones; warnings about harmful chemical substances in farmed Scottish salmon; concern at the long-term effects of heavy pesticide use in agriculture; and many others. More recently, two issues causing public anxiety are the proposed commercialisation of genetically modified (GM) crops, and the measles, mumps and rubella (MMR) vaccine. Governments frequently have to face such issues, and in doing so, have to acknowledge the importance of scientific expertise in formulating policy, the difficulties in interpreting scientific advice, and, just as important, the best way to present scientific findings to the public.

Technology and economic growth are driven by scientific knowledge, and this rather obvious connection between science and the production of wealth explains why modern states, at least in the developed world, organise science to serve national ends. All of the issues listed above are the result of the modern state's preoccupation with wealth creation. Governments actively encourage the use of technological expertise to develop more and better products and processes that make industry more efficient and social life easier. The above statement by Eve Novotny, a member of 'Scientists for Global Responsibility', which is a forum for scientists concerned about science's potential for good and for harm, sums up the concern that some sections of society have expressed in recent times, regarding the relation between science and society. There is a wide discussion of these issues in science and environmental journals as well as in the newspaper media. This concern is about science and scientists: 'Where science has gone wrong', (Theocharis and Psimopoulos 1987); 'The

honesty of science is being compromised at every turn', (Tudge 2004); and about food and environmental issues 'Why are they foisting GM crops on us?' (Ruddock 2004); 'Radioactive Waste in Farmed Fish', (Hiscott 2003); and 'How science fails the environment' (Wynne and Mayer 1993).

Issues involving the use of scientific advice in policy-making lead to serious questions about the use of that advice by governments. For example, do administrators manipulate scientific opinion by using it to legitimate favoured political positions? Conversely, do scientists have their own agenda that influences the advice they give to politicians? Is it ever possible for scientists to offer entirely neutral or disinterested advice to ministers? If so, is it practicable for ministers to transmit such advice unvarnished to the public? Who is liable for damage to the environment when technology goes wrong?

1.1.2. AIMS OF THE RESEARCH

One study written over a decade ago noted that '(t)he world of the late twentieth century is dominated by science and technology. These twin pillars of the modern world have the capacity both for great good and for great harm.' (Barker & Peters 1993: 4). This judgement still holds today, and the aims of this research are to examine the role of science in policy-making in Britain, and to evaluate how governments go about handling uncertain scientific knowledge in an age of public risk consciousness and anxiety about the effects of technology on human health and the environment. These aims will be facilitated through four case studies of policy areas concerning scientific advice where scientific uncertainties are considered to have been present. The four case studies are: organophosphates (OPs); genetically modified organisms (GMOs); bovine spongiform encephalopathies (BSE); and the controversy over the MMR vaccine. The case study analysis will focus on the following research questions:

- *Who are the scientific advisers to policy makers and what does knowledge about them tell us about their place in the policy process?*
- *Is science that is commissioned by government just a protective shield used to justify decisions made by ministers?*
- *To what extent do ministers put a political spin or gloss on the scientific advice they are given, especially when they explain that advice to the public?*
- *Do governments only pay lip service to the idea of precaution?*

1.1.3. IMPORTANCE OF THE RESEARCH

This research was carried out at a time when the credentials of science are being critically assessed by the public as never before, and the implications for governance are enormous. Will the public's confidence in science ever be restored, and thereby its trust in governments which rely on scientific validation for many of their policies? Perhaps that confidence and trust depends on a new relationship being developed between scientists and the public - based less on blind belief in the authority of science, and more on a partnership between scientists and the public, in which scientists share their uncertainties and admit their limitations, and the public takes on a greater burden of responsibility for interpreting scientific evidence. At a recent meeting of the British Association, its president made a speech in which she said: 'If people don't know about something, and scientists are not prepared to talk about it, using a language that is understandable, then it is reasonable that people get fearful' (*Guardian* 2004). In this changing milieu, this study is a timely investigation of the place recently and currently occupied by science in framing governmental policies.

1.2. Overview of the Literature

There are two types of literature review used currently in academic research: the self-standing literature review, which takes the form of a whole chapter or section of a chapter; and the integrated literature review, where the literature is introduced where it is relevant throughout the study. The latter type is used in this Thesis. Thus, this section will give a brief overview of the main fields of literature encountered, and the literature relevant to the subject matter of each chapter will be introduced in more detail in those chapters.

The topic of the relationship between science and government, in its broadest context, has spawned a vast literature. The American scientist, Harvey Brooks, has divided the relationship between science and government into *science in government,* and *policy for science.* The first deals with matters that are political or administrative but depend on an expert or scientific input, such as the regulation of pesticides or GMOs. The second is about the development of policies for the management of technological and scientific resources. So Brook's distinction is between advising government and public policy (Brooks 1964, quoted in Jasanoff 1990: 4-5). However, my literature overview will examine the topic under three main themes: the nature of scientific enquiry and some criticism of scientific method; the politics of expertise; and the system of advisory scientific bodies. Thus, it will begin in a broad way, ranging over works that examine science as an institution, and its relations with society, then cover works on how science has been used by government, and finally focus on works on the specific area of the scientific advisory system itself.

1.2.1. SCIENTIFIC ENQUIRY: THE IDEAL AND SOME PROBLEMS

Any consideration of issues such as science's relations with government needs to look at the place of science and scientists in decisions about hazard and risk, and there is a vast literature on this topic. The view that science is an institution that aims for rationality and objectivity stems from Weber's celebrated analysis of social authority. From his three forms of authority - traditional, charismatic and legal-rational - science was, for Weber, the prime example of legal-rational authority Gerth and Mills 1970: 79). Lewis Wolpert, an eminent British scientist, neatly sums up this viewpoint: 'Science is a special way of knowing and investigating and the only way of appreciating the process is to do it. Only in this way can people come to recognise a key feature of science – there is only one correct explanation for any set of phenomenon' (Wolpert 1997: 21). This positivist model of science states that scientists are neutral, objective pursuers of the truth. For example, Merton (1973) sets out 'norms' for science in which scientific investigation is impersonal, disinterested, sceptical and collaborative. In this model, positivist 'methods are based primarily on deduction, experiments are replicable, theories are predictive, and the scientific endeavour is considered to be value-free' (Barrett and Raffensperger 1999: 110). But these ideas are being questioned, and as the scientific community does not itself address the controversy fully (Fuller 1997: 15), writers in other academic disciplines, such as historians, philosophers and sociologists, are doing it.

The social standing of science has been the subject of a long interdisciplinary clash since the end of the Second World War. By 1945, science had become very important and influential, both militarily and in industry. However, the involvement of scientists in munitions manufacture and the atomic bomb were creating public concern, with questions being asked about how scientists fit into society, culturally. Modern societies are dependent on the power of science and technology but cannot simply rely on scientific knowledge and authority remaining the privilege of scientists alone; otherwise the public will become alienated from the very power that creates the wealth of society. Furthermore, they may lose confidence in science when scientists publicly disagree. This problem became exacerbated by the growing gap between the sciences and the arts, a gap which precipitated the so-called two cultures debate. C.P. Snow, who was both a physicist and a novelist, tried to bridge the gap between sciences and the arts in his 1959 lecture, *The Two Cultures* (Snow 1993). Snow noted that the gulf between scientists and literary intellectuals had grown wider as science had become more specialised and complex, and that the practitioners of the two disciplines knew little about each other, resulting in great difficulties in any communication between them.

There are a number of studies that criticise the traditional picture of scientific authority. In particular, they provide a critique of Popper's rationalist philosophy of science, which argues that only those scientific claims that had successfully run the gauntlet of attempts to falsify them were to be accepted as scientific (Popper 1972: 33). Thomas Kuhn, for example believes that Popper's theory does not fit how scientists actually work. He argues that the 'facts' and accepted theories of science were the result of a continual process of negotiation among scientists. Scientific ideas were acceptable so long as they conformed to the existing paradigm of scientific understanding within disciplines; scientists do not go out to falsify other scientist's claims nor do they discover the 'unknown' - they only seek to uncover the 'known' or what the paradigm tells them to expect from the experiments in the laboratory. In other words, scientists know what they are looking for in advance (Kuhn 1970). 'It is the paradigm, rather than any features of the natural world, that defines what problems are worth solving and shapes scientists' expectations of what they are likely to see when they investigate nature' (Jasanoff 1990: 13).

As sociologists began to study science empirically for the first time, they looked at the way in which scientists justify their claims and found that they don't do things much differently from other disciplines. That was the basis for the academic squabble that became known as the 'Science Wars' (*Nature* 1997). Much of the dissent was initiated by a group of academics from sociology, history and philosophy that became known as the Edinburgh School. Two members of this group, Harry Collins and Trevor Pinch wrote *The Golem: What Everyone Should Know About Science* (1993), which purports to show that science is an uncontrollable monster (from the Golem in Yiddish mythology). They conclude that scientists at the research front cannot settle their disagreements through better experiments, more knowledge, more advanced theories, but turn wildly varying results into neat and tidy scientific myth. However, these academics are quite adamant they are not anti-science.

1.2.2. THE POLITICS OF EXPERTISE

Dealing with environmental hazard is now a problem, in that people who once regarded science and technology as a way of solving problems are now afraid of the food they eat, the air they breathe and the water they drink. According to Ulrich Beck, this is because technological and cultural changes in contemporary society generates a 'risk society' that, he argues is a condition of western societies where risks created by the impact of science and technology do not appear to be under the control of protective institutions (Beck 1992). Beck's work expresses contending visions of how society should be organised, but he believes that, whereas in earlier times, risk management was confined to industry, in what he calls 'second modernity' (risk society), it is central to the 'social institutions of industrial

society' (Beck 1992: 54). Risk, insecurity and pollution, and the idea that there are innumerable hazards generated by the modernization process, are important elements of modernity, according to this perspective, which is also shared by Giddens (1990) and Lash, Szerszynski & Wynne (1996). Giddens, for example, believes that today 'the baseline for analysis has to be the inevitability of living with dangers which are remote from the control not only of individuals, but also of large organisations, including states' (Giddens 1990: 131). This has led some to urge that in future, environmental policy issues should be based on an interaction between social and cultural factors and professional experts, with a much wider participation than at present – manifesting, as one academic puts it, as 'citizen science' (Irwin 1995). So the management of risk is a very important responsibility of government, and, of course, it is a wider responsibility than just technological risk: without limited liability law, bankruptcy law, social security, to name a few key risk management policies, the economic growth that governments world-wide strive for would hardly exist. But dealing with technological risk presents particular problems for government: a balance has to be struck between the risks inherent in technological activity and the benefits to society that derive from it.

In attempting to strike that balance, we encounter a divide between (1) the purely scientific approach to risk management – the reductionist approach that concentrates on establishing causal links between observable effects of technology and the probable cause – and (2) the approach adopted by those who argue that the selection of risks by society is not linked to objective risk measurement or the physical reality of the risk, but reflects moral, political, economic and power positions that are value-laden and culturally constructed (Douglas & Wildavski 1982; Douglas 1985; Cutter 1993). As John Adams noted in his work on risk, '...the view that there is a distinction to be made between, *real, actual, objective, measurable risk that obeys the formal laws of statistical theory* and *subjective risk inaccurately perceived by non-experts* is still the mainstream position on most of the research literature on safety and risk management' (Adams 1995: 10, italics in original). But the positivist or reductionist approach to solving environmental problems has a number of critics. The belief that breaking down an area of investigation into its smallest components because only these directly observable and measurable parts matter, is opposed by a number of academic studies (Wynne 1992; Weale 1992; M'Gonigle 1999; Stirling 1999). One such study concerned with expert advice is highly sceptical of the power of science to reduce uncertainties that surround policy problems, or even that 'science yields the truth' (Collingridge & Reeve 1986: 7). These authors argue that policy cannot be based on science:

> experts are generally expected by their paymasters to provide hard facts expressed in precise numbers, and are not likely to be aware of the in-exactitude attending all quantification. Scientists may therefore disagree about the exactness of specific items of data, particularly probabilistic data, which undermines the usefulness of their results for the making of policy. (Collingridge & Reeve 1986: 26).

Collingridge and Reeve conclude that the allotted role of science in policy-making cannot be fulfilled, and that great resources are wasted in the production of huge technical tomes. They believe the political process is distorted, and that the real questions at issue are not debated, 'while arguments go on between a handful of qualified experts over minute technical points' (Collingridge & Reeve 1986: 158).

The idea that the management of risk and hazard is purely a problem for scientific or technical experts applying the methods of quantitative science, has prevailed for a long time, but it is becoming increasingly recognised that today, risk management also involves the 'skills of governance' (De Marchi & Ravetz 1999: 743). In the policy process, as Majone (1989) notes, areas of debate such as scientific and technological issues are difficult to institutionalise and also difficult to resolve because of the divide between scientific/expert opinion and public participation. Majone refers to Weinberg's notion of trans-science, questions of fact that can be stated in the language of science but are unanswerable by science because they transcend science (Majone 1989: 3). Majone argues that if scientists cannot claim that their knowledge can be proven knowledge, but can only produce persuasive evidence and reasonable argument, how can policy be justified and legitimated, because 'scientific knowledge is always tentative and open to refutation.' (Majone 1989: 43). As this knowledge is fallible, there is no demonstrable certainty, and therefore, results can only be established by convention – a consensus of experts in the field, setting up methodological and professional norms – the rules of the scientific game.

Majone compares scientific method to craft. When evaluating data and experimenting, scientists are using skills which are not themselves scientific, but are acquired practices and procedures – the 'research process depends more on 'knowing how' than 'knowing that' - he calls this 'a craft, a social process, rather than a purely logical activity' (Majone 1989: 44). These skills are partly personal, partly social and institutional; craft knowledge as opposed to theoretical knowledge. These are professional norms.

Majone goes on to argue that an analytical argument is a blend of factual propositions, logical deductions, evaluations and recommendations, which includes mathematical and

logical arguments, statistical inferences, references to previous studies, expert opinion, and value judgements. Because of this complexity, it is not possible to prove or refute any final conclusion. Therefore, he argues, experts, analysts and scientists use criteria derived from craft experience, including careful attention to the quality of the product, a sense of responsibility to the client and the craft guild, and acknowledgement of materials and tools which apply also to the policy analyst who operates with concepts, theories, data and technical tools (Majone 1989: 44).

1.2.3. SCIENTIFIC ADVICE TO GOVERNMENT

The provision of technical expertise to ministers is the subject of a large section of the literature. How policy makers find the right level of expertise for the issue under consideration, and how scientific knowledge is created and (often) manipulated, is the subject of a great many studies, two in particular are Barker & Peters (1993) and Peters & Barker (1993). Barker and Peters are interested in the advice *process,* and they address some basic questions about the role of advice in government. Both texts examine the nature of information which might be available to government; the range of impacts that different forms of information might have on policy; the type of institutions governments have developed to cope with information; and the role of different levels of information or knowledge on styles of decision-making. Barker and Peters argue that some policy fields, while exceptionally hard to grasp, can nevertheless, with the right technical background, find solutions in science, while other issues turn on technical questions which have no generally known scientific answers (Barker & Peters 1993:1).

At the heart of government in Britain there is a system of advisory bodies known as advisory non- departmental public bodies (ANDPBs), which forms a network of committees, commissions and *ad hoc* panels, and they play an important part in government decision-making. In those areas where scientific advice is needed, government departments can call on the expertise of a complex network of such bodies. Many of these committees also carry out a regulatory role such as monitoring, scrutinizing and licensing. These specialist bodies 'judge the safety of medicine, processed foods, scientific releases into the environment, the nuclear industry, pesticides, and so on.' (Weir & Beetham 1999: 193).

The relationship between science and the administrative aspects of central government is the subject of a vast literature, focusing in particular on the role of government and industry in funding scientific research. Wilkie (1991) charts the way the British state has sponsored science since 1945, and the growth of scientific research bodies funded by government until

the 1970s, when there was a change because 'of government's wish to apply the discipline of the market place.' (Wilkie 1991: 4).

In order to address the research questions listed above, a knowledge of relations between scientists acting as advisors to government, and civil servants who stand between the scientists and the ministers making the final decisions, is required. Gummett (1980) finds that the style of policy-making has not changed in the last 60 years. A more recent account by Weir and Hall of the relationship between scientists and central government which examines the current advisory system is concerned about the effects of commercial interests on the system of advice. While the authors accept the probity and dedication of the experts on the 17 bodies sampled, they found it difficult to rule out the possibility that representatives of the affected industries on the committees can unduly influence their decisions (Weir & Hall 1994). Similar conclusions were drawn by Thomas Barlow, a research scientist himself, who in an article entitled *Science plc*, argued that science and business have become more entangled than ever, and while this may be good for economic growth, it can be bad for scientific authority (Barlow 1999).

The work of Sheila Jasanoff, which mainly considers the regulation of science and technology in the United States of America, sees environmental knowledge as being shaped by organisational culture, and shows how this is limited to formal legal processes. On the problems of science informing policy, Jasanoff believes that a technical policy decision needs a judicious mixture of scientific and non-scientific judgement, but must avoid allowing experts to 'use up' that part of decision-making, which should remain political (Jasanoff 1990: 9). Jasanoff also has views on policy-making in Britain which are similar to those made by Weir and Hall and Barlow, above. In her study of the BSE crisis, for example, Jasanoff notes the consensual nature of the British advisory system, where policy is formulated by a closed system of the 'great and the good' (Jasanoff 1997: 227).

So where does this Thesis stand in relation to the literature on science and politics? Although the studies reviewed tell us much about the social standing of science and how science fits into the political process, much of it is in the nature of general surveys, either histories of science-government relations, or summaries of the arguments about science and scientist's place in society. All of this gives some insights into the problems for government and science but does not help us understand the problems faced by expert advisory bodies, and this Thesis is concerned with the specific task of exploring how scientific bodies actually arrive at solutions to problems and how this is used by government. The works of Barker and Peters, while debating the problems surrounding this advisory process, do not go into

detail about how the advisory system works. Gummett's book (1980) is a definitive survey of the relationship between science and the administrative machine of British central government, and contains descriptions of Whitehall scientists and scientific civil servants, but it is very dated, and there have been important changes in funding arrangements and civil service organisation during the 26 years since this book was published. The present research does not attempt to rework this literature, nor does it aim to produce a further study on expert advice to government. Rather, it aims to look at specific cases of policy-making in contemporary Britain through theoretical perspectives in order to see where the actual decision-making is located, and if there is a particular culture at work.

1.2.4. IMPLICATIONS FOR POLICY

Studies on the links between science and politics, whether they are academic articles, polemical essays, or official studies and reports, are numerous, and reference has been made to many of them throughout this Thesis. However, in attempting to achieve the aims of the research – to analyse and evaluate how governments go about handling scientific uncertainty – it seems that despite the quantity and variety of literature on risk; risk assessment and management; expert advice to government; and scientific uncertainty, there are, to my knowledge, no *in-depth* studies of specific instances of how governments use the scientific advice system that attempt to place policy problems within the dual framework of sound science and the precautionary principle. There are, of course, numerous, usually short, case studies in this literature, such as, acid rain; leukaemia at Sellafield; and the effects of lead in petrol, but they do not examine in any great depth, the way government scientific expert bodies actually work. And although there have been numerous studies on two of my four cases - BSE, and the regulation of GM technology - there has been no study that compares the two, nor has either OPs in sheep dip or the MMR case been covered in the social sciences literature. My use of sound science and the precautionary principle to examine these issues is helpful in highlighting how government policy has been made over recent years in respect of such issues. My conclusions suggest that it would be of value for the government, or perhaps the parliamentary select committee that reviews administration, to examine the workings of scientific advice provided to government, with a view to determining why the government is still resisting the precautionary approach to environmental policy-making.

1.3. Hypothesis

Historically Britain has resolved environmental problems by commissioning scientific research that is based on conventional scientific method. This, I propose, is a sound science approach that often resists demands from environmental non-governmental organisations (NGOs) and consumer pressure groups, to adopt a more precautionary approach. On the

other hand, during the 1980s, the British Government gradually came to accept the wisdom of the precautionary approach as a general rule, and it signed up to international treaties and EU Directives that included explicit commitments to the precautionary approach. The case study evidence presented in this Thesis demonstrates the tensions that have arisen over the government's commitment to precaution, and the many political pressures that have sometimes prevented more precautionary decision-making. Policy decisions that ENGOs believed should have been based on a precautionary approach were in fact based on what the government of the day decided was politically expedient. Conversely, the GM crops case, as we shall see, demonstrates how early regulation that was considered adequate for a novel technology, came under political pressure, and caused a move to more precautionary research.

In summary, it seems that while the reductive, quantitative scientific approach did change to include knowledge other than scientific knowledge, governments remain suspicious that a fully precautionary approach to environmental problem solving may pose a threat to the activities of industry and to technological innovation. My hypothesis is therefore that:

> *The British Government, while accepting the precautionary principle as guidance in environmental policy-making, to which, as an EU Member State, it is firmly signed up, still has some reservations about whether this may threaten the activities of industry and interfere with technological innovation.*

1.4. Theoretical Framework

1.4.1. SOUND SCIENCE AND THE PRECAUTIONARY PRINCIPLE

The theoretical basis for the Thesis will be organised around two approaches to environmental policymaking: the sound science approach and the precautionary approach. Many of the environmental issues mentioned above, reveal a split between those actors who take a mechanistic view of science that relies on the presence of firm evidence of risk, (a simple cause-and-effect approach), before taking any remedial action; and those who would take a more precautionary stance, which entails that where ever there is a potential problem with a technology, some form of risk assessment must be carried out to ensure it is safe.

These distinct views of how governments may approach environmental and public health problems will be used to analyse the specific policy areas and discover whether there is a fit between actual policy approaches and the theoretical approaches. Chapter 3 is devoted to a detailed explanation of these opposing theories.

1.5. Methodology, Evidence and Presentation

The methodological approach of this project is a qualitative one and was chosen because the study of the inter-relations between governmental institutions and a wide variety of societal actors is a highly complex issue which needs an exploratory and interpretive handling of evidence in order to explain the social interactions of scientists and politicians. The alternative quantitative approach, which requires reliable 'hard' and replicable data, did not seem likely to be able to achieve this. Ultimately, the aim was to locate an evaluation of the government's science policy-making within a framework of theoretical and empirical research into the relations between science and public policy.

The research was carried out by the use of four case studies that analyse the way in which British governments have used the advice of expert bodies to formulate policies on organophosphate (OP) in sheep dip; the commercialisation of GM crops; the BSE crisis during the period 1985 to 1998; and the MMR vaccine policy. The case studies have been carefully chosen because they are significantly both similar and dissimilar. The similarities are threefold: first, three of the issues are agricultural; second, they are all politically salient; third, they all involve deep controversy over scientific evidence. The dissimilarities are fivefold: first, the OP issue and the BSE affair have comparative long histories (over thirty years and 13 years respectively) whereas the GM issue and the MMR problem are of comparatively recent origin. Second, the BSE affair and the MMR problem are examples of specific sets of events, unlike the OP and GM issues, which continue to unfold; third; the OP and BSE issues affect a small number of known people, whereas the GM issue could potentially affect many, as well as the natural environment; and making changes in the MMR immunisation policy may precipitate an epidemic of measles; fourth, the damage done by OPs and BSE has already been inflicted, whereas the fears raised by GMOs and MMR relate largely to the future; fifth, the sheep dip problem and the BSE crisis involved mainly one governmental department - the Ministry of Agriculture, Food and Fisheries (MAFF), now reorganised and renamed as the Department for Environment, Food and Rural Affairs (DEFRA) - whereas the GMO problem, because it is linked to the biotechnology industry, involves several Government departments and agencies for example, the Department of Trade and Industry (DTI), the Department of Health (DH) the Office of Science and Technology (OST); while the MMR policy only involves the DH and its expert committees.

There have been some constraints on what I set out to do in this Thesis. In particular, time constraints prevented a more thoroughgoing examination and analysis of the highly complex scientific advisory system at the centre of the Thesis, which will require a larger survey of the system and the members than I was able to undertake. A study of this type

could include the way in which scientific research is funded, and the peer review system that is so influential in research funding, because the system of scientific advice is linked to these issues. Also relevant is the power of interest groups, and it would be useful to research the way industry front groups produce 'educational' material (both in print and on the internet) that may influence the debates. A further suggestion for future research is an analysis of other cases, to see whether my findings of the British government's continued adherence to the sound science principle at the expense of the precautionary principle, is replicated elsewhere.

1.5.1. WHY CASE STUDIES?

Case study as a research strategy is a useful method as it centres on building explanations for complex social phenomena and is preferred where quantification of data is not the aim, and the qualitative data can be presented in a narrative fashion, and where several cases are presented for comparison purposes. The strength of the case study is 'its ability to deal with a full variety of evidence – documents, artifacts, interviews and observations' (Yin 1994: 20), and it is the most appropriate strategy when 'how' and 'when' questions are being posed. The nature of the research questions in this Thesis, itemized earlier, involves questions of 'how' and 'why', and suggests therefore, an approach that Yin names an explanatory case study (Yin 1994:1). Therefore, the approach taken in this Thesis is to present each of the four chosen topics as an explanatory case study. By doing this the events of the four topics can be analysed in order to establish sequences of events which are then used to test the theoretical concepts. The case study chapters have all been designed to follow a standard format – a brief introduction to the topic; an outline of the points at issue; the background to the issue; a discussion of the technical problems involved; the scientific research undertaken; governmental policy and the regulatory process; and a final discussion section to identify whether a sound science or precautionary approach has been employed.

1.5.2. DATA GATHERING METHODS

Evidence to support the theoretical perspectives and the case studies has been gathered in a number of ways. First, in constructing the theoretical framework within which I intend to analyse the events of the case study topics, it was necessary to begin with an historical account of science and technological policy making in British governance in the post-war period. This was not, of course, original research, but a synthesis of currently available evidence from the literature reviewed above.

Second, for both theory and the cases, an in-depth investigation of the government's scientific advisory committee system was needed: an examination of their organisation, structure and recruitment of members.

Third, evidence to support the case studies was gathered in a number of ways. The main method of obtaining data was the study of official and non-official documents such as Parliamentary Select Committee reports, government departmental reports (for example, DEFRA's GM Science Review Panel Report), and White Papers; scientific research reports from university departments; academic journal articles; and contemporary newspaper reports. This evidence was supplemented by interviews with Members of Parliament, members of advisory committees; research scientists and members of advocacy groups such as OP Information Network and Green Alliance. Additional material is from library-based sources on the four case study topics. A comparative analysis was carried out on the four case studies.

1.5.3. INTERVIEWS

The interviews mentioned were undertaken to provide insights into aspects of the policy areas dealt with in the Thesis that could not be obtained from archival sources. They were designed to answer the research questions listed earlier and were conducted either face-to-face or by telephone, and of a semi-structured nature in that there was no rigid framework for the interviews. They began with questions to elicit facts about the interviewee's background and occupation, followed by questions structured around either the theoretical issues (that is sound science and precautionary science), or the research questions listed above, depending on the interviewee. This interview strategy fits with the case study method because, as Yin states '...case study interviews are of an open-ended nature, in which you ask key respondents for the facts of a matter as well as for the respondents' opinions about events' (Yin 1994: 84).

Fourteen interviews were conducted with various actors who, it was thought, would throw light on the research questions and the theoretical models. In addition to these personal interviews, opinions expressed by a large number of people, academic practitioners; politicians; biotechnology industry representatives; and spokespeople for consumers groups, who gave presentations at a number of conferences, were included. Of those interviewed, two were research scientists who were chosen because they had not served on any government advisory body and were interviewed in order to get some idea of how research scientists work. These research scientists were Dr Elaine Mutch, a researcher at the Medical School at Newcastle University, who is currently working on a project concerning OPs in sheep dip commissioned by DEFRA; and Dr Bill MacFarlane Smith, who is a Research Fellow at the Scottish Crop Research Institute (SCRI) with many years of researching GM crops. Two agricultural scientists were interviewed for similar reasons. These were Professor David Harvey and Dr John Lingard, both specialists in agricultural economics at

Newcastle University. Three other academic scientists, Professor Alistair Hay, Dr Mike Joffe and Dr Vyvyan Howard, are currently serving as members of Government advisory bodies, and were interviewed to gain insight into the workings of scientific advisory bodies. They were asked questions that focused on risk assessment, and precautionary versus sound science themes. Two politicians selected for interview because of their experience on science and government, were Michael Meacher, MP, who was Minister of State for the Environment during the course of the development of regulations for GM crops and also had a serious interest in the use of pesticides in agriculture; and Dr Ian Gibson, MP, who is currently the Chairman of the Parliamentary Select Committee on Science and Technology and was questioned about an MP's ability to deal with scientific matters that come before the House of Commons. In order to understand the pressure group perspective on the policy areas considered in this research, three members of such groups were included in the interviews: Alison Craig of the Pesticide Action Network (UK) provided help on sources of information regarding OP use in agriculture; Elizabeth Sigmund of OP Information Network provided many insights into sheep dippers' problems; and Julie Hill of Green Alliance who served as a lay member on ACRE for 9 years, was a member of the Government's GM Science Review Panel and is currently Deputy Chair of the Government's Agricultural and Environmental Biotechnology Commission (AEBC), provided useful insights into what it is like to be a lay member of government advisory committees. Two academics who had served on the GM science review panel, Carlo Leifert, a Professor of Ecological Agriculture, and Dr Andy Stirling, a social scientist specialising in risk management, provided valuable information on the workings of this panel. Insights from the point of view of occupation and environmental health were provided by an interview at Stirling University with Professor Andrew Watterson, an occupational and environmental health researcher. A list of these interviewees is in Appendix 1.

As mentioned above, in addition to these interviews, a number of conference presentations provided useful insights, notably speeches by Professor Sir David King and Professor Robin Grove-White on scientific uncertainty; and presentations by Dr Mae-Wan Ho, Dr Arpad Pusztai, Professor Joe Cummins and Dr Stanley Ewan, on their views about GM crop research. Professor Peter Saunders gave a comprehensive presentation on the precautionary principle, while Bernard Marantelli put forward the biotech industry viewpoint. Green group concerns were provided in presentations by Dr Brian John of GM-Free Cymru and Laurence Woodward of the Elm Farm Research Centre on organic farming and GM crops. Full details of these presentations are also in Appendix 1, with details of the conferences/briefings listed in Appendix 2. Printed copies of the individual presentations were obtained and these were supplemented by personal notes taken at the time they were

presented. Understandings and insights from these interviews and presentations have been incorporated into the Thesis where appropriate and relevant.

1.6. Structure of this Thesis

Although this Thesis is about science/government relations in Britain, the research topic needed to be put into the wider context of the history of the governance of science in Britain, and the specific arrangements for scientific and experts advice to governments. Similarly, the case study topics needed to be seen against a background of the nature of scientific enquiry. These matters are dealt with in Chapter 2, which sets the overall context for the Thesis.

Chapter 3 provides a theoretical model of how governments in Britain deal with risk and environmental hazards. The chapter begins by outlining the development of environmental politics in Britain, demonstrating its traditional fragmented approach to solving environmental problems, and in more recent years how the culture of science advice has slowly changed to a more inclusive approach to environmental decision-making. The chapter then conceptualises two approaches to policy-making on environmental issues: sound science and the precautionary principle. The Chapter explores these concepts fully and explains how the selected policy areas are analysed in order to see whether or not there is a fit between the actual policy approach and the theoretical approach.

The following four chapters examine the specific policy areas outline above. Chapter 4 examine the decades-old problem of ill health in those people involved in OP sheep dipping. The study outlines the regulatory regime in place for the control of pesticides, and investigates the scientific advisory bodies concerned with this problem.

Chapter 5 investigates a more recent policy problem for policy makers. It describes the issues and controversies surrounding the government's eagerness to introduce GM crops into Britain. The case study covers the potential risks to biodiversity of the commercialisation of products resulting from this technology; examines the regulatory regime for this issue; and evaluates the Government's strategies for allaying public fears about GM crops and food.

Chapter 6, unlike the previous two case studies, which are ongoing policy problems, looks at a historical example of a policy fiasco, and mainly relies on the Phillips Report (2000), House of Commons Select Committee on Agriculture reports and other archival records. The chapter describes the discovery of BSE, a new disease in cattle; examines the scientific evidence and how it was handled by governmental expert bodies, and evaluates the official research and regulatory control system.

Chapter 7 is an example of the workings of medical science, which demonstrates how irresponsible media reporting created public anxiety over a previously uncontroversial vaccination policy (MMR) based on sound science, and forcing the Government to consider a more precautionary approach.

In each of these case studies, I provide both a chronological account of events, and an analysis of the Government's policy options and decisions, its regulatory stances and research efforts, to determine whether it maintained a sound science or a precautionary science approach to policy formulation.

One of the problems in pursuing these aims was the danger of becoming too involved in the detailed scientific and technical details of the issues and resorting to the specialist language of science. To this end, I used, where possible, lay explanations of scientific research, and any technical data that I thought necessary to include is kept to a minimum.

The final chapter, Chapter 8, concludes by analysing and comparing the case studies under the themes of how scientific evidence and expert advice was used; disagreements about scientific evidence, method, evidence and uncertainty; and examines these themes across the four case studies.

CHAPTER TWO

The Governance of Science in Britain: Setting the Context

Britain has produced 44 Nobel laureates in the last 50 years, more than any country except the US. But this statistic does conceal a problem we must acknowledge. Only eight of those laureates are in the last 20 years. We have relied for too long on tradition and sentiment to aid scientists. We need strong funding and strong public support, not just the warm glow of our traditions. (Speech by Tony Blair 23.5.2002).

2.1. Introduction

It is a commonplace observation that the world today is one in which scientific and technological advances enable us to live much more comfortable lives than in past generations. Technology is an integral part of human life: it is difficult to 'belong' if one does not communicate by telephone or email; many people have lost the ability to calculate without the pocket calculator; and processed food is part of today's busy lifestyle. And, of course, governments in modern states enthusiastically encourage the wealth-creating potential of new scientific knowledge and new technologies. This has changed society. Advances in transport technology have changed employment and residential patterns; medical discoveries have improved lifestyles and extended life expectancy; while telecommunications technology has altered not only the way we do business (email, fax, internet and mobile phones), but also our social life and leisure pursuits. So a key tenet of modern political economy is that new technologies should be allowed to enter markets in order that they may help shape society (Grove-White 2001: 467). This means that in developed countries, capitalism is the driver of modern economics primarily because it provides the funds for research that produces technological innovations, and that science and technology are at the heart of the political economy.

The championing of science is therefore a logical and perhaps obvious aim of modern government. However, striving for scientific excellence creates some problems as it solves others. 'Human-made catastrophes appear to have increased with industrialization as we built devices that could crash, sink, burn, or explode.' (Perrow 1984: 11). Three Mile Island, Bhopal, Sevesa, Chernobyl and acid rain are all well-known examples of large-scale

technological failures causing grave environmental degradation in recent years; while BSE and the outbreak of foot and mouth disease in Britain and parts of Europe during 2001 are recent examples of failures in agricultural technology posing potential harm to human and animal health. In Britain during the past few decades, there has been a considerable amount of time given to studying the problems of technological innovation and associated risks. For example, there are Royal Society reports on *Risk Assessment* (1983 and 1992); Royal Commissions on the Environment (RCEP) reports, on *Environmental Pollution* (1998), and *Setting Environmental Standards* (1998); and Parliamentary reports such as that on *Science and Society* from the House of Lords Technology Select Committee (House of Lords 2000). But these have been top-down scientific assessments and have left the public more or less out of the debate.

In carrying out risk assessments, scientists use their own traditional methods of investigation which entails that knowledge develops incrementally over time, with acceptance of new facts taking many years, and in some cases decades. This approach is the accepted way, the scientific method of the scientific community. However, modern society demands scientific assessment much more quickly. Will that new cosmetic cause skin rashes? How much pesticide can be in river water before it becomes dangerous to fish health? Governments require answers to such questions as a matter of urgency and cannot wait several years for the scientific community to agree on new knowledge. The inability of scientists to give firm opinions quickly on issues is therefore, a real problem for governments and the general public. Governments are faced with the prospect of attempting to incorporate scientific uncertainty into legal regulation, while at the same time facing the public demand for immediate reassurance.

There are, then, challenges for scientists, policy-makers and the general public, and there are no shortages of critics. According to Ulrich Beck, we are living in a risk society: 'The once highly praised sources of wealth (the atom, chemistry, genetic technology and so on) are transformed into unpredictable sources of danger' (Beck 1992: 51), and, therefore, the uncontrolled introduction of new technologies is not an unmitigated blessing, as the increasing use of technology seems to produce a rapidly extending array of negative side effects (Hetman 1977: 4).

This chapter aims to put the chosen research area and the case study topics into the context of Britain's science-government relations by considering, in part one, some of the theoretical perspectives on the nature of scientific enquiry, and some of the problems of the system of expert advice to government. Part two will outline the history of science-government

relations in Britain since 1945 and examine the institutions involved in the governance of science.

PART I

2.2. The Politics of Expert Advice

Dealing with the hazards associated with scientific discovery and technological innovation in the pursuit of wealth requires expert assessment and management by scientists, civil servants and politicians. But attempts to define risks and hazards and ascertain whether they are serious enough for some form of remedial action, often ends with scientific uncertainty about the issue in hand. Mishandled scientific issues may create a crisis of confidence in the general public. The BSE affair provides a good example of this: the Government's use of scientific advice was central to the crisis: all of the official and ministerial pronouncements during the crisis emphasised the scientific evidence used in their decision-making. This resulted in conditional and contingent scientific conclusions becoming assertions of 'fact' that created a false sense of certainty (Willis 2001:12).

Collingridge and Reeve (1986) examine the traditional relationship between science and policy-making and the myth that 'science yields the truth' (Collingridge & Reeve 1986: 7). These authors argue that policy cannot be based on science because scientists tend to disagree about the exactness of items of data, which is unhelpful when applying the results to policy-making (Collingridge & Reeve 1986: 26).

Yet expert scientific and technical advice is very important and becoming increasingly more so. But as issues such as the BSE crisis show, the advisory system in Britain is not working well. The problem for policy-makers is that most policy fields require elements of scientific or technical expertise of some sort in order to cope with the complexity of the issue in question. Barker and Peters (1993: 2) have compiled a useful classification of the levels of technical difficulty in public policy fields (see table 2.1), and demonstrate how at a basic level, the policy field may have complex and elaborate detail yet must be understandable to the many actors involved, within a set of rules for guidance; while at the highest level, the policy field has technical difficulties bordering on the unknown, where there are no scientific answers. 'At the highest levels of technical difficulty, the experts cannot claim to know enough to create a scientific consensus or even to maintain a fairly stable scientific difference of opinion....Any policy based on some particular view or guess as to the facts of the matter would be speculative.' (Barker & Peters 1993: 3). It is this particular level that is at the heart of my Thesis. As Weinberg puts it:

> Many of the issues which arise in the course of the interaction between science or technology and society – eg. the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science – hang on the answers to questions which can be asked of science and yet *which cannot be answered by science.* (Weinberg 1972: 209 – italics in original)

He calls this *trans-science*, questions of fact that can be stated in the language of science but are unanswerable by science because they transcend science (Weinberg 1972: 209). Therefore we must accept that scientists can 'only supply more or less uncertain factual information about probabilities, but never answer the question: which risk is acceptable and which is not.' (Beck 1998: 14).

Of course, there are two different points being made here. First, Barker and Peters make a technical point, that the science can be so complex that it defies understanding even by experts at the moment. But Beck makes a categorical point, that there is a difference between technical knowledge and ethical opinion. However, as Ho observes, the distinction between 'fact' and 'value' is much more blurred than this. 'Science is not to be seen as a collection of irrefutable, neutral "facts", divorced from ethics, or politics, and independent of how we observe at the fundamental level.' (Ho 2002).

So, in addition to the ethical issues which lie outside the realm of science, there are important value-laden issues which lie within the realm of science. Given these ambiguities, it is hardly surprising that recent policies involving the handling of uncertain scientific knowledge, such as the afore-mentioned BSE crisis during the 1990s, have led to serious questions being asked about the use of expert advice by governments, and have resulted in a climate of public mistrust in science. The House of Lords Select Committee on Science and Technology recognised this in a recent report that considered how uncertainty and risk may be quantified and communicated. Referring to the problem that 'scientific input to policy traditionally relies on "independent experts"', it pointed out that the concept of independence has become problematic, particularly because of the increasing commercialisation of research (House of Lords 2000: 3). For instance, according to one medical practitioner, '(a)round half of postgraduate education for doctors is funded by industry. And around two-thirds of clinical trials in Britain are funded by the pharmaceutical industry' (Feinmann 2003: 63). Practices such as peer review and declarations of interest had not helped to dispel public distrust, and a 'radically different approach to the process of policymaking in areas involving science is called for.' (House of Lords 2000: 3). It is important, therefore, to study the

scientific advisory system in detail. First, however it would be helpful to consider the nature of science and technology.

Table 2.1: Six levels of difficulty in public policy fields

Policy field's character	Possible examples in health care
Elaborate detail	The organisation and monitoring of community doctors, and other medical service's records and routine provision.
Complexity	Organisation and monitoring of hospital services or the supply of different types of nursing care.
Technical difficulty but – like those above - amenable to non-expert study	Priority distribution of scarce resources such as kidney machines; operating theatre use.
Technical difficulty which those with expert training (eg epistemological data or probabilistic mathematics, statistics, economics, medicine) can appreciate and judge.	Strategic budget plans based on epidemiological data or probabilistic analysis of future health care needs; cost-benefit studies of potential health care priorities.
Technical difficulty bordering on the scientifically unknown, and with rival and controversial scientific views on offer.	Various claimed cures, reliefs, vaccines, etc for important diseases or conditions; various medical strategies for coping with major health threats such as AIDS, drug addiction or degenerative conditions among the elderly.
Scientifically unknown: no rival claims from experts.	Diseases (such as Alzheimer's or Parkinson's) with no known treatment or cure and no claims yet entered by medical researchers.

(Source: Barker & Peters 1993)

2.3. The Nature of Scientific Enquiry

2.3.1. WHAT IS SCIENCE AND TECHNOLOGY?

According to the Dainton Report, '...science is a means of obtaining knowledge about the structure and characteristics of the animate and inanimate world, and its importance to human society is that such knowledge is at the base of nearly all human activities.' (Dainton 1971: 2). Science arose from early scholar's attempts to understand the world around them. By the

middle ages, philosophy was dominated by three powerful teleological influences: Plato, Aristotle and religion. By the seventeenth century, scholars began to focus more empirically on the physical world. The distinctly systematic approach to the search for understanding reality seems to have begun with Francis Bacon (1561 – 1626) who was interested in knowledge for its own sake. His book *Novum Organum* (1620) signalled a radical departure from the traditional method of scientific enquiry by grounding human understanding in observation and experience and rejecting the Aristotelian teleological method. Bacon believed that Aristotle was too concerned with logical possibilities and did not consider enough actual physical things and events. And so in modern times, scientific method is generally thought to be a development from the natural sciences; in particular from classical mechanics, a branch of physics, which can be seen in the work of Isaac Newton, who attempted to explain the movement of visible objects over space and time (Fuller 1997: 16). Modern science is considered to be valid knowledge because it adheres to a certain methodology: a step-by-step process, a typical exposition of which would be:

1. Observe and describe some phenomenon.
2. Form a hypothesis to explain the phenomenon and its relationship to other known factors, usually through some kind of mathematical formulae.
3. Use the hypothesis to make predictions.
4. Test those predictions by experiments and further observations to see if they are correct.
5. If not, reject or revise the hypothesis. (Wolfs 2000).

Closely connected to scientific method is the idea of peer review, a system in which groups of experts (usually anonymous) are set the task of passing judgement on the work of other research scientists. Peer review is used after the research has been completed to decide whether the results should be accepted for publication in a scientific journal. Generally, scientists accept the system as a necessary and fair way of judging the validity of scientific research and a way of protecting against scientific error and bias. However, some people believe that peer review can 'institutionalize conflicts of interest and a certain amount of dogmatism.' (Rampton & Stauber 2001: 198). On this view, the problem with the peer review system is that because in the modern world science is divided into ever-increasingly specialised sub-groupings, the peer reviewers are likely to be either colleagues or competitors of the scientists they review. An important medical scientific journal, recognising this, has recorded its dissatisfaction with the system:

> The problem with peer review is that we have good evidence on its deficiencies and poor evidence on its benefits....We know that it is expensive, slow, prone to bias, open to abuse, possibly anti-innovatory, and unable to detect fraud. We also know that the published papers that emerge from the process are often grossly deficient *(BMJ* 1997: 759).

In a recent article in the *New York Review of Books,* Richard Horton, editor of *Lancet,* complains of the pressure on editors of science journals to adopt positions favourable to industry. He explains how a pharmaceutical company will sponsor a scientific meeting: speakers will be invited and paid a fee to present papers on a drug on which they have known views. The company will then convert the presentation into an article for publication, usually as part of a collection of papers from the symposium. The collection is then offered to a medical publisher who will seek a reputable journal to publish the papers, commonly as a supplement to the main journal. The peer review process is minimal in these cases (Horton 2004b). An ex-Minister also reflects this view, 'companies have learnt that small investments in endowing chairs or sponsoring research can produce disproportionate pay-offs in generating reports, articles and books which may not reflect the public interest, but certainly benefits corporate bottom lines' (Meacher 2004 – personal interview).

Where does technology fit into this system? It is usually assumed that technology arises from science, that technology is applied science. However, technologies such as cooking techniques, medical remedies, the plough and the water wheel were not developed through the application of pre-existing science: they were not discovered through the use of any natural laws, but arose from collective learning. Therefore, while science and technology are, of course, connected, it is not wholly one-sided, with technology dependent on science.

2.3.2. THE PUBLIC UNDERSTANDING OF SCIENCE

There are certain attitudes to science that are sceptical and antagonistic. When considering the public understanding of science, it is important to be aware of influences that may affect that understanding. These include those environmentalists, and others, who charge science and technology with squandering natural resources and for poisoning the environment. One academic scientist warns '...that scientists should be less uncritically self-serving...' and 'be more thoughtful about the applications of the results of their research.' (Shils 1971: 449). On the other hand, NGOs such as Greenpeace and Friends of the Earth (FOE) are often charged with being anti-science, because in their campaign on such issues as climate change, chemical pesticides and GM agriculture, 'they [NGOs] are all too slick, you know, and who gets to the public first wins the argument (Gibson 2004 – personal interview). It is, therefore,

crucial that the public understand the purpose of science and its place in government policy-making, because people now question authority, including scientific authority more than ever. This point was addressed by the House of Lords Select Committee on Science and Technology, in its report on *Science and Society*. The report noted that 'when society has a problem with science, it is often over the question of uncertainty and risk. How uncertainty and risk can be quantified and communicated are questions of great concern, with no simple answers' (House of Lords 2000:7). A good current example of this is the way parents reacted to suggestions that the MMR vaccine may cause autism, despite reassurances from the government's Chief Medical Officer and several research exercises which concluded the vaccine was safe. The Government has to some extent addressed this issue by drawing up guidelines on the use of scientific advice in policy-making (OST 2000). Nevertheless, the issue of taking into account public attitudes to science, which entails a great range of values, is a concern for governments. The Royal Commission on Environmental Pollution (RCEP) recognises this in its 21st Report, *Setting Environmental Standards* (1998). While scientific appraisal and risk assessment were to remain central to standard setting, there was a recommendation to extend the circle of consultation to include public values (RCEP 1998: 136).

There are some who are sceptical of the idea of public values being included in the policy process. A 'socially inclusive approach' is bad for science because 'whatever the views of ordinary people, they still only remain subjective opinions' (Durodie 2002a: 33). However, some recent research refutes this viewpoint. A report on public perception of GM technology reveals that in Europe the lay public's perceptions of agricultural biotechnologies are not, as some might suppose, based on subjective or emotional responses, but are based on empirical knowledge, although this is different to the specialised knowledge used by scientists (Marris et al 2001:9). The report lists three kinds of lay knowledge:

- Non-specialised knowledge about the behaviour of insects, plants and animals (for example, 'bees fly from field to field'), which it seemed to them was often ignored or obscured in specialised scientific discussion.
- Knowledge about human fallibility, derived from their daily experience, which had taught them that formal rules and regulations, though well-intended, would not, in the real world, be fully applied.
- Knowledge about the past behaviour of institutions responsible for the development and regulation of technological innovations and risk (Marris et al 2001: 10).

The social standing of science has been the subject of a long interdisciplinary clash since the end of the Second World War. At that time, science had become very important and influential, both militarily and in industry. However, the involvement of scientists in munitions manufacture and the development of the atomic bomb were creating public concern, with questions being asked about how scientists fit into society, culturally. Modern societies are dependent on the power of science and technology, but cannot simply rely on scientific knowledge and authority remaining the privilege of scientists alone, otherwise the public will become alienated from the very power that creates the wealth of society. Furthermore they may lose confidence in science when scientists publicly disagree. This controversy has resulted in a debate about the nature and uses of science.

The main dichotomy in this debate is between (1) those who believe that the classic scientific method renders a scientist's knowledge quite distinct from other bodies of knowledge and that science is a vehicle for delivering the truth; and (2) those who argue that the production of scientific knowledge is highly influenced by social factors, and is therefore a social construct.

The former approach asserts that science as an institution aims for rationality and objectivity through the use of quantitative methods and measurable phenomena. Scientific knowledge, then, is said to have been proved to be true because it corresponds to the natural world. Or, in the opinion of one science writer '.(s)cience requires dispassionate distance and detachment from the objects of its study – meaning it isn't always suited to "accessibility", "inclusion" and "dialogue"' (Durodie 2002a: 33). According to this view, science aims at transcending other forms of human belief because it is a form of knowledge based on fact, whereas other forms of belief lack validation: for example, moral convictions are evaluative and not based on generalisations from observed instances of moral conduct. 'Moral beliefs do not reflect reality but are intended to dictate to it.' (Yearley 1988: 18).

An important characteristic of scientific method is its supposed objectivity. However, critics argue that there is a subjective element of value-judgement that is inevitable in conducting scientific investigations. For example, in the case of a toxicology investigation, the setting up of an experiment would include the deciding on test parameters, the choice of the test species, the scope of the mission, age and sex of the animals to be experimented on, the route and duration of the test substance, the length of the observation period and many other factors (Coleman 2002: 3). All of this is subjective judgement, which is unavoidable in human affairs in general, and in the conduct of scientific investigations in particular.

The work of Thomas Kuhn, an historian of science, shows how, although scientists customarily regard science as driven by the search for truth, scientific activity is governed by a set of intellectual assumptions agreed by the scientific community (a paradigm) where existing theories have been agreed and all research is made to fit the paradigm (Kuhn 1970: 10-11). This is what Kuhn named *normal science*. But in relation to environmental policy, these traditional accounts of scientific practices may have limited use because many of the structures and phenomena involved are extremely complex and often bedevilled by uncertainties. In this case, the puzzle-solving of normal science is not enough, and a *post-normal science* approach is necessary, which involves a wider consultation of actors than scientists (Funtowicz & Ravetz 1999).

One scientist, Terence Kealey, a clinical biochemist and science writer, is keen to separate the institutions of science from the scientists. Science the institution, he asserts, should be trusted because it 'is the wonderful abstract process by which observations are meticulously and objectively made, hypotheses are fairly tested, and experiments are honestly performed. But science in the real world is the process by which scientists earn their salaries.' Scientists, he states, are human beings and he believes that public choice theory (the argument that individuals will act in their own interest) applies strongly to scientists because they ' have spun a semi-divine aura of rectitude and purity around themselves that protect them from the usual criticism that most professional groups encounter' (Kealey 1997: 262).

Some social scientists who are critical of scientific method, particularly in the arena of environmental problems, use this line of argument. They argue that social and cultural processes are at work that are not recognised under classic scientific investigative methods (*inter alia* Douglas 1985; Douglas & Wildavski 1982; Cutter 1993; Irwin & Wynne 1996). In this approach, environmental risk analysis is not linked to objective risk measurements or the physical reality of risk; rather it 'reflects moral, political, economic and cultural power positions that (are) value laden and culturally constructed.' (Cutter 1993: 22).

This is a problem for policy-makers, because if scientists cannot claim that their knowledge can be proven knowledge, but can only produce persuasive evidence and reasonable argument, how can policy be justified and legitimated?

PART II

2.4. The Governance of Science in Britain

2.4.1. SCIENCE-GOVERNMENT RELATIONS IN BRITAIN SINCE 1945 – A REVIEW

In Britain, as elsewhere, there has been enthusiasm about the adoption of new technologies for the benefit of society. This can be seen clearly in the recent DTI White Paper: *Excellence and Opportunity – A Science and Innovation Policy for the 21st Century* (DTI 2001) that states:

> To be a successful nation we must make sure our science base is strong and excellent, that we have the facility to quickly transform the fruits of scientific research and invention into products and services that people need to improve their well-being and quality of life. (DTI 2001: 2).

In this White Paper, the government argues that if Britain is to become the 'scientific hub of the world economy' the country must invest in science, with the government playing the role of an investor, facilitator and regulator of science and innovation (DTI 2001).

However, while governments in Britain have been patrons of science in recent times, science did not have much real impact on political life until developments after the Second World War, when, against the background of the Cold War, science and government together became important for the development of weapon systems and nuclear power and the reorganisation of the peacetime economy.

After 1945, the structures created during the war to channel scientific advice to decision-makers had to be re-organised for peacetime use. The Attlee government created such institutions as the Advisory Council on Scientific Policy (ACSP) whose membership included the secretaries of the research councils and the chairman of the then University Grants Committee. One of ACSP's early responsibilities was the supply of scientific manpower. A further innovation was a taxation policy that gave industry incentives to join or to form industrial research associations (Wilkie 1991: 54). These, and other changes, resulted in much closer links between science and government, with scientists, economists and other specialists increasingly integrating into government administration and planning.

Government-science institutions in Britain have never been centralised in any one government department; rather scientific bodies and agencies have grown piecemeal over time. But in general, the administration and financing of science, has, since 1916, been organised around research councils, a system of grant awarding bodies operating under the

loose supervision of special committees of the Privy Council and its Chairman, the Lord President (Vig 1968: 3). This meant that while government funded science, it was channelled through a system of independent bodies, thus allowing scientists 'almost untrammelled freedom to pursue whatever research they found interesting' (Wilkie 1991: 125). These funding arrangements have changed since the 1960s.

During the 1960s, increasing international economic competition led to concern over the character of scientific research and over the quality of scientific and technological education. The period 1959 – 1964 saw a serious science policy debate in which it was recognised that the current system, a hodge-podge of wartime institutions, was not working efficiently and that there was a need for co-ordination of the various agencies and for a rational system for deciding priorities for the distribution of funds for scientific research and education (Vig 1968: 35). This was at a time of worsening economic conditions, and the government was under pressure to take some action. A Committee of Inquiry under Sir Burke Trend in 1962 looked at the importance of government funding of scientific research and considered whether changes were needed in the procedures whereby agencies were financed and held accountable for their expenditure (Gummett 1980: 42). The report revealed that the Higher Civil Service had no one with a scientific background, and furthermore, that the civil service scientific system did not constitute a coherent and articulate pattern of organisation. The report recommended the creation of machinery for determining priorities between research councils. With amendments by the Wilson Government, this set a pattern for the organisation of government science that has prevailed ever since (Wilkie 1991: 77).

This period of policy reform led to the creation of new institutions such as the Department of Education and Science (1964), a Ministry of Technology and the Science Research Council (1965). During the decade 1955-65, total government spending doubled on research and development (R&D), and quadrupled on civil science and technology (Vig 1968: 58).

The Heath Government of the early 1970s set up a review of the functions of government departments, and one particular enquiry with profound consequences for science resulted in the Rothschild Report of 1971. This report argued that those who benefit from science should pay for it. 'However distinguished, intelligent and practical scientists may be, they cannot be so well qualified to decide what the needs of the nation are, and its priorities, as those responsible for ensuring that those needs are met. This is why applied R&D must have a customer' (Rothschild 1971: 8). This report resulted in the future application of the customer-contractor principle to R&D by government departments. In the words of the report: 'the customer says what he wants; the contractor does it (if he can); and the customer pays' (Rothschild 1971:3). This made changes in the longstanding position of research

councils funding arrangements; it effectively transferred a substantial portion of their budget to Ministers to enable them to commission research projects (Gummett 1980: 52). The Rothschild Report also introduced the system of departmental chief scientists as advisers to ministers.

The Conservative government elected in 1979 was more firmly committed to the discipline of the market place, and there began, in the opinion of one analyst, a period of the disillusion and decline of science, and '(m)any scientist found difficulty in adjusting to this regime.' (Wilkie 1991: 96-7). Scientists had, from then on, to think carefully how to justify their research to those who now controlled the funds. Furthermore, in 1988 the government announced that basic, so-called 'blue skies', not-for-profit research was not considered important, and that henceforth, universities and research councils were to be encouraged to switch to more applied research (Wilkie 1991:98). One important change affecting the funding of universities was the replacement of the University Grants Committee (UGC) with the Higher Education Funding Council (HEFC) in the 1980s. The UGC which had substantial representation from the universities and some discretion on its actions, allocated grants to universities from sums allocated by central Government. The Conservative government replaced this body with an executive quango, and kept reserve powers to direct its work. The government eventually merged the new quango with the body that allocated funds to the former polytechnics, to form HEFC. Representation of universities on HEFC was reduced in favour of business and industry in order to bring universities more in line with the world of business. In 1995, HEFC had 7 of its 13 members with business experience. This trend was reinforced in the White Paper published in 1993, entitled *Realising Our Potential,* that aimed to reorganise the research councils to improve Britain's competitiveness and quality of life by maintaining excellence in science, engineering and technology. The White Paper said that research councils were to develop 'more extensive and deeper links....with industry', and in future would be required 'to recruit more of their senior staff from industry' (OST 1993). This requirement resulted in industry representatives sitting on the strategy boards of research councils. For example, 'in 1990/00 the BBSRC strategy board had 15 members, of which 5 came from industry.' (Mayer 2001: 6). This hit research councils hard, as they were no longer able to obtain research contract income from government departments to supplement the core grant from the Department of Education and Science. This intention to bring industry and universities closer together was put into effect when science policy and its budget became the responsibility of the DTI, and the OST was moved from the Cabinet Office to the DTI. This, according to one writer 'underlined the fact that science policy is now driven by the technological interests of industry rather than being under broader social control.'(Mayer 2001: 6). All of this seemed to undermine the balance

between researchers following their own curiosity, and government directing money into projects that it considers beneficial to national wealth creation: the latter became overwhelmingly predominant. In summary, the period since 1945 saw a re-organisation of science from a fairly loosely managed system in which there was scientific freedom to explore research areas that may have no practical application, to a system almost entirely geared to the needs of business and industry.

2.4.2. THE PRESENT SYSTEM

The New Labour Government, elected in 1997, continued this economic perspective on science policy, though with a more centralized administrative structure. OST, which was moved back to the Cabinet Office in 1999, is headed by a Chief Scientific Adviser (CSA), who advises the Prime Minister and the Cabinet on science, engineering and technology matters. Currently there are six research councils headed by a Director General who advises the Secretary of State and the Minister of Science at DTI on the allocation of the science budget. An important group within OST is the Trans-Departmental Science and Technology Group (TDSTG), which advises the government on science and technology issues that cross-departmental boundaries. (OST 2001).

Funding for science was increased by 15% in 1998 and 7% in 2000. The Blair government is establishing strong links between universities and business through specific schemes, such as University Challenge, Link, and Faraday Partnerships and the Higher Education Innovation Fund (DTI 2001). Most of these links ensure that most of the increase in science funding is tied to work with industry. Furthermore, in 2002, the government introduced a new tax credit for research and development. This amounted to a £400 million boost to innovation, affecting £11 billion of expenditure by 1,500 large companies in the UK (Ho 2002: 2).

The present government seems to accept that the world increasingly depends on scientific advance; and it stresses the need for sound science to inform its policy decisions. It has established a set of principles for facilitating this, published as *Guidelines 2000: Scientific Advice and Policy Making* (OST 2000). Furthermore, in the wake of the BSE scandal and other well-publicised health scares, it was felt there was a need to recapture public confidence in science and scientific advice. Accordingly, the government began to review its regulatory framework. Three new institutions emerged from this review: The Foods Standards Agency (FSA); the Agricultural and Environmental Biotechnology Commission (AEBC); and the Human Genetics Commission (HGC). Their role goes beyond a narrow scientific

assessment, as 'they look at the "big picture," taking ethical and social issues into account, as well as the science.' (House of Commons 2001: xviii).

Historically in Britain, there was no overall policy relating to environmental protection. What does exist, is the sum of many traditional or ad hoc arrangements such as common law, statutes, special agencies, procedures and policies. In other words, 'a pragmatic response to specific problems and the evolution of relevant scientific knowledge...' (Lowe & Flynn 1989: 256). It was not until 1970, that a ministry - the Department of the Environment (DoE) - was created for the development of an environmental policy. In more recent years, international obligations have played an important part in the direction of Britain's environmental policy. Britain is a party to agreements such as the Vienna and Montreal Conventions on the protection of the ozone layer in 1885 and 1987, and the United Nations (UN) conference on Environmental and Development (The Rio Conference) in 1992. Furthermore, Britain's membership of the EU has tied the government's hands in many ways over its ability to handle environmental issues independently, to the extent that today over 80% of British environmental policy originates in the EU (Jordan 2000: 262).

Although environmental issues were not included in the Treaty of Rome, from 1972 onwards, the then European Economic Communities (EEC) created a series of Environmental Action Plans to deal with pollution and environmental awareness education. The Single European Act (SEA), which created the internal market, was important for environmental policy because it established the principle that environmental policy should be one of the direct concerns of the Community itself (Connelly & Smith 2003: 269), and in its modified form in Article 174 of the Treaty of European Union 1991, it proclaimed that 'Environmental protection requirements must be integrated into the definition and implementation of other Community policies'

In the EU Commission itself, science plays an increasing role in the formulation of policy. In the EU system of governance, policy develops through negotiations between a variety of actors that include national politicians, civil servants and other professional and EU Commission officials and scientists. The nature of EU policy and decision-making is highly technocratic. Policy sectors are very complex in their subject matter, and often scientific or expert knowledge and bargaining not only help solve problems but also shape policy (Radaelli 1999).

The Commission of the European Communities (CEC) is organised into Directorates of policy areas, each with a Commissioner, a Director-General and groups of affected interests.

Policy emerges from loosely organised and flexible policy communities, containing actors from both national and supranational levels, based on coalitions and bargaining between domestic interest groups, the relevant departments in member state governments, Europe-wide interest groups, and the relevant directorate-general within the Commission (Peters 1992: 117). This is a very complex system of decision-making, 'which is designed to allow Member States and the Parliament to have their say, while still giving the Commission quite considerable power in the last resort.' (De Marchi & Ravetz 1999: 752).

In recent years, the EU has brought its characteristic technocratic approach to bear on matters of risk assessment and management. In April 1999, the Council of Ministers adopted a resolution urging the Commission to:

> be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer related activities and develop as a priority clear and effective guidelines for the application of this principle (CEC 2000).

In response, the Commission prepared a position on risk and precaution that is detailed in a paper: *Communication from the Commission on the Precautionary Principle* (CEC 2000). The essence of this policy is that in specific circumstances where scientific evidence is insufficient, inconclusive or uncertain, and there are indications through preliminary objective scientific evaluation of reasonable grounds for concern, then the precautionary principle is the correct risk strategy to use (CEC 2000: 8-9).

Clearly, the government in Britain is constrained by its agreement to EU arrangements on the governance of science and environmental issues, which have 'undoubtedly increased the need for cross-departmental coordination, in terms of developing national negotiating positions prior to the development of [EU] policy and during the implementation of whatever commitments are eventually entered into.' (Jordan 2000: 262).

2.4.3. DEFINITION OF POLICY

'Policy' is a concept denoting the analysis and practice of the way we are governed, and it is about problem-solving and decision-making. Colebatch (2002) conceives of two elements in the policy process – one is authoritative; the other is participative:

- An exercise in control or authority, for example, by elected leaders over bureaucrats,
- A vehicle for contesting the existing order and asserting the right to participate. (Colebatch 2002: 2).

Thus there are two dimensions to policy; first is authority or rule, whereby authorized decisions are transmitted downwards. On this view, decision-makers 'select courses of action in accordance with the values they hold' (Colebatch 2002: 23), (such as party policy); and second, the participation of different organizations which sees policy in terms of 'structuring of action' (Colebatch 2002:23), that is, deliberations outside of hierarchical authority. These two elements are not mutually exclusive: they can co-exist, as in the UK.

Participation in the policy process on the basis of authority means that those in authority, in the case of British Government, cabinet ministers, are there as of right, while the bureaucrats and advisers, also involved in the task of formulating policy have to defer to the authority of Ministers. However, there is interdependence between both types of participants: ministers may have the last word, but they need the advice of experts, and departmental administrators to manage the policy process.

However, policy is not something that only happens in government, it is also associated with business, academia, consumer pressure groups and NGOs, or any organization that has to mediate its relationships with the outside world (Colebatch 2002: 3), and in particular, with government. The experts and administrators employed by government form a statutory pool of expertise available to ministers, but these existing pools of expertise are often challenged as new expertise is developed. This is clearly seen in the environmental arena. As economic and technological change impacts on social life, it causes the emergence of new actors, academic, consumer and professional, expressing concern about environmental issues. Thus, new bodies of specialized knowledge are developed which are able to challenge the practices of government experts, who then have 'to justify their plans in terms of a different body of expertise' (Colebatch 2000: 30).

2.5. Expert Advice to Government

As government has become more complex and technical in nature, there has been an increasing need for outside advice. From the 1960s onwards, there was an increasing use by government of extra-governmental agencies to carry out a variety of public functions. These organisations became known as QUANGOs (quasi-autonomous non-governmental organisations), a term coined by Anthony Barker (Barker 1982). The term employed by Whitehall is non-departmental public bodies (NDPB), and they form a network of committees/commissions that play an important part in national government decision-making but are not part of government departments. They operated 'to a greater or lesser extent at arms length from Ministers.' (Cabinet Office 2002: ii). In 1999, there were some 6,450 executive and advisory bodies in existence (Weir & Beetham 1999: 231).

The main functions of the Government's advisory system are to:

- Advise on science at the basic level,
- Provide risk analysis,
- Build on the basic advice and risk analysis to make policy recommendations.

NDPBs vary in function; some make regulations (executive NDPBs such as the Environment Agency which manages and regulates the water environment and control of pollution); others carry out funding functions, (such as the Research Councils); and some offer advice to Ministers on a range of scientific, technical and other specialised issues (such as the Human Genetics Commission which provides Ministers with strategic advice on the big picture of human genetics).

There is no Act of Parliament regulating the establishment of advisory bodies, although some commissions and committees have statutory authority in which their role is set in law. In general, NDPBs are set up under ministerial prerogative powers that allow Ministers to seek advice from anyone at any time. It is government ministers or civil servants who decide on the members of these bodies and they are not accountable in law for their appointments (Weir & Beetham 1999: 221). Members of advisory committees are recruited from the universities, professional institutions, industry and many other non-governmental organisations.

2.5.1. THE POLICY PROCESS AND POLITICAL CULTURE

Understanding the relationship between technical expertise and policy-making is of crucial importance here. One analyst has made the case that very strong policy cultures exist that influence the enactment of those policies through 'technocratic expertise' (Hellstrom 2000). Helstrom argues that the political and administrative enactment of technical expertise is carried out through 'culturally infused policy frameworks' (Hellstrom 2000: 500). His argument is supported by a comparative analysis of French and German nuclear regulation. He demonstrates how the closed and highly centralised administrative system of French government, while formulating nuclear policy, avoided parliamentary debate and public controversy. By contrast, in Germany, policy-making is open and more technocratic, and public scrutiny and adversarial positions are integrated through formal rules, a style of bureaucratic legalism; the idea being that public action should take place through lawful procedures – (the *Rechsstaat,* a state ruled by law) (Weale 1992: 74).

In Britain, top civil servants have much influence in policy-making, and as one work on comparative politics argues, 'Britain has a bureaucratic rather than ministerial government' (Martin and Stronach 1992: 260). The role of these administrators is to cooperate in the development of policy in line with ministerial initiatives, to provide advice and help build policy options. They also have 'to defend a department' and 'influence discreetly the climate of opinion about the department', in interdepartmental committees and other forums, and to make decisions that are in accord with the minister's overall objectives. (Rose 1989: 89).

Bureaucratic policy culture works in a particular way. Officials working within government departments have particular responsibilities that often grant them considerable discretion. Such actors, working in a variety of organisations that participate in the policy process or problem-solving groups, may have widely differing ideas on solutions to problems. These differences can be of an intellectual nature or characterised by the institution they represent. Moreover, they will tend to act in ways that protect the well being of that institution. The result is that power and advantage are distributed unequally among participants. This inevitably leads to coalitions of people forming competing sub-groups of officials within the policy forum. Each sub-group is identified with an alternative solution or course of action put forward for consideration. The interests reflected will be defined through the perspective of the bureaucratic group. Conflicting preferences then emerge which eventually lead to one sub-group triumphing over the others. The final outcome of this process is therefore the result of the power and skill of each side on the issue under consideration, and this may be as important as the strength of their arguments or the attraction of the goals sought.

In the context of the policy areas covered in this Thesis, the main government department displaying a particular culture is MAFF (now DEFRA). Martin Smith has examined the development of British agricultural policy which he described as being structured in two ways; the original ideological structure, that is, the shared beliefs of farmers and officials in the common goals of agricultural policy since 1945; and the institutional structure that developed over this period (Smith 1992). The institutional structure included a single decision-making centre based on MAFF, the government's Annual Review of Agriculture, and more recently, EU institutions such as the Council for Agriculture and the Commission (Smith 1992: 29-30). Smith concluded that it is a closed policy community, and he highlighted the importance of MAFF which maintained a close relationship with the National Farmers' Union (NFU) and MAFF officials, and which set the 'rules of the game', determining how various interest groups should act in order to obtain access to the policy community (Smith 1992: 30).

A vivid account of the cultural politics of science and decision-making in MAFF and DH during the BSE crisis is provided by Dressel (2000). Dressel attributes the government's non-precautionary stance on public health during the BSE crisis to the 'Thatcherite culture' of the government at that time, in which there was a culture of discretion that 'strengthened the power of the civil service'. Interviews conducted by Dressel revealed that ministers expected civil servants to 'take a low key on BSE issues....in order not to jeopardize the British economy' (Dressel 2000: 6). This idea of policy culture influencing political decision-making is important when examining the British science advisory system.

2.5.2. THE SCIENCE ADVISORY SYSTEM

Scientific advice to government is provided by ANDPBs, a network of expert committees that carry out the regulating roles of ministers such as monitoring, scrutinising and licensing, which involves specialised knowledge. They 'judge the safety of medicines, processed foodstuffs, scientific releases into the environment, the nuclear industry, pesticides, and so on' (Weir & Beetham 1999: 219). These scientific advisory committees consist of groups of specially recruited outside experts with a range of expertise, experience and impressively high formal qualifications, many with jobs in such areas as the pharmaceutical, biotechnology and chemical industries, while others are academic scientists working within universities, some of whom are also members of the Royal Society. There are a number of civil servants involved with this advisory system who are drawn from the sponsoring Departments. They 'set the committees' agendas, provide much of the data on which they act, work closely with the chairpersons, and usually draft the minutes and even their reports and conclusions.' (Weir & Beetham 1999. 223). Indeed, many advisory committees have a civil servant as Chairman. For example, Professor Sir David King, the Government's Chief Scientific Officer, chaired the GM Science Review.

Many recent issues such as GM foods, problems with agriculture, and the safety of mobile phones, have emphasised the increasing dependence of governments on scientific advice to inform their policy decisions. This was further highlighted in the Phillips Report on the BSE crisis, and caused the government's OST to introduce the guidelines for official advisory bodies mentioned earlier. There has also been a move towards involving experts other than in scientific disciplines, and some advisory bodies now include members who are termed 'lay' members. The House of Commons Science and Technology Select Committee's fourth report on the Scientific Advisory System stressed that the role of the lay member was to bring an alternative perspective to advisory committees and not to represent an interest group. The report recommended that generally at least two lay members should be appointed to scientific advisory committees (House of Commons 2001: viii). Lay membership has been difficult to

define adequately, but it does not mean that lay members have no scientific background; it may simply mean that they have a scientific discipline other than that possessed by the main members of the committee. Even those without scientific qualifications may nevertheless be experts, for example, ACRE has appointed a farmer, an expert in agriculture. The Advisory Committee on Pesticides, in addition to the expected membership with specialist qualifications in toxicology, epidemiology and biological sciences, also has two lay members: one a consultant in food consumer affairs, and the other a university lecturer in environmental science (see table 2.2). The AEBC, a strategic advisory body, has a membership that includes an organic farmer, a freelance broadcaster, the Director of GeneWatch, (a specialist interest group), a barrister specialising in environmental law and a social scientist (from Lancaster University).

Table 2.2. A Selection of Scientific Advisory Committees: An Analysis of Membership

ACRE	13 members: 12 scientists, and 1 farmer
ACNFP	15 members: 14 scientists and 1 consumer representative
VPC	28 members: 26 scientists or veterinary scientists, 1 lay member, 1 working farmer
COT	15 members: 13 scientists, 2 lay members (1 consumer affairs, 1 public interest)
ACP	20 members: 18 scientists and 2 lay members (1 consumer affairs)

Some lay members are chosen from consumer groups. One such person is Julie Hill of Green Alliance, who served nine years on ACRE and is currently the Deputy Chair of the AEBC. She thought that her job on ACRE was to 'take the broader view, to put a point-of-view and challenge the process rather than the science'. She did not see herself as having responsibility 'to intervene in the arguments about whether gene x or gene y was going to move around and cause problems, but to have a consistent approach to the arguments' (Hill 2004: personal interview).

In terms of environmental hazards, one analyst of environmental issues notes the central role played by natural scientists in the British system of policy making (Weale 1992: 212). This means that '(u)nless and until a cause-effect relationship is proven, scientific advice is, usually, to do nothing.' (Carter & Lowe 2000: 182). Dryzek agrees with this, noting that the absence of conclusive science became the standard reason for the British government's inaction on such major environmental pollution issues as 'acid rain, carbon dioxide, chlorofluocarbons, coastal pollution and sludge dumping in the North Sea.' (Dryzek1997: 139). It is a 'sound science' approach to environmental policy, which means that a scientific understanding of cause-and-effect relationships is a necessary condition for rational policy-

making (Weale 1992: 81). Wynne and Mayer (1993) note the existence within the sound science principle, of a 'reductionist' approach to scientific enquiry: the breaking down of complex systems into less complex constituents where there is a high degree of control over the system being studied, enabling precise observation of the behavioural correlations between small numbers of variables. In environmental research, this means breaking down an area into its smallest components in the belief that only these directly observable and measurable parts matter.

Wynne and Mayer believe that this form of investigation precludes richer forms of reasoning that may be just as well-founded in the available evidence. An example offered by the authors is of German marine scientists studying eels in the North Sea, whose investigations revealed that of the blood samples taken from eels in a contaminated area, 80% contained bacteria, while only 4% of the blood samples taken from eels in an uncontaminated area contained bacteria. At the time, there were no reports of tumours in the eels that corresponded to the level of bacteria. There was, therefore, no-cause-and-effect relationship between the contamination and the eels' health considered to have been established, and according to Wynne & Mayer, for British scientists it would have ended there. But, as the authors observe, a different approach would be to consider high bacteria counts as indicators of an impaired immune system, which in the longer term could develop into tumours. Such indirect causation is invisible from the reductionist perspective of 'good' science (Wynne & Mayer 1993: 34). Wynne and Mayer conclude that Britain has evolved a culture of "good science" which is so narrowly constructed that it cannot accommodate ignorance and the complex interaction in the environment' (Wynne & Mayer 1993: 33).

Another criticism of the British approach is that the science advisory system is open to the charge of commercial manipulation. As discussed in part one, the commercialisation of research has created the 'potential for conflict between scientific practice and commercial interest' (Barlow 1999: 38). Advisory committees such as the Committee on Safety of Medicines (CSM), Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Advisory Committee on Releases to the Environment (ACRE) have a preponderance of scientists with links to industry in the area in which they are working. One recent newspaper report revealed that Ministers have been worried by the 'connections between science experts and leading drug firms'. This news item claimed it had seen confidential DEFRA documents that record concern expressed by Environmental Minister Michael Meacher, that almost three out of four members of the ACP either own shares in, or work for, major biotechnology and drug corporations (Barnett & Townsend 2003b: 2). This concern is borne out by an examination of recent annual reports of the

above advisory committees that shows links in the form of consultancies, shareholdings, grants, pensions and even directorships. Examples of this tendency are illustrated in Table 2.3. below. Members of such bodies, of course, have to declare their interests in issues they are assessing, but there is no way of knowing whether a committee member has been influenced in the advice they have given.

Moreover, as one scientist (a research fellow at Balliol College, Oxford) noted, 'a scientist who works regularly for an industry is more likely, over the course of a career, to start seeing things in the same way that the industry does.' (Barlow 1999: 40). For example, it would be difficult for an academic to gain expertise in drug interaction without having to work closely with the pharmaceutical industry, and therefore it is difficult to know how impartial his advice would be. Other analysts have noted that where ANDPBs are connected to industrial or commercial activities, they form closed policy communities of civil servants and organised interests that are able to influence government policies at a formative stage, almost without any public scrutiny (Weir & Beetham 1999: 222).

The way in which experts are recruited is another important consideration. Advisory committee members are very carefully selected and the civil service has the responsibility of servicing the whole process of public appointments within government departments. The House of Commons Public Administration Select Committee has raised the question of whether there has been a withdrawal of ministers from the appointment process, with civil servants moving into the patronage vacuum (House of Commons 2003: 25). The Select Committee believes there are two points where a senior civil servant has the opportunity to exert influence. First is when they take instruction from ministers on the criteria for an appointment with suggestions for potential applicants; and second, when they write up submissions to the ministers on the final choice between candidates at the end of the appointment process. And, of course, it is a senior official who establishes the appointment panel, takes the chair and takes part in the interviewing, short-listing and final selection of candidates House of Commons 2003: 25).

A recent innovation, resulting from a recommendation of the Nolan Committee on standards in public life, is the appointment of an independent assessor to monitor the appointment process. However, although these assessors are supposed to be independent of the appointing Department, they are often former senior civil servants. The Public Administration Select Committee found this unsatisfactory as, although they can 'offer a great deal of experience to the process of selecting candidates...' they are 'likely to share implicit assumptions with the departmental civil servants with whom they work that could influence

Table 2.3: Examples of Scientists Links to Agro-Chemical Companies

Name of Scientist & Committee served on	Nature of Interest & organisation
Prof. M. Gale, *member, GM Science Review Panel*	Dep. Consultant, Bioscience Ltd, Norwich. Director, John Innes Centre.
Prof. C. Leaver, *member, GM Science Review Panel*	Consultant to Syngenta, Stiefel Laboratories Ltd, Trustee, John Innes Foundation
Prof. Nigel Poole, *member of ACRE*	External & Regulatory Affairs Manager, Zeneca
Mr J. Orson, *member ACP*	Director, Morley Research Centre, undertaking trials for agro-chemical companies (Syngenta, Monsanto)
Prof. I. Kimber, *member COT*	Employee of Syngenta, shareholdings in AstraZeneca
Prof. N.A. Brown, member COT	Consultancies: Merck, Pfizer, Glaxo-Smithkline, Searle
Prof. A.D. Dayan, member VPC	Consultancies: Novartis, Roche, Schering Plough, Searle; shareholdings: Astra Zeneca, Glaxo Welcome
Prof. G. Gettinby, member, VCP	Shareholdings AstraZeneca
Prof. Q.A. McKellar, member VCP	Consultancies, Novartis Animal Health
Prof. A. Nolan, member, VCP	Consultancy: Vetrapharm Ltd
Prof. Phil Dale, member AEBC	Leader of Genetic Modification &B Biosafety Research Group, John Innes Centre
Dr E. Dart, member AEBC	Chairman, Plant Bioscience Ltd, shareholder: Syngenta, AstraZeneca

Source: Annual Reports of Advisory Committees 2001

their assessments' (House of Commons 2003: 27). Indeed, one witness before the Public Administration Select Committee commented that:

> The present system gives departments too much power to influence the composition of the body through assessments, short-listing and selection panel membership. Civil servants who are not panel members may have an undue influence, e.g., by expressing their views either privately beforehand or during the selection process. There is a case for a selection

process with the emphasis on independence rather than departmental wishes (House of Commons 2003: 26).

According to one former minister, Michael Meacher, most of the work of drawing up a list of names for service on committees is done by civil servants on the 'old boy' network, people known to the civil servants because they move in the same social circles. Meacher is not happy with this system, stating that it 'is just a metropolitan thing, the usual networking that goes on in and around London.' He also said that while he was a minister, if he challenged civil servants over this way of selecting candidates, he was always told the list contained the 'best candidates' (Meacher 2004: personal interview). A study by Democratic Audit found that 'members were often recruited through professional networks of contacts and previous service on other quangos – 'the old white lab coat' rather than the 'old school tie.' (Weir & Beetham 1999: 222). Two scientists interviewed for this research said they had to go through a selection process; one said he was asked about his politics (Hay 2004: personal interview), and the other, serving on a different type of committee, was subjected to an initial interview with civil servants in the presence of an independent assessor, then later by a Minister (Howard 2004: personal interview). This method of recruitment is likely to result in a very consensual approach to the issues the committees consider.

An American scholar, Sheila Jasanoff, who works in the area of the regulation of science and technology in the US, and who closely followed the unfolding BSE crisis in Britain during the 1990s, believes that the British scientific advisory system is consensual and closed, which encourages small secretive networks of the 'great and the good'. By 'great and the good' she means that '...trust is created through embodiment in trustworthy people: peers, professors, tested public servants, representative of establishment interest groups or responsible citizen organizations.' (Jasanoff 1997: 227). Furthermore, she finds that discussions are usually carried out in private, with the conclusions of their deliberations passed to policy-makers in confidence, and any published reports are rarely backed by records of what actually happened in committee (Jasanoff 1997: 228). One scientist, a member of several HSE toxicology committees and sub-committees, believes, 'you have to be prepared to make compromises because if you hold out for an absolutist, pure, position all of the time, you are not going to get anything – its just stalemate...' (Hay 2004: personal interview). This is all very reminiscent of the notion of 'club government' argued by David Marquand, where the 'atmosphere of British Government was that of a club whose members trusted one another to observe the spirit of the club rules...' (Marquand 1988: 178).

This is a reflection of policy-making in general, in Britain, as McCormick indicates:

> ...British policy-makers often think of themselves as custodians of the public interest, and feel that they can understand the best interests of the public with minimal reference to the public itself. One of the characteristics of British politics is secrecy: the government limits public access to information in the belief that a passive public will accept what the government thinks is in the public interest (McCormick 1991: 11).

Little, it seems, has changed in a quarter century since Philip Gummett's book *Scientists in Whitehall* analysed the relationship between science and policy-making in British Government. In his chapter on the problems of scientific advice, Gummett lists the resources and skills required by scientists acting as advisers to government. Among the skills he lists are:

- An 'acquaintance with other scientists and scientific institutions, which enables him to suggest candidates for advisory committees and government posts...'

- Enjoys a prestige as a scientist which public officials often use in order to obtain backing for their policy proposals (Gummett 1980: 108).

The system of appointing to advisory bodies in the USA, while having similar links between scientists and industries, is different from the British system in two respects. The first difference is that in the USA, the expert committees, boards and commissions, appoint members through an informal process in which experts are tested in either consultancies on specific issues, or as members of ad hoc sub-committees, to see how they perform, before being appointed to a committee of a main board. (Jasanoff 1990: 243). The second difference is that, according to Jasanoff, 'persons do not command much faith in late twentieth century US politics.'; rather, 'trust is reposed in formal processes, such as rule-making and litigation...' (Jasanoff 1997: 228).

The closed nature of the UK system is exacerbated by the fact that the scientific advisory system is not a proactive one, but instead responds to issues that arise or to requests for information from Government. In order for the Government to make sense of the answers and information it receives, it needs to have sufficient 'in house' expertise to be able to evaluate committee recommendations as an 'intelligent customer' (House of Commons 2001: 41). This can be a problem, because government often does not have sufficient in-house expertise and depends increasingly on outside academics for scientific advice (Barlow 1999: 39).

Furthermore, the UK method of developing policy through government departmental consultations with networks of organised interests of professional groups and advisory bodies is very time consuming. The Phillips Report on the BSE crisis, for example, noted that:

> the production of written documents by officials and by advisory committees frequently entailed a process of wide consultation and drafting refinement. This was a "Rolls-Royce" system, but one which tended to result in lengthy delays. Consultees would be tempted to suggest drafting improvements, which would then result in a further round of consultation. These were often not changes of sufficient substance to justify the delay that they caused (Phillips 2000, vol 1: 1217).

This Rolls-Royce system was characterised by Phillips in terms of 'the best being the enemy of the good' (Phillips 2000, vol 1: 1217).

2.6. Conclusions

In this chapter, an attempt has been made to place the concerns of the present research topic within a wider context by raising some questions about what constitutes scientific knowledge, and the difficulties for governments in utilising scientific advice because of the problems of using normal science to solve environmental policy problems where, inevitably, there is complexity and uncertainty. More narrowly, the chapter reviewed the policy framework that exists in Britain, showing the far-reaching changes made during the last twenty-five years in the arrangements for research funding. The chapter concluded by examining in detail the scientific advisory system focusing on the criticisms that have been made of its lack of independence from industry. The next chapter aims to outline in detail two theoretical perspectives on how environmental policies are developed in Britain.

CHAPTER THREE

The Governance of Science in Britain: Theoretical Perspectives – *Sound Science versus Precaution*

Understanding the nature of risks and uncertainty is an important part of the scientific understanding needed both for many public policy issues and for everyday decisions on our personal lives....Once again it must be argued that better understanding fosters better public and personal decisions. (Royal Society 1985.10).

3.1. Introduction

The previous chapter discussed some of the dilemmas that governments encounter when regulating scientific and technological innovation, and it highlighted the problem of providing expert advice to Ministers who are faced with the responsibility for creating the legal regulation of environmental hazards but then often find no scientific agreement among experts on the solution, and in some cases find that the science is non-existent (trans-science).

This chapter aims to provide a theoretical model of how governments in Britain actually deal with environmental hazards. My argument is that the Government's approach has, in the recent past, generally been based on sound science, but that it proclaims its commitment to the precautionary principle. The chapter will explore in depth the characteristics of these two approaches to environmental problems in order to construct a lens through which to analyse the four policy areas. It will give an outline of two contrasting ways of policy-making in risk situations: sound science and precaution. There will be a review of these two differing positions, with a detailed analysis of their characteristics. But to begin with, the first part of the chapter will revisit British environmental policy, charting its background and outlining its characteristics.

3.2. British Politics and the Environment

Public policy making in Britain has its own distinctive style. As Weale noted fourteen years ago, policy-making is managed in a flexible way, with policy 'conceived of as a series of problems, constituting cases that have to be judged on their merits', and with no 'general principles governing particular areas of policy.' (Weale 1992: 81). Furthermore, this style is characterised by a process of consensus and consultation with affected interests. As one study of environmental policy noted:

> British policy-makers often think of themselves as custodians of the public interest, and feel that they can understand the best interests of the public with minimal reference to the public itself....The result is that much of Britain's regulatory policy-making is designed and carried out by selective consultation with interest groups. (McCormick 1991: 11).

As noted in Chapter 2, the British government historically has had no coherent policy towards environmental issues, and had dealt with environmental problems in an *ad hoc* manner since Victorian times, resulting in a confusion of agencies, legislation and procedures. Yet as McCormick (1991) also notes, Britain has an impressive record of responding to environmental problems. The Alkali Inspectorate created in 1865 was the world's first environmental inspectorate; the world's first planning act was the Town and Country Planning Act of 1947; and the world's first air pollution control legislation was created in the Clean Air Act of 1956. Early influences on environmental matters came from popular nineteenth century reform movements and charitable bodies concerned with wildlife and the preservation of nature. Examples of these include the world's first environmental group, the Commons, Open Spaces and Footpaths Preservation Society, 1865; and the Society for the Protection of Birds, founded in 1889 (McCormick 1991: 31). But despite these achievements, Britain has 'an underlying record of what might variously be described as environmental lethargy, apathy or ignorance on the part of successive British governments.' (McCormick 1991: 9). The British approach to environmental problems has generally been a reactive one, and as environmental problems are cross sectoral in nature, environmental policy has emerged in a fragmented and piecemeal way (Lowe & Flynn 2000: 256).

In understanding the UK approach it is important to note how environmental problems are defined. In their book, *Acid Politics* (1991), Boehmer-Christiansen and Skea distinguish between pollution as an *effect*, and pollution as *undesirable material*. This point is crucial to how pollution matters are dealt with by scientists and policy-makers. By defining pollution as an 'effect', we emphasise the need for evidence of environmental damage: '(p)ollution requiring scientific proof of causality creates the need for evidence which will stand up to the tests of scientific rationality and legal cross-examination.' – a sound science approach. This leads to pollution becoming 'a concept with which scientists and lawyers can live and prosper' (Boehmer-Christiansen and Skea 1991: 15). By this they mean that scientists often argue over concepts such as dose-response relationships and critical loads on eco-systems, and decisions take a long time with potential solutions to the problem being postponed until evidence becomes clearer: a wait-and-see approach. The authors explain that treating pollution as an effect is a traditional practice in Britain and also in international law (Boehmer-Christiansen & Skea 1991: 15), focusing attention on the damage or harm caused by pollution. By contrast, treating pollution as 'undesirable material' focuses attention on

pollution as an evil in itself, irrespective of any evidence of damage or harm that it may cause. This approach lends itself to a more pragmatic approach with cooperation between engineers and regulators over solutions to pollution problems. This is because pollution defined in this way can be measured by using physical parameters such as the total quantity of pollutants discharged over time. As Boehmer-Christiansen & Skea state:

> The regulation of pollution is enormously simplified by this definition because it ignores the complex relationship between the quantity of a material introduced into the environment and the subsequent harmful or undesirable effects. It is a deceptively common-sense definition which is unacceptable to both science and law – unless governments agree to it (Boehmer-Christiansen & Skea 1991: 16).

This approach is more in line with the German approach to environmental policy-making – that is, a precautionary approach.

3.2.1. THE EMERGENCE OF ENVIRONMENTAL POLITICS

The environment became a salient issue in politics worldwide in the 1960s and 1970s with the growth of the environmental lobby and the realisation that the undesirable effects of industrial development were beginning to be seen to affect health, lifestyles and the environment. During the 1970s, governments in developed nations generally dealt with environmental issues in a top-down way, believing:

> that environmental problems could be dealt with adequately by a specialist branch of the machinery of government; that the character of environmental problems was well understood; that end-of-pipe technologies were typically adequate; and that in setting of pollution control standards a balance had to be struck between environmental protection and economic growth and development. (Weale 1992: 75).

This approach can be seen in the UK both in the creation of a new Department of the Environment in 1970, responsible for a range of problems that affect the environment, and in increased pollution control legislation during the 1970s, such as the Health and Safety Act 1974; and the Control of Pollution Act (COPA) 1974, which codified much of existing practice and also introduced new regulations for waste disposal.

However, the debate over ecological issues became more apocalyptic as a result of the Club of Rome's report *Limits to Growth* (Meadows, et al 1972), which predicted, on the basis of computer models, that the exponential growth of populations and economies in a world of finite resources must lead sooner or later to disaster. At around this time, the

western, or developed world began to see that economic development and the environment were not separate issues, but interdependent. This can be seen by the nature of some of the international level conferences. For example, the United Nations (UN) Conference on Human Environment held in Stockholm, in 1972, debated the problems of economic development and population increases.

During the 1980s there was a further surge in interest in environmental issues. The idea of linking the environment and economic development through the concept of sustainable development was the subject of a three-year process of consultation and negotiation at the conference of the UN World Commission on Environment and Development (WCED) in 1987. The report of the Commission, *Our Common Future*, known as the Brundtland Report, created the idea that development should only proceed if it conserved resources for future generations. This is the concept of sustainable development: 'Humanity has the ability to make developments sustainable – to ensure that it meets the needs of the present without compromising the ability of future generations to meet their own needs.' (WCED 1987: 8). In essence, Brundtland aimed to emphasise conservation as a central issue of economic development, instead of making it merely peripheral to it.

3.2.2. THE DEVELOPMENT OF ENVIRONMENTAL POLITICS IN BRITAIN

In Britain, the then Conservative government endorsed the concept of sustainable development at the Toronto meeting of the G7 summit in June 1988, and subsequently produced two major documents to formulate a strategy for implementing sustainable development in Britain (Carter & Lowe 2000: 171). This strategy began with a White Paper: *This Common Inheritance* (DoE 1990). However, the proposals in this White Paper were mainly procedural, to help coordinate policy within government, rather than substantive. Nevertheless, it did lay out the general principles that should guide environmental policy, such as recognising that some problems needed international solutions; that the public should have greater access to information on the environment; that measures should be based on best scientific and economic evidence; and that precautionary action should be taken where justified. Some of the more radical aims contemplated by the then Secretary of State for the Environment, Chris Patten, were, however, scuppered by the powerful producer interest groups (farmers, industrialists, road-builders and car manufacturers), through their sponsoring departments in Whitehall (Carter & Lowe 2000: 172).

After the UN Conference on Environment and Development (the'Earth Summit') at Rio de Janeiro in 1992, at which those countries involved agreed to implement Agenda 21, John Major's government published a consultation document entitled *Sustainable Development:*

the UK Strategy (DoE 1994a). This was to be the national strategy for sustainable development based on decisions taken at Rio. However, like *This Common Inheritance,* this document contained no new policies but simply repeated existing commitments. Britain's whole attitude to the principle of sustainable development led one commentator to assert that it was 'proof of just how far the concept can be stretched, believing that the British government saw no need to create new policy initiatives on sustainable development', and therefore 'confirming its position as a laggard in the sustainability stakes.' (Dryzek 1997: 128). As a result, little progress was made on environmental issues.

This lacklustre approach can be explained by two key ideological commitments of the governments during the 1980s and 1990s, which made any progress on environmental issues difficult. First, the Conservative governments believed that the state should exist only to 'provide the framework within which economic agents can pursue their goals; it is not to impose some collective view about where and how economic development is to take place.' (Weale 1992: 87). The Conservative government disliked intervention, planning and regulation: governments should not be involved in the regulation of industrial processes and new technologies. Second, under Margaret Thatcher's leadership during the 1980s, there was an imperative to keep strict control over government expenditure. This meant that it was difficult to develop regulations to control pollution, because many areas where regulation was needed, such as energy and water, were then in public ownership, and investment in pollution prevention measures would add to public expenditure.

An issue arose during that period which exemplifies the UK's minimalist approach to environmental policy - the linking of the Sellafield nuclear processing plant to childhood leukaemia. There is a long established link between exposure to radiation and leukaemia, and in the early 1980s, a TV documentary argued that the incidence of children's leukaemias in Seascales (near the Sellafield nuclear processing plant in Cumbria) was ten times the national average. The official enquiry into the issue (Black 1984) confirmed that there was a high incidence of the disease in the area, but stated that the link with radiation from Sellafield was 'unproven'. This hard-nosed response was justified by claiming that it would be irresponsible for government to squander taxpayer's money on solutions to complex issues when no evidence was at hand to suggest there was a causal link between a particular activity and a manifest problem.

In the past politicians had regarded the environment 'as an unimportant and largely self-contained area of political activity' (Jordan 2000: 264). The New Labour government that came to power in 1997 seemed to be committed to a more proactive stance on environmental matters and has embraced sustainability in a more enthusiastic way than the previous

conservative governments, by factoring environmental considerations into 'core' areas of policy-making. But as one academic noted: '(a)mbitious objectives on renewable energy, climate change and integrated transport are proving harder to deliver than expected', with headway only being made 'when political and economic circumstances permitted' (Jordan 2000: 275). Nevertheless, during New Labour's time in government there has been a trend towards a more collective or inclusionary way of approaching environmental risk assessment, which has modified Britain's sound science based traditional approach. There are signs that the culture of advice to government is changing. The review of the regulatory framework, and the *Guidelines for Scientific Advice* (OST 2000) outlined in Chapter 2, lays down new definitions of what is meant by the term 'expert', and what constitutes 'relevant' advice to government. *Guidelines* defines 'scientific advice as including not only the natural and applied sciences but also the social sciences and humanities' (OST 2000, para 3). Expert sources are taken to include not only 'eminent individuals, and learned societies, advisory committees, or consultants, but also professional bodies, public sector research establishments, lay members of advisory groups, consumer groups and other stakeholder bodies' (OST 2000, para 12).

In addition, several reports over the past few years, such as the House of Lords Select Committee on Science and Technology report, *Science and Society* (2000); the House of Commons Select Committee report *The Scientific Advisory System* (2001); and more specialised reports, such as the Phillips Report on BSE (Phillips 2000) and the Stewart Report on Mobile Phones (IEGMP 2000), all demonstrate a more deliberative and inclusive approach which addresses problems of risk by including the judgements of a broader range of affected parties. The Phillips Report, in particular, stressed the need for government departments to ensure that recruitment to membership of expert committees should be based on an expanded definition of who is an expert, and urged 'members of committees themselves to identify clearly and precisely their remit, and for the advice itself to be honest about uncertainties' (Frewer and Salter 2002: 141). This more inclusive approach to environmental decision-making is owed to the Government's commitment to precaution: as far back as 1990, the Government acknowledged precaution, as one of five principles, as a guide to policies on the environment (DoE 1990: 34).

In short, the British record on environmental policy has shown ample evidence of the sound science approach, but in more recent times the government appears to have moved to a more precautionary approach – at least on some policy areas, such as pollution and GMOs – as we shall see.

Summarising this section, therefore, we can say that in the past, Britain's approach to environmental issues has been somewhat fragmented and half-hearted: considerations about environmental protection issues seem to have taken second place to concerns about economic growth. But while economic growth is still paramount in the policy positions of politicians, more recently, there has been a gradual move towards a more deliberative, inclusive approach to decision-making in the regulation of risk. The remainder of this chapter will be devoted to the discussion and analysis of these two models of decision-making in environmental policy – sound science and the precautionary principle.

3.3. Sound Science and the Precautionary Principle: two models of science in Environmental Policy

Many recent issues that have posed potential threats to the environment or human health have become the subject of controversy, not only if they are new, but because of competing views over proposed solutions, or even as to whether a problem exists. Many of these issues reveal a split between those actors who take what can be described as a 'mechanistic', 'hard' science, or 'sound' science approach, relying on firm evidence of risk, and those who recommend precautionary action when there appears to be significant risk. The former approach is a culture in which the public must rely on the "expert" to decide, using conventional positivist, quantitative methods; where demands are made for verifiable evidence of proof of damage; and where the government's own experts are chosen selectively, while at the same time efforts are made to discredit "outside" expert opinion. It is also a culture of avoidance; in some cases evidence that is controversial is presented to the public in ways that play down its importance. In summary, this idea, a positivist approach, which I will call sound science, is that unless a causal link between an activity, process, or product can be scientifically demonstrated, then government will be reluctant to take remedial action, often claiming that it cannot justify the public expenditure under those circumstances.

By contrast, the precautionary approach, perhaps better known as the precautionary principle, '...assumes that science cannot always provide the insights needed to protect the environment effectively, and undesirable effects may result if measures are taken only when science does provide such insights' (Jordan and O'Riordan 1995: 62). The precautionary principle entails a willingness to take action in advance of hard evidence of proof; the onus of proof is upon polluters to demonstrate that their operations are safe. There is an assumption that polluters are guilty until they can prove their innocence and there is openness and honesty about uncomfortable data. This approach 'is about making decisions in the presence of uncertainty and *before* there is "sufficient scientific evidence"' (Adams 2000: I, italics in original). Since the 1980s, advocates of the precautionary approach have challenged the

positivist approach and are slowly changing the policy discourse (Stirling 2003a:48). As noted earlier, documents such as the Phillips Report on BSE and the House of Lords Select Committee on Science and Technology report (2000), have discussed risk as a more deliberative process, and have brought the idea of precaution into the risk debate. This can also be seen in the increasing number of occasions where precaution is included in international protocols and agreements.

At issue here is the difference of approach to technological risk between (1) those who would propose a sound science approach which emphasises the cost of remedial action and the interests of industry and places the burden of proof on the objectors, and (2) those who would take precautionary action when there appears to be a significant possibility of risk to health or the environment, and place the burden of proof on the initiators of new technologies. This debate between sound science and the precautionary principle is the basis of my theoretical framework. However, using concepts such as 'sound science', 'mechanistic science', 'precautionary principle' and the 'precautionary approach' may lead to confusion. It is therefore necessary to clarify the main theoretical concepts of this Thesis: sound science and the precautionary principle.

3.4. The Characteristics of Sound Science and Precautionary Methodology

If we accept that both sound science and the precautionary principle are policy tools, then it is important to analyse the ideas that they are based on. Therefore, what follows is a detailed analysis of two models of environmental policy-making, based on the concepts of sound science and precautionary principle and an examination of the two types of science that support these concepts. These are summarised in table 3.1, where a distinction is made between the Precautionary Principle and the Precautionary Approach. As we shall see, this distinction is basically between a stronger and a weaker version of the precautionary idea. In the following chapters the two theoretical models (sound science and the precautionary idea) will be used to analyse the four case studies. However, it should be stressed that these two models are ideal types and it is acknowledged that it is unlikely in practice that all scientific research will fall neatly into any of the models.

Table 3.1. Characteristics of Sound Science and Precaution

	Sound Science	Precautionary Principle	Precautionary Approach
Authority of Science/scientists	Separation of science from social issues Exclusive peer review system	Multi-disciplinary approaches Inclusive peer review system	Multi-disciplinary approaches Inclusive peer review system

	Consensus	Co-problem solving Open-ended dialogue	Co-problem solving Open-ended dialogue
Definitions of hazard	Direct harm measured by few variables	Disruption of biological, ecological or social system	Disruption of biological, ecological or social system Proportionality of response to suspect activity Cost-effectiveness of action
Points of Reference	Restricted in temporal scope Focus on molecular/organic levels	Ecological or evolutionary time and multi-generational nature All species	Ecological or evolutionary time and multi-generational nature All species
Error and burden of proof	Scientific experiments designed to erroneously claim there is no effect rather than to erroneously claim there is an effect – (assumes no harm until harm is proven)	Scientific experiments designed to erroneously claim there is a hazard rather than to erroneously claim they are safe – (assumes there is harm until harmlessness is proven) Explanations in terms of patterns and associations Burden on proponents/producers	Scientific experiments designed to erroneously claim there is a hazard rather than to erroneously claim they are safe (assumes there is harm until harmlessness is proven) Explanations in terms of patterns and associations Balance of risks of taking action to prevent suspect activity, against the risk of taking no action
Evidence and Data	Empirical, experimental Quantitative Replicable Deductive	Analytical, experimental, empirical Qualitative and quantitative Inductive and deductive	Analytical, experimental, empirical Qualitative and quantitative Inductive and deductive
Uncertainty	Lack of data or Trans-scientific	Indeterminacy Measures to be taken even when no cause & effect relationship has been established	Indeterminacy Weighs up the level of scientific uncertainty and potential risk of damage as part of management decision

(Adapted from Barrett and Raffensperger 1999: 109)

3.4.1. THE AUTHORITY OF SCIENCE AND SCIENTISTS

Claims to scientific authority are based on Merton's scientific norms, that is, the activities of science are based on the principles of objectivity and verifiability; scientific efforts are cooperative and collaborative; are disinterested (no emotional or financial interests involved);

and are conducted under organized scepticism (wait until the facts are known before making judgements) (Merton 1973). Thus science is said to be a value-free, neutral discipline, with scientific explanations based on empirical evidence, free from the prejudices of religion, politics, or any 'non-science' way of thinking. All positivist scientists subscribe to these ideals. The consequences of this are that:

> When an area of intellectual activity is tagged with the label "science", people who are not scientists are *de facto* barred from having any say about its substance; correspondingly, to label something "not science" is to denude it of cognitive authority. (Jasanoff 1990: 14).

Science, is therefore, 'deemed to be "expert" knowledge and scientists are the "experts"' (Barrett and Raffensperger 1999: 110), where boundaries are drawn between science and policy thereby closing off science from policy, thus preventing non-scientists from challenging or reinterpreting claims labeled as "science" (Jasanoff 1990: 236). In terms of Government advisory committees, this means the need is to recruit experts who have considerable standing among their peers, are trusted by the Government, or as Jasanoff asserts, 'the great and the good' (Jasanoff 1990, *op cit.*). Autonomy is further reinforced by boundaries around specific scientific disciplines because research studies have to be validated by peer review, which is exclusive to the scientific professionals, a process that some believe is mostly concerned with upholding the interests of its members in recognition, authority and 'dependable knowledge' (Jasanoff 1990: 64). In the sound science approach, the science that policy-makers look for is one that can justify regulatory decisions, though this means that scientific objectivity may be sometimes sacrificed to suit the political choices of the government.

However, the environmental and health problems that science aims to remedy are, more often than not, beyond the scope of any single scientific discipline, and therefore, research into such problems need to be multidisciplinary in terms of the natural sciences, but should also include social sciences and others to create a more inclusive peer review system – a feature of the precautionary idea.

The authority of science and scientists under the precautionary idea is a more inclusive one with due consideration given to social and cultural contexts. This is necessary because environmental and health issues exist in a complex world where a variety of ecological systems are at work, and attempting to solve such issues on the basis of individual scientific disciplines does not necessarily work best. Therefore, the methodology that is required to implement the precautionary idea is a multidisciplinary approach that utilizes the social sciences as well as the natural sciences, and even opens up the debate to include the public.

In terms of peer review, it invites contributions from a wide range of actors. For example, in regulating GM crops, farmers and "Green" consumer groups, with a wealth of experience in farming and observing agricultural methods, can make a useful contribution. In short, the precautionary idea 'recognizes.... that research priorities, data, and conclusions are shaped by social context and values' (Barrett and Raffensperger 1999:116), and that science, while essential, is only one of several components of problem-solving.

3.4.2. DEFINITIONS OF HAZARD AND RISK

In environmental terms, hazard is the interaction of technology, society and the environment. Hazards can be polluting in nature, as in the use of pesticides, or as in large-scale industrial failures such as nuclear power plant accidents, or chemical spills (Cutter 1993: 2). Hazards are therefore socially constructed, and 'as such they are imbedded in larger political, economic, social, and historical contexts and are inseparable from them' (Cutter 1993: 2). This idea that hazards are socially constructed has important consequences for the way they are investigated by science – as we shall see.

Risk, on the other hand, is the measured likelihood of the occurrence of hazard – and is a function of two variables: the *probability* of an impact and its *magnitude* (Stirling 1999: 9). The task of assessing hazard is further complicated by the fact that the risks associated with particular hazards may be of varied kinds and differing magnitudes, in that a particular technology may pose more than one hazard and have multiple magnitudes. For example, in assessing the technological risk associated with GM crops, consideration should be given to human health (toxicity, allergenicity, nutrition and unexpected effects); the environment (biodiversity, effects on wildlife, genetic pollution); agriculture (weed control, sustainability); and the economy (consumer benefit, profitability, effects on organic farming). But as Stirling notes, the conventional, positivist response to this diversity of issues is to adopt a 'single major yardstick of performance' for the measurement of 'all the various aspects of risk using this as a metric' (Stirling 1999: 9). In conventional risk assessment this unit of measurement is human mortality, although some complex regulatory appraisals employ measures of human morbidity effects (Stirling 1999: 9). One problem with this reduction of all the diverse dimensions of risk is to ignore consideration of many of the qualitative and incommensurable effects exemplified above. As Stirling concludes:

> The crucial point with regard to many of these dimensions is that, as with many of the different classes of impacts, they are irreducibly qualitative in nature. Even where some effort at quantification under an individual dimension is felt possible, the resulting values

> will be *incommensurable* in the sense that they cannot readily or unambiguously be reduced to a single measure of performance. (Stirling 1999: 10).

Institutionally, there is a distinction between science and values in public policy decision-making: a separation of science into risk assessment procedures, and values into risk management by government. Risk assessment is the technique used by government to find the balance of risks of technological activity against its social benefits. This activity, in sound science terms, is based on reduction and quantification originating in well-defined intensive risk systems, such as mechanical engineering. During the 1980s, the Royal Society *Report of the Study Group on Risk Assessment* (Royal Society 1983) was, according to Stirling, 'the canonical exposition of risk policy (Stirling 2003a: 48). It was a scientific understanding which 'views "risk" as the probability that a particular adverse event occurs during a stated period of time, or results from a particular challenge. As a probability in the sense of statistical theory, 'risk obeys all the formal laws of combining probabilities' (Adams 1995: 8). But as Brian Wynne notes, this approach is not suitable for problems such as environmental systems on a global scale where the background to the problem can be complex (Wynne 1992: 113). For these problems, Wynne believes, 'the limitations of available knowledge are potentially more serious because the system in question, not being a technological artifact, cannot be designed, manipulated and reduced to within the boundaries of existing analytical knowledge' (Wynne 1992: 113).

One critic of current risk assessment procedures, Dr Vyvyan Howard, a member of the Government's Advisory Committee on Pesticides (ACP), thinks the current process of risk assessment is merely a tool to "prove" technologies are safe. He believes that on some occasions, risk assessment reports are presented as sound science, despite the use of unrealistic assumptions, which are not explicitly stated and tend to be hidden in the text:

> ...what people [scientists] try to do is to produce a hefty tome, full of acronyms and other undecipherable words, and so you disenfranchise most of the population immediately because they don't know where to start on them. And then there is a learning curve; you've got to learn what they are getting at. Then they put this on the table as proof that it is safe because they have done a risk assessment. You have to look very carefully at these things to see which hazards have been assessed and whether there has been any data generated. I've seen risk assessments where there isn't one bit of data in it! (Howard 2004 – personal interview).

In summary, while the efforts of sound science centre on seeking the direct effects of hazard, the precautionary idea searches for cumulative, secondary and indirect interactions. Thus, the precautionary idea would frame the scientific questions in broader terms, to

'consider local-and-global ecological and social conditions, and often raises questions about alternative technologies, 'rather than attempting to establish an acceptable level of risk at the outset' (Barrett and Rafensperger 1999: 116).

3.4.3. ERROR

In the search for proof of hazard, resort is often made to statistical methods. In statistical enquiry, a hypothesis is put forward and statistical tests conducted in order to falsify it. This is known as the *null hypothesis*. In scientific experiments, for example, attempting to find a link between a toxic substance and symptoms of ill health, the statistical exercise may suggest there is no link, when in fact there is a link. This is known as a false negative, or in statistical terminology, a Type II error. This is a feature of conventional scientific method whereby it is considered better to erroneously claim that there is no link, than to erroneously claim that there is a link: '...science errs on the side of "no effect" and, therefore, requires stringent standards of experimentation and replication to prove there is an effect' (Barrett and Raffensperger 1999: 112). However, the null hypothesis approach, of following false negatives, can lead to a scientific dead end, with, in our example, no link being proven. This position aids regulatory policies because it allows government to say there is no proven harm, therefore it can proceed to develop what may be questionable technology – a feature of sound science (Barrett and Raffensperger 1999: 112).

The converse of this, a Type I error, or false positive, occurs when experimentation finds there is a link when there is no link. In this case, the experimenter may conclude that because of fundamental statistical problems, such as the sample size being inadequate or the result being due to chance or a statistical fluke, the null hypothesis is rejected. This may raise doubts about the certainty of the result and may generate more research, by asking questions such as: was the positive correct? What contextual factors lead to a positive result in this particular instance? In this process the burden of proof falls on those who argue that the statistical result (the false positive) raises doubts about the certainty of the results – a more precautionary methodology.

3.4.4. BURDEN OF PROOF

Customarily, the law appears to privilege those who cause harm rather than the victims of the harm. Claims for damage are only upheld if the victim can prove that the damage was reasonably 'foreseeable'. In this situation '...the law offers little inducement to developers or operators of industrial processes to take adequate precautions with regard to the environmental impacts of their activities' (Jordan and O'Riordan 1995: 66). There are, of course, good reasons for having conventions such as burdens of proof: they provide barriers

to mistaken research that could undo the scientific status quo (Cranor 1999: 78). In sound science terms, placing the burden of proof with the researcher is useful because it prevents wasteful use of scientific resources and time.

Most definitions of the precautionary idea imply that the burden of proof is shifted, to some degree, onto the developers of new technology, and away from the victims of that development. The precautionary idea generally argues that decision-makers should act in advance of certainty to protect people and the environment from harm. This suggests that the burden of proof be shifted onto the developers of new technologies to show there will be no environmental harm before the new technologies are approved (this is the case in the licensing of new medicines). As one academic put it: 'All it actually amounts to is this: anyone who is embarking on something new should think very carefully about whether it is safe or not, and should not go ahead until reasonably convinced that it is safe. It is just commonsense.' (Saunders 2004). However, reversing the burden of proof onto developers has its own problems, because it 'raises profound questions over the degree of freedom to take calculated risks, to innovate, and to compensate for possible losses by building in ameliorative measures (Jordan and O'Riordan 1999: 28).

3.4.5. EVIDENCE AND PROOF

Scientific research of the type used to validate public policy is positivist in nature and follows the procedures of conventional risk assessment methods, that is, methods designed to collect data that is quantitative and verifiable, and thus able to establish risk and causality. This approach states that if the risk assessment finds no evidence of hazard, then the technology in question must be safe. However, there may be some difficulty in accumulating the knowledge required to establish risk. As one academic scientists notes, finding relevant data on toxic substances is difficult because, for example, 'carcinogens have long latency periods...operated by obscure mechanisms, rarely leave causal "signatures", and moreover, different substances cause different kinds of harm by different mechanisms' (Cranor 1999: 78). The case of research into GM crops shows this tendency: early confined field trials found no evidence of hazard, therefore GM crops were said to be safe. In sound science, this usually means calls for more research. The problem here is that continuous research may produce more of the same negative results. Finding positive results, on the other hand, is more difficult. As Barrett and Raffensperger put it:

> ....definitive proof of hazard may require an environmental disaster to occur....This situation presents a paradox for research on broad-scale environmental hazards: Negative

> data tell us little about possible effects; yet seeking positive data may condone using "society as a laboratory" (Barrett and Raffensperger 1999: 113).

In applying the precautionary idea to environmental hazards there is a broader, more flexible use of data and evidence that goes beyond the narrow sound science approach. The precautionary methodology does not reject scientific method but in addition to it also looks to more indirect relationships such as correlation, patterns and associations, and is more flexible in that it takes into account qualitative data, such as anecdotal evidence: the observations and experience of local people as well as quantitative data.

3.4.6. UNCERTAINTY

It is clear that there are uncertainties, ambiguities and sometimes ignorance, in the process of attempting to define hazard and risk, with a view to ascertaining whether they are serious enough for some form of remedial action. As a result, there is scientific uncertainty which goes beyond the range of known, observable uncertainties that are recognised within the parameters of the system being researched. As Wynne puts it: 'scientific knowledge gives prominence to a restricted agenda of defined uncertainties – ones that are tractable – leaving invisible a range of other uncertainties, especially about the boundary conditions of applicability of the existing framework of knowledge to new situations.' (Wynne 1992: 115).

In a seminal work, Wynne (1992) has produced a typology to identify four different kinds of uncertainty: risk, uncertainty, ignorance and indeterminacy. *Risk* is considered to be when we 'know the odds' – that is, when we know the boundaries of the system under investigation, and are able to measure in some way the factors involved. *Uncertainty* represents knowledge of the parameters of a system – 'limitations of observational and measurement techniques' (Salter 1988:201). *Ignorance* is that which is not known: for ignorance to be identified, new knowledge must be discoverable. The last category, *indeterminacy*, is the 'recognition of the open-ended and conditional nature of knowledge and its embedded-ness in social contexts' (Hunt 1994:117). This fourth category recognizes that social behavior has to be included into the policy process, and generally fits the categories of the precautionary principle and the precautionary approach in Table 3.1.above. It highlights the point that the conventional debate on risk implies that risk is always quantifiable, but in doing so it reduces scientific uncertainties to the notion that what is studied by experts is controlled and all ambiguities are solvable.

The precautionary idea focuses on 'indirect, secondary, cumulative, and synergistic interactions' (Barrett and Raffensperger 1999:116). The precautionary idea while not rejecting the reductionist, quantitative, narrowly scientific model to resolving environmental

problems, adds to it a connection to 'collective democratic interests.' That is, it has 'the potential to provide a forum in which a more holistic view of the liberal democratic settlement' to include 'collective interests and values as well as those of capital and liberal individualism.' (Feintuck 2005: 327). The idea of precaution, and its application to the management of risk, is characterised by the acceptance of the limits of scientific knowledge; its openness to alternatives; the placing of the burden of proof on the initiators of technological change, rather than remaining with victims having to seek compensation; and the inclusion of the views of wider society as well as those of science and industry.

The precautionary methodology is necessary when dealing with scientific uncertainty. But what is scientific *certainty*? This can be explained by Wynne's category of risk, when we know the odds. It is a linear process which results in the determination of causality, or the level of risk, and these can be expressed as probabilities. But, as we have seen in Chapter 2, this way of decision-making is burdened with subjective assumptions. Moreover, the activity or process in question may be of a novel nature - falling within the realm of trans-science where it has not been possible to assign probabilities to outcomes. This is the condition of uncertainty. In such cases, as one study notes: 'once it is acknowledged that the likelihood of certain outcomes may not be fully quantifiable, or where certain other possibilities may remain entirely unaddressed, then uncertainty and ignorance, rather than mere risk characterizes the situation' (Harremoes et al 2002: 188).

3.5. Sound science in policy-making

The sound science approach to environmental and public health problems suggests that policy-makers simply consult the appropriate scientific experts who search for causal links between a reported problem and the product or process allegedly causing the problem. Results are then reported back to Government and decisions are made rationally on the scientific recommendations. But as we shall see there are a number of issues surrounding sound-science based policy.

3.5.1. PROBLEMS SURROUNDING SOUND SCIENCE-BASED POLICY

When there are problems with a particular technology or product regarding its implications for health or the environment, it is normal for governments and industries involved to expect investigations into the issues to be conducted in accordance with conventional scientific method, that is, impartial, objective enquires by scientists with specialised knowledge, using tools such as risk assessment and cost-benefit analysis. Decisions are then said to be grounded in good scientific evidence. In a study of science used in policy making, Liora Salter defined this as 'mandated science', that it is: 'science for the

purpose of making public policy', and this consists of '...the studies commissioned by government officials and regulators to aid in their decision making.' (Salter 1988: 2). Government committees set up to provide advice on specific issues use these scientific studies which are based on the norms of science, i.e., by conventional scientific method involving peer review and publication in academic journals. But it also includes a body of literature that is either not published at all, or only in non-academic journals and with no peer review process. These consist of scientific studies carried out by the industries concerned, for example, a study of a pesticide to be submitted to Government in support of a licensing application. According to Salter, academic research and these proprietary studies are both types of 'mandatory' science (Salter 1988:2). Overall, both give the impression of a process that is based on the norms of conventional science.

However according to Salter, publicly commissioned science 'presents an idealized picture of scientific enterprise' (Salter 1988: 197). Because policy makers have to justify their actions in the political process, science for them, needs to be of a type that can be 'justified and explained to a wide variety of publics and interest groups' (Salter 1988: 5). It must appear rational and give clear choices. Under this pressure it has, therefore, become idealized, that is, it relies on the images of conventional scientific method: it is said to be value-free – separating values from science; the scientific method ensures credible results; and it a public enterprise - it is produced and vetted through public debate - peer review and publication (Salter 1988:5).

But this is not an accurate portrayal of science in the service of policy-makers. First, science is not value free: as discussed in Chapter 2, there is a subjective element of value-judgement that is inevitable in conducting scientific investigations. The falsely ideal picture allows policy-makers to argue that their decisions are based on rational, value, free, independent science. Second, conventional scientific methodologies do not always guarantee clear-cut conclusions because standard scientific methodologies may produce conflicting conclusions that cannot always be resolved by further studies conducted in this way. This can, at times, result in endless technical debate, issuing in decisions that suit the government's preferred position, rather than the correct decision. Third, because the process includes industry-initiated scientific studies that have not been peer reviewed or discussed widely in academic literature, it undermines the idea that it is a public enterprise (Salter 1988: 6).

This idealised picture of science, it has been suggested, may be used as a protective shield to justify policy decisions (Barrett and Raffensperger 1999: 108), and has led to the term 'sound science' being used to justify to the public the grounds for a decision or regulatory

position. For example, at the 1993 North Sea Interim Ministers Meeting, the then Minister for the Environment, Tim Yeo, referred to the need for decisions to be made on the basis of 'sound science.' (MacGarvin 1994:74). Yet, although scientists often use this term sound science in ministerial speeches and pronouncements, it has never, to my knowledge, been defined definitively in official documents.

3.6. Precautionary principle or precautionary approach?

As noted by Cooney and Dickson, there is considerable debate as to whether the terminology 'precautionary principle' and 'precautionary approach' are equivalent or used differently depending on the context (Cooney and Dickson 2005: 5). The fact that much of the literature agonises over the significance, meaning and application of the precautionary principle, indicates that it has one central difficulty – lack of clarity of meaning. One marine biologist argues that it is 'entirely an administrative and legislative matter and has nothing to do with science' (Gray 1990). In fisheries research, the precautionary principle is seen as a hard-line approach that requires complete prohibitions, and in general the precautionary principle appears to 'mandate that risk averse actions always be taken' (Cooney and Dickson 2005: 5).

One convenient way of coping with the problem of defining precaution is to categorize it into 'strong' and 'weak' versions (Morris 2000). In its strongest formulation, and preferred by 'green' NGOs, environmentalists and interest groups, the precautionary principle can be said to insist upon absolute proof of safety before allowing new technologies to be adopted. This formulation can be seen clearly in the Wingspread declaration. A number of academic scientists and lawyers, environmentalists and government researchers from the US, Canada and Europe, undertook the task of attempting to outline ways in which the precautionary principle could be integrated into decision-making. This group of people convened a Conference at the Wingspread Conference Centre, Racine, in January 1998, which resulted in the issue of a consensus statement defining the Precautionary Principle:

> When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof (Raffensperger and Tickner 1999: 8).

Here the onus is placed on the polluters to prove beyond doubt that his/her polluting activities will not damage the environment: that is, there has to be *certainty* that no harm will befall the environment if no intervention is made. This has caused Sunstein (Sunstein 2005: 4) - to express some concern about the use of the precautionary principle. In his view such a strong version focuses on risks to the exclusion of benefits and fails to take into account

trade-offs between risk and benefit. By contrast, a weaker version of the precautionary principle which was agreed in the Ministerial Declaration of the UN Conference on Environment and Development (the 'Earth Summit') in Rio de Janeiro – popularly known as the "Rio Declaration", states:

> Where there are threats of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing *cost-effective* measures to prevent environmental degradation (Principle 15, Rio Declaration – emphasis added).

This is a weaker version than the Wingspread formulation because it has added the caveat that any measures taken should be 'cost-effective', and is often seen as a management approach to dealing with risk and uncertainty. The US Commission on Ocean Policy, for example, has produced a definition which it terms a precautionary approach, and which weighs the level of scientific uncertainty and the potential risk of damage as part of every management decision:

> To ensure the sustainability of ecosystems for the benefit of future as well as current generations, decision makers should follow a balanced precautionary approach, *applying judicious and responsible management practices based on the best available science* and on proactive, rather than reactive, policies. Where threats of serious or irreversible damage exist, lack of full scientific certainty shall not be used as a justification for postponing action to prevent environmental degradation (US Commission on Ocean Policy 2004: 36 – original emphasis).

This is the idea of proportionality: that remedial measures should be tailored to a chosen level of protection. In this formulation, the focus is on the *magnitude* of the effect. Rather than simply saying "there is uncertainty therefore we should not proceed," we are weighing up the level of that uncertainty. In other words, the application of precaution 'is context and case specific, that is it depends on the level of risk a society considers acceptable for a specific substance or activity at a given moment in time' (Christoforou 2003: 206). Similarly, the EU Commission has stated:

> Proportionality means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk (CEC 2000: 3).

To summarize these two positions, there is a continuum between the strongest formulation of the precautionary idea which forbids any activity until its proponents demonstrate it has no damaging environmental impacts; and the weaker version of the precautionary idea which requires regulators to balance the risks (ecological, economic and social) of taking action to prevent an activity, against the risks of taking no action. Henceforth, I shall use the term 'precautionary principle' to denote the stronger versions on this continuum, and the term 'precautionary approach' to denote the weaker versions on this continuum.

Since the 1970s, the precautionary idea has emerged, in one form or another, as guidance in environmental risk management and has gradually gained international acceptance, having, over the years, become enshrined in numerous environmental treaties and declarations, such as the Ministerial Declaration of the Second International Conference on the Protection of the North Sea (1987), and the Ministerial Declaration of the UN Conference on Environment and Development (1992). The German (stronger) version of the precautionary idea, the *vorsogerprincip* (foresight or taking care), was incorporated in European environmental legislation, including the 1992 Environmental Action Programme, and is referred to in the 1992 Treaty of European Union (although without a clear definition). However, it has been observed that the stronger form of the precautionary idea sits

> Uncomfortably with the traditionally 'British' style of environmental policy making, which has been to emphasize the importance of balancing cost, risk and benefit factors in order to elucidate the most efficient use of the environment's innate capacity to absorb waste (Royal Commission on Environmental Pollution 1984: 40).

This reflects the fact that which definition used is dependent on the national regulatory system concerned. The US, for example, prefers what it terms the precautionary approach because, as one academic has observed, US representatives in international discussions object to the use of the precautionary principle, 'mainly citing that it is not sufficiently well defined and hence lends itself to misuse *as a basis for protectionist measures'* (Konig 2000: 125, italics in original). The EU, on the other hand, prefers a formalised idea of precaution that provides a legal basis for regulatory decision-making, which recognizes scientific uncertainties, and monitors for change (Konig 2000). In contrast, the Canadian Government, in a discussion document, does not distinguish between the two terms (Government of Canada 2001).

Whatever the version used, however, the idea of precaution is ambiguous and controversial. When the above-cited definitions of the precautionary principle are seen as formulaic statements many questions are raised that only serve to further confuse. In these

versions for example, how do we define 'threat' and 'damage'? Who decides what is a 'lack of full scientific certainty'? What are the criteria for 'cost-effectiveness'? These kinds of questions, as Stirling notes, 'reproduce many of the issues '...that relate to...'conventional reductive quantitative approaches to risk assessment' (Stirling 2003a: 50). With such contested meanings it is easy to attach subjective interpretations to arguments about the benefits or dangers of using the precautionary idea. The fact is, as with debates on sustainability, the concept of precaution is a hotly contested topic. NGOs and environmentalists, for example, are enthusiastic about the precautionary principle, Greenpeace, in particular, believes it to be a 'scientifically sound philosophy' (Johnston and Simmonds 1990: 402). At the other extreme, is the view that:

> The precautionary principle has become an excuse for imposing arbitrary regulation. Accepted at national level, it is applied by unaccountable international bodies, such as the UN and its various affiliates, to notional problems promoted by environmental, consumer, and other 'civil society' organisations. The international bodies then promote the drafting of international treaties which, once signed, are used by national regulators to justify the imposition of restrictions that could not have been obtained through purely national legislation (Morris 2002: viii).

This view criticises environmentalists who, it argues, insist that in the management of risk there must be 'no trials without prior guarantees against error' (Wildavski 2002: 22).

A similar view asserts that the precautionary idea only serves as an obstacle to scientific innovation. Some scientists, for example, complain that the precautionary principle 'cannot be a valid principle for evaluating evidence,' because uncertainty about a proposed new technology exists even before anything has been produced, and the precautionary principle would instruct us not to proceed any further– it would stifle discovery (Holm and Harris 1999: 11). There is also a criticism that the precautionary idea is over-sensitive to risk. An article reviewing a book on the precautionary principle asserts that '[t]he precautionary principle represents the cowardice of a pampered society.' and demonstrates 'an exaggerated sense of risk on the part of the general public' (Browne and Taverne 2002: 66). An example of this is that given by Durodie, who fulminates against 'unaccountable environmentalists and consumer advocacy groups' who see risky products everywhere 'and seek to regulate human activity' (Durodie 2000:170). Durodie exemplifies this trend by reference to the EU Commission's ban on the use of phthalate softeners from PVC toys. 'The ban is no more than a cowardly and rearguard attempt on the part of the Commission to legitimate its authority by appealing to consumers under the guise of protecting health' (Durodie 2000: 170).

Another view on the precautionary idea focuses on the concept's emphasis on regulatory intervention, both domestically and internationally, which is at odds with the deregulatory agenda that prevails in Anglo-American politics, where the emphasis is on market mechanisms (Feintuck 2005: 373). In international trade, for example, there are currently disputes between the US and EU over the presence of bovine somatotropin in exported beef which are being adjudicated in the WTO. In this view precautionary delays are an excuse: '...the US Government has argued that the invoking of the Precautionary Principle, in itself, implies a retreat from the disciplines of sound science in risk assessment (Stirling 2003a: 52).

On the other hand, both 'strong' and 'weak' versions of the precautionary idea can be seen as closely connected to 'collective, democratic interests and the public domain, which it may serve to reassert in the face of increasingly dominant private interests' (Feintuck 2005: 372). This view is concerned that 'the global political discourse is increasingly premised on a neo-liberal vision which may have the effect of foreclosing debate involving social values', and, therefore, 'the precautionary principle appears to have the potential to provide a forum in which a more holistic view of the liberal democratic settlement may be taken, incorporating collective interests and values as well as those of capital and liberal-individualism' (Feintuck 2005: 372).

This approach to precaution recognizes the open-ended and conditional nature of scientific knowledge and that therefore decision-makers should act in advance of scientific uncertainty to protect people and the environment from harm. 'In essence, the precautionary principle moves the focus of decision making (and hence the questions asked by decision makers) from one of risks, which are highly uncertain and difficult to measure, to one about solutions to problems, for which we can often have a greater level of certainty' (Tickner 1999: 163).

So we can see that ideas on precaution range from those who demand absolute proof of safety – the extreme interpretation of the precautionary principle, to at the other end of a continuum, those who believe precaution is harmful and in fact is anti-science. On this expanded version of my original continuum, somewhere in the middle are those who believe that the precautionary principle is a useful tool for the management of technological risk, by balancing the costs and benefits of intervention and non-intervention (the precautionary approach).

3. 7. The two models: discussion

From the above analysis of the two models, it is clear that they are difficult to define in any hard and fast way: not least because both the sound science and the precautionary idea

make use of conventional scientific method to produce hard evidence. Nevertheless, the models can be summarised as follows.

3.7.1. A SUMMARY OF THE TWO MODELS

Sound science claims to use a positivist approach to science and considers this to be 'a powerful and neutral tool capable of predicting accurately risk and causality' (Christoforou 2003: 208). This view may be an idealized one, which does not take account of the subjectivity that enters all human affairs, scientists not excepted. As one thinker noted: 'natural scientists have...been uncomfortable recognizing the existence (let alone the operation) of "social systems", preferring instead the precision of isolated variable, controlled environments, and quantitative calculation to which physical forces more easily lend themselves' (M'Gonigle 1999: 126). In terms of science used to validate public policy, this can mean ignoring anecdotal evidence or local knowledge on the issue in question. Moreover, reductionist and quantitative procedures imply the reorganisation of human behaviour to conform to the models of human behaviour embedded in the standardised models. But Wynne argues that the social world does not always fit the standardised models, because of the diversity of social situations, with multiple factors that defy reductionist tendencies (Wynne 1992: 119). Wynne illustrates his argument with the example of the UK government's recommendation that co-disposal of toxic and domestic waste in landfill sites was safe. This decision was based on studies where management of the landfill sites used during the research carefully managed what was deposited on the sites. But the recommendation can only remain valid if future dumping at these sites is subject to the same strict management conditions used in the experiment (Wynne 1992: 119). In other words, the knowledge gained from the studies is conditional upon the same standardised human behaviour built into the studies being carried on in future. But this cannot be guaranteed. Thus, it is suggested, sound science methods do not always produce recommendations that can work in reality.

Further, this ideal model does not take account of the fact that much research that is compiled or reviewed by government expert committees is not peer reviewed and has never been discussed in a public forum, being owned by the industries concerned. This has the effect of undermining the independence of the scientific recommendations. Another important factor is that the sound science approach does not find it easy to deal with uncertainty. This may be because there is disagreement about what is known about a particular issue, or there may be agreement about the facts, but the facts are interpreted in different ways. Finally, because sound science is portrayed as value-free and dispassionate in its processes it can easily be used to legitimate environmental and health based regulations on

grounds of objectivity, despite embodying subjective assumptions. What is needed is to put scientific evidence in context by including other forms of knowledge, such as the views of stakeholders and the wider public (Willis 2001: 10).

The precautionary idea, on the other hand, suggests strategies for reducing or mitigating the stringent scientific standards of proof for legal purposes in order to take action to protect the environment and human heath (Cranor 1999: 75). This means anticipating threats of severe damage by paying attention to scientific uncertainty, and in the weaker version of the precautionary idea, by considering *cost-effective* measures to prevent the perceived damage.

Governments clearly need the rationality that hard scientific evidence brings to the appraisal of risk, because environmental and health problems need sound scientific evidence to discover where the uncertainty is located. But in the absence of such evidence, in other words, where there is scientific uncertainty, the precautionary methodology is the tool to deal with these situations. The precautionary idea 'provides both substantive and procedural rationality to the politics of risk regulation' (Christoforou 2003: 205)

3.8. Conclusions

Proponents of sound science believe that precaution in risk assessment is misguided because it is difficult to 'find a generally applicable and universally acceptable definition of the precautionary principle' (Christoforou 2003: 205), and that it imposes an unrealistic burden of proof on technological innovation. However, many of the arguments put forward by critics of precaution are not about risk issues at all, but are libertarian arguments about excessive regulation of society or are about its alleged affect on trade policy.

The precautionary idea in either weak or strong formulations is based on science but its application is conditional upon the presence of uncertainty, and where no causal link has been established. It is also an ethical principle, as it expects the burden of proof to be shifted to the innovator to demonstrate either the safety of the product/technology, or that the level of acceptable risk will not be exceeded.

As we have seen, the precautionary idea divides into a stronger version (the precautionary principle) and a weaker version (the precautionary approach). But it is interesting that at their respective extremes, both sound science and the precautionary principle insist on absolute proof: sound science insisting on absolute proof of harm; the precautionary principle insisting on absolute proof of safety. However, for the most part, technological risk assessment and management decisions should not be seen as a choice between sound science and precaution, but rather as incorporating elements of both. That is,

it 'involves the adoption of a more long-term, holistic, integrated and inclusive social process for the governance of risk' (Stirling 2003a: 52). In the case studies that follow, it can be seen that where the precautionary idea is identified as having been used in policy decisions, it is in its weaker formulation, the precautionary approach, rather than in its stronger formulation, the precautionary principle.

3.9. The Following Chapters: the case studies

How, then do the concepts of sound science and precaution relate to the way governments in Britain go about handling uncertain scientific knowledge? And how can the concepts be used to examine case study evidence of policy-making? In the next four chapters, in four carefully chosen case studies where the British Government has had to utilise scientific and technical expert advice in order to resolve environmental or health problems, we will use the models of sound science and precaution as tools of analysis and elucidation. The case studies have been designed in a particular way to aid this analysis. They all outline the policy problem in question, then analyse the empirical material to explore the links between scientific evidence, expert advice, and policy options open to the policy-makers, and decisions made by the Government. In our analysis, we will explore the reasons for these different governmental strategies using the features of sound science and the precautionary idea as defined above.

CHAPTER FOUR

CASE STUDY 1: Ill-Health in Sheep Farmers: The problem of organophosphates in sheep dip

> *...although the substantial body of evidence that has now accumulated gives little support to the hypothesis that low-level exposure to OPs can cause chronic disease of the nervous system, it does not exclude the possibility that at least some of the illnesses that were described to the Working Group as following such exposure are indeed a manifestation of toxicity (Woods 1999: 93).*

4.1. Introduction

This case study considers the problem of dipping sheep with dip solutions containing organophosphorus pesticides, and the efforts of farmers and their representatives to get the government to accept that it causes serious health problems for anyone using these products. It will describe the characteristics of the group of chemicals containing OPs, their use by sheep farmers, and the putative effects on human health. The study will examine the policy options and decisions made by the Government, the scientific evidence on OPs and sheep dip that were available to the expert bodies that considered the issue of control of pesticides, and the difficulties in developing a hypothesis on the toxicity of OPs and in establishing causal links. The case study suggests that the Government adopted a sound science approach rather than a precautionary one.

4.2. What is the Issue?

4.2.1. THE PROBLEM FOR FARMERS

Farmers and members of their families have for many decades complained that sheep dip containing OPs has affected their health. They complain of headaches, flu-like symptoms, blurred vision and other problems following a period of several weeks dipping. Many also complain of depression, exhaustion, short-term memory loss and confusion (Sigmund 2003c). At a seminar organized by the National Farmers Union (NFU) and the British Medical Association (BMA) on 2 June 1995, many farmers and doctors called for an immediate moratorium on OP dip and compensation for those whose health had been affected.

There are several pressure groups that work on behalf of farmers on this issue. The most high profile of these groups are first, the OP Information Network (OPIN), which is an independent organization funded by charitable sources, and concentrates solely on the problem of ill health related to occupational exposure to OPs; and second, the Pesticide Action Network (PAN UK), a branch of an international, non-profit organization, with the much broader aim of attempting to eliminate the hazards of pesticide use and the reduction of dependency on pesticides. Campaigners estimated that in 1990, there were as many as 2,500 farmers who could be suffering from the use of OPs in sheep dip (Walker 2001). During 1999, PAN UK organized a group action to sue for compensation (PAN UK 1999a); while OPIN has compiled a list of 800 victims of sheep dip, and there are believed to be 25 children among them who have learning difficulties and physical abnormalities (Brown 2000). There is an All-Party Group on OPs in Parliament that meets ministers from time to time and keeps up-to-date on research into OPs. This group has in the past recommended a moratorium on all OPs until an accurate assessment can be made of toxicity and the mechanism of damage.

According to OPIN, Governments do not seem to have given GPs the full facts about the effects of exposures to OPs. OPIN was set up in Cornwall in 1989, following 'concerns about reports from GPs...of curiously similar and inexplicable symptoms being reported to them by sheep farmers – at certain times of the year' (Sigmund 2003a) Since then, OPIN has researched this problem and discovered official papers on exposures to OPs, such as an HSE paper published in 1971 which, it was discovered, was 'not intended for farmers and doctors' (Sigmund 2003a). This paper described the symptoms of OP poisoning, and warned about its ability to permeate protective clothing. As long ago as 1951, the Zuckerman Committee reported that the main problem with OPs were their extreme toxicity and chronic effects. The committee laid down recommendations for training of doctors and regular health monitoring of OP-exposed workers so that they could be taken off work with OPs if 'early symptoms were found' (quoted in OPIN 1995). The Report also recommended that a system should be set up to warn rural GPs if work involving OPs was going on in their area, so they could be prepared for symptoms in patients. But, according to one pressure group, none of this was ever put into practice (OPIN 1995). Farmers and doctors expressed amazement that they were never told of the existence of this research (Sigmund 2003a).

An environmental journalist has suggested that in the wake of the BSE crisis, MAFF is 'reluctant to investigate OPs too closely because officials feared that they would be blamed if

injuries could be proved' (Brown 2000). Brown also claimed that during the years that it had been compulsory to dip sheep, the ministry knew that OPs were dangerous to health. Yet, as Elizabeth Sigmund told me, much of the early research on biological monitoring of workers exposed to OP insecticides was never made available to either farmers or doctors (Sigmund 2003a).

4.2.2. SHEEP DIPPING

Sheep are prone to skin parasites such as keds, lice, blowfly and sheep scab. It was a government requirement that farmers dip sheep once a year to deal with these parasites but changes in regulations now mean that only those sheep diagnosed as being infected with sheep scab have to be dipped. Sheep scab re-appeared in Britain in the 1970s, and compulsory twice-yearly dipping was introduced, but this failed to eradicate the parasite.

Sheep scab, caused by the mites *Psoroptes ovis* or *Sarcoptes scabiei*, is a serious matter because infestations can cause serious loss of body condition in sheep, and it entails increased veterinary expenses (Goodwin 1979: 85). Moreover, the value of sheep hides sold may be affected because sheep scab infestation creates holes in the hide. Sheep scab was a notifiable disease until 1989, but in 1992, dipping ceased to be compulsory, although MAFF made it clear that farmers who did not deal promptly with an outbreak of sheep scab would be prosecuted under the Welfare of Farmed Animals Regulations (PAN UK nd). There is also a code for the welfare of sheep in which it states that 'sheep should be protected by dipping by the use of an effective preventive chemical agent.' (DEFRA 2002b). According to the National Office of Animal Health (NOAH), since the decision to end compulsory dipping, 'sheep scab is now endemic throughout Great Britain' (NOAH 1999b).

Dipping is a practice designed to get rid of these parasites. It is usually done some weeks after shearing when there will be sufficient wool length to hold the dip (Johnston 1983: 118). Winter dip products contain waterproofing ingredients to help fleece shed water (Hart 1985: 70). Cosmetic dips or "show dips" are carried out usually before a sale where, in particular breeds, a curl in the wool is desirable (Hart 1985: 73).

A dip bath or tank may be rectangular with the operator at the side of the bath, or circular with the operator on a central island. They may also be a portable galvanized or fiberglass tank (Johnston 1983:118). The dipping site should be designed in such a way that the dip can readily

be disposed of. There is also a spray method whereby the dip is administered through showers or jetters.

The bath is filled with clean water to a marked level and dip added to the water at a prescribed rate. The dip must be topped up because the solution is filtered out by the wool. A typical bath will hold between 2,000 and 2,500 litres of dip solution. In plunge dipping, the animal is lowered into the tank backwards and must remain in the tank long enough for the dip to penetrate to the skin (Johnston 1983:122). A "T" shaped ducking stick is used to push the head under two or three times. In the dunking method sheep are place in a cage with a wire mesh floor and lowered into the dip (Johnston 1983:118). Dipping is a messy and arduous process that can last for several days at a time (Blackmore & Clark 1994: 39).

4.2.3. WHAT ARE OPs AND WHY ARE THEY CONSIDERED DANGEROUS?

The term 'organophosphates' describe a large range of chemicals with a wide spectrum of physical and chemical properties. They are an organic derivative of phosphoric or similar acids and were first produced in 1854, but developed as chemical warfare agents by Germany during the Second World War because of their action in inhibiting an enzyme known as acetylcholinesterase. This affects certain nerve junctions in animals as well as parasympathetic effector sites (the heart, lungs, stomach, intestines, bladder, prostate, eyes and salivary glands). In humans, these particular OPs have similar actions to those seen in other species. They were introduced as insecticides to replace organochlorines because OPs were considered to be safer (OPIN 1999a: 9). According to the Pesticides Safety Directorate (PSD), OPs can be carefully selected, on the basis of their chemical structure, so that they are very effective agents against their target pest or insect, while following the recommended precautions can control the risk to humans (PSD 2002: 1). OPs that were chosen for animal medicines were selected for their efficacy, cost effectiveness and wide safety factors. They were also thought to be kinder to the environment.

It is accepted by scientists that single high doses of OPs can cause immediate acute symptoms in humans and animals. In humans, exposure to sheep dip can lead to a set of acute symptoms - such as increased bronchial secretions, excessive sweating, nausea, vomiting, diarrhea, and blurred vision, - that can sometimes occur immediately after a session of sheep dipping and can persist for many days (Mutch 2004: personal interview). There are also recorded case histories that consider the possibility of heart disease (Care 1996), and brain damage linked to OP sheep dip (PAN UK 2001). These symptoms can be found in anyone who has a place in the process,

including the farmers or dippers, drivers who transport dipped sheep, those who shear the wool, and factory workers who process the wool, as well as families of those involved. The toxic action is thought to result from the inhibition of acetylcholinesterase, an enzyme essential for normal nerve impulse transmission. The OP chemically combines with the acetylchholinesterase enzyme and inactivates it (Woods 1999.13). Research has shown that a 30-50% reduction in this enzyme's activity in the blood is sufficient to produce the symptoms described above (Parliamentary Office of Science and Technology (POST Note 1998: 4).

OPs were introduced into sheep dip in the 1960s under various sheep scab orders, and farmers were expected to use a government-approved sheep dip (OPIN 1999a). The three main OP sheep dips remaining on the UK market are Coopers Ectoforce Sheep Dip (Schering-Plough), Osmonds Gold Fleece Sheep Dip (Cross VetPharm Group, Ireland), and Paracide Plus (Animax). They all contain diazinon as the active ingredient. During the 1980s, about 40 million sheep on 18,765 farms were dipped about twice a year (PAN UK nd). Exposure of humans to OPs can be by absorption through the skin during handling the concentrate; or when applying the diluted OP dip; or from inhalation of droplets if using a spraying method; or through oral exposure – by operators eating after dipping without having washed their hands.

Manufacturers of the dip solutions do not seem to be actively involved in a programme of long-term monitoring for potential health problems of users. A Channel 4 television documentary "Poison Dip" approached six manufacturers of dip in 1993 about their products. Replies to their enquiries revealed that employees testing the dip were regularly examined and that their blood was tested for the presence of enzyme suppressing substances. Tests of these kinds provide some indication of acute exposure but do not offer any real clue to medium or long-term health problems (Rogers 1993: 246).

4.2.4. THE WIDER IMPLICATIONS OF OP USE

Disposal of waste sheep dip, both OPs and synthetic pyrethroids (SPs), can be a problem for human life and the environment. The disposal of such waste, and the substances from the washing of fleeces of treated sheep into soakways or onto land can contaminate groundwater. The EU considers that this may breach the 1980 Groundwater Directive which states that dip must be incinerated or dumped in licensed landfill sites. However, incineration of used dip has to be done through a reputable specialist waste contractor and is prohibitively expensive, while disposal to landfill sites is also likely to be expensive for farmers because of transport costs. Research studies by the National Rivers Authority (NRA) on the disposal of sheep dip have been

inconclusive, but indicate that 'some pollution of water resources is likely to occur in intensive sheep farming areas as a result of sheep dipping and dip disposal operations (Blackmore & Clark 1994: 38).

It has been estimated that 200 million litres of sheep dip is disposed of each year from around 50,000 dipping facilities (*Pesticide News* 1999). The NRA were unclear about the effects of low exposure to low concentrations of OPs ingested in drinking water over long periods of time, but thought the risk was much 'less than that faced by the persons carrying out the dipping.' (Blackmore & Clark 1994: 39). According to one interest group, Environment Agency tests on water in streams in mid and north Wales found traces of SPs which is highly toxic to aquatic life (Wye Foundation nd).

OPs have also been linked to the ill health of soldiers who took part in the invasion of Iraq in 1991; the so-called Gulf War Syndrome. Some soldiers have complained of health problems since returning to the UK. Their symptoms include muscle and joint pain, fatigue, nausea, and depression – not unlike those reported by sheep dippers. The Ministry of Defence (MOD) has denied there is such a disease as Gulf War syndrome, and there is not much agreement among researchers as to the cause of the ill health, although it has been suggested that OPs used to protect troops from chemical attacks may be a factor. The troops were issued with packs of Nerve Agent Pretreatment Sets (NAPS), which contains pyrodistigmine bromide, as a protection against soman, a form of nerve gas held by Iraq. The British Army also used large quantities of OPs as insecticides to delouse Iraqi prisoners, spray latrines, canteens and hospital tents. Some recent studies suggest that the combined effects of combat stress and exposure to pyrodistigmine bromide and OP pesticides might have contributed to the development of delayed neuropsychiatric symptoms (OPIN 1999b).

4.3. Policy Options and Government Decision

MAFF have long argued that there has been no clear evidence that sheep dips cause any unacceptable human risk when used according to label instructions (PAN UK nd). The government's position on OPs is that they are safe if used according to manufacturers' instructions. MAFF have stated that 'all farmers must now qualify for a certificate of competence to handle sheep. Dipping should be safe as long as farmers take adequate precautions and wear protective clothing.' (*Chemistry and Industry* 1996).

4.3.1. POLICY OPTIONS

The problem for governments when presented with complaints about OPs is that there are few obvious solutions to the dangers of sheep dip. For the Government to simply put a stop to the use of OP dips is not an option because, a) the sheep would suffer and therefore, MAFF would be in breach of its own animal welfare regulations, and b) the animal hides would not be saleable because of imperfections caused by parasites. There appear to be only two viable options: (1) ban the use of OPs and seek an alternative substance that will be just as effective, or (2) continue the use of OPs but implement stronger regulations for the use of personal protective equipment (PPE) and handling and disposal of OP.

Option one exists in an alternative substance, synthetic pyrethroid (SP) dips, which were introduced in the early 1990s. Whereas OP dips are highly effective on sheep scab because they persist for longer on the skin and fleece, but are also highly toxic to humans and the environment, SP dips have a low effectiveness on sheep scab and a low toxicity for humans, but are thought to be one-hundred times more toxic than OPs to many forms of aquatic life (Mutch 2004: personal interview), and are more expensive to buy. Moreover, because of its toxicity to the environment, there are difficulties and considerable expenses involved in disposal of the used SP dip. Of the non-OP treatments available, only three can be used to treat both ticks and sheep scab. Furthermore there is evidence of sheep scab being resistant to SPs, and such resistance could build up if their use became more widespread (House of Commons 2000).

Table 4.1 compares both types of dip solutions. There has been some research into the possibility of non-chemical and vaccine treatments for ectoparasite control, but according to the HSE, there are no new products in sight (HSE 2002: 118).

Table 4.1 Comparisons of Usage OPs and SPs

Type of Chemical	Time scale of Usage	Effectiveness On sheep scab	Toxicity to Humans	Toxicity to Aquatic Life	Can it be Easily neutralized?
OPs	Used solely until the early 1990s	High	High	High	Not easily
SPs	Introduced in the early 1990s	Low	Low	Very High (100 x more toxic)	Yes

It has been suggested that farmers could do without dips, or at least cut down on their use, by developing better sheep husbandry strategies. Some organic sheep farmers, for example, have

used specially selected sheep species, combined with better husbandry techniques, which cuts down the need for dipping:

> ...(t)here are ...alternatives, so how come organic farmers can use much lower levels of synthetic pyrethroids, but with better animal husbandry, and ensure the welfare of the animal? (Watterson 2003: personal interview).

Seeking alternatives to OPs does not appear to be one that has been seriously discussed by MAFF in the past, although MAFF's successor, DEFRA, does now seem to have commissioned some research into alternatives. For the past decade, option two has been the preferred course of action of MAFF.

Under both EU and UK law, before any animal treatment is sold it must go through a stringent licensing procedure, and have a "marketing authorization". Moreover, veterinary surgeons who dispense medicines and animal health distributors who sell to farmers, are trained and qualified by examination, and there has long been advice on the handling and disposal of OP products; both from manufacturers of OP products and from government sources, but these precautions were initially minimal. The current specification for PPE is outlined in the 1998 HSE leaflet AS29 (rev), *Sheep Dipping*. The advice in this document is that dippers should wear a face shield, a boiler suit, a PVC apron, Wellington boots, waterproof leggings, and specified rubber gloves. In the debate on the dangers of OP dips, the government has been able to use the recommendations of experts that there would be no harm to health so long as specified safety protocols were followed by users. The cans containing the dip concentrate had been redesigned by adding a larger extendable plastic spout to reduce splashing, but there still remains the problem of the dip running back down the spout and accumulating on top of the can (*Pesticide News* 2000b). According to PAN UK, most of those who come into contact with dips are not adversely affected and there are many professional dippers who have shown no ill effects. 'However it also seems to be the case that some unfortunate people who do wear protective clothing and observe manufacturers' instructions have also been made ill' (PAN UK nd: 2).

One farm manager at an agricultural college who for many years dipped sheep once a year, had health problems said to be caused by OPs. He recorded the fact that he had not been given advice or protective equipment when he started work at the college. He relied upon manufacturers' label advice but believes they did not give proper safety advice or warnings about what symptoms to look out for. And, according to a clinical neurophysiologist who examined

him, his illness was clearly due to sheep dipping, because be had only ever worked with sheep and had had no contact with other chemicals (Chemical Hazard Handbook 1999).

There are many occupational health studies of the effectiveness of this protective clothing during sheep dipping operations. Most of the studies agree that pesticide penetration through recommended PPE is minimal and that the protective equipment is therefore adequate if used correctly, but admit that the wearing of rubber and PVC garments in hot weather, while carrying out hard physical work imposes a 'real physiological burden on wearers' (HSE 2002: 75). One Veterinary Medicines Directorate (VMD) study found that wearing PPE did not have a significant impact on the reporting of health symptoms (Dunn 2002: 10). Moreover, the PPE is subject to immense wear and tear during dipping operations. It is notable, however, that over time the official advice has changed:

> Initially the recommended PPE – such as gloves, pinafores and boots, etc, were made of rubber. Then we found that solvents in dips rotted rubber, so nitrile was advised. When OPIN questioned inhalation as a route of exposure, VMD denied its significance – but within weeks was advising the use of gas masks (Sigmund 2003a).

Similarly, there have been a number of studies on farmer's compliance with governmental and manufacturers' advice on the use of PPE. One example of this is the HSE survey of 696 farms and 1800 people involved in dipping. The survey revealed a high disregard for the PPE rules among operators, many of them did not even possess a face shield and many of them did not wear gloves (HSE 2002: 174). From a questionnaire study, it was evident that farmers generally don't understand fully the risks of exposure to sheep dip (HSE 2002: 178). This is borne out by the experience of Professor Alistair Hay, a member of an HSE advisory sub-committee on communication in industry who assesses the average reading age in industry at about that of a 12 year old (Hay 2004: personal interview). This situation is very reminiscent of Wynne's argument, cited in Chapter 3, that scientific reductionism assumes that human behaviour is *reorganised* to conform with the human behaviour embedded in the standardized models. Hence scientific knowledge about the effectiveness of PPE is conditional upon dippers operating strictly according to the recommendations in the studies.

OP manufacturers' central line of defence in this matter is that OPs are safe as long as they are used in accordance with the safety advice on product labels. But this argument does not stand up to scrutiny. When farmers began using OPs, the concept of OP poisoning did not exist, and between 1976 and 1992, OP dip containers merely stated that the chemicals were potentially

hazardous, but did not recommend protective clothing and equipment. Nor did containers carry the warning signs of the skull and crossbones. (Driver 2003: 21).

4.3.2. GOVERNMENT DECISIONS ON OPs

The concern shown over this matter by those groups representing sick farmers, press reports, and questions asked in Parliament, prompted the Government to refer the matter to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). On 22 May 1998 a Working Group of the COT met for the first time under the Chairmanship of Professor Frank Woods. The remit of the group was 'to advise on whether prolonged low-level exposure to OPs, or acute exposure to OPs of a lower dose than causing frank intoxication, can cause chronic ill-health effects' (Woods 1999: 91). The Veterinary Products Committee (VPC) and the Advisory Committee on Pesticides (ACP) were also asked to consider whether the study affects MAFF advice on the safety of OPs (BBC News Online 1999a).

The COT working group reported its findings in December 1999 (Woods 1999). The working group based its deliberations on a search of the scientific literature up to June 1999 (29 studies, including the reports outlined above). They concentrated on the effects on human health of a general class of OPs, using human data relating to the chronic neurotoxicity of OPs, and they listened to those who had suffered illness that might be linked to exposure to OPs. It was a very cautious report, questioning the mechanisms that play an important role in the causation of adverse health effects by OPs. The working group listed various shortcomings in the studies reviewed, and attributed them to:

- Differences in those taking part, that might affect their performance on neurophsychological tests;
- The size of the studies, being not large enough to establish random variation;
- Sampling problems – some may be volunteering because they were ill; and some samples restricted to current workers, excluding those who had no employment, perhaps through ill health.

The Working Group also claimed they were limited in their research by a lack of clinical data, i.e. a lack of systematic description of the clinical features of a large case series. They had searched through the government's existing departmental schemes for reporting adverse reaction to medicines – for example, the Medicines Control Agency's "yellow Card" scheme and the

Veterinary Medicine's SARSS scheme - but only a small number of cases with no consistent pattern were found. SAR reports, in particular, give insufficient data on the components of dipping (for example the use of dip/handling and the sheep/work load); and many respondents fail to give explicit information concerning their exposure history (Dunn 2002: 16).

The Woods Report concluded that:

- the balance of evidence supports the view that neuropychological abnormalities can occur as a long-term consequence of *acute* OP poisoning, but
- evidence relating to long-term, low-level exposure to OPs (insufficient to cause acute toxicity) is less convincing; and
- evidence relating psychiatric illness to OPs is insufficient to allow useful conclusions.

But the report also recommended further research, in particular into the issue of whether the effects of exposure to OPs is restricted to a small sub-group of people (Woods 1999: 91-2).

Three regulatory committees, the VPC; the Committee on the Safety of Medicines (CSM), and COT, advised the government that ill health from prolonged low-level exposure to OP sheep dip remain unproven and on the basis of current knowledge no general withdrawal of OPs from the market was necessary, but they endorsed the need for further research. The government accepted the line argued by the VPC, COT and PSD, that risk to humans can be controlled by following prescribed precautions, and it insisted that there is no clear evidence that sheep dip causes any unacceptable human risk provided these best practices are adhered to. The government accepted its own expert advice that studies so far have not been able to prove the link between dippers' symptoms and the OPs contained in the dips. However, in response to the COT's verdict on the Institute of Occupational Medicine (IOM) report, on 20 December 1999, MAFF withdrew OP sheep dip containers from the market until manufacturers could introduce improved packaging that 'will minimize operator exposure to OP concentrate.' (MAFF 1999). This meant the temporary withdrawal of sheep dip products from the market pending the redesign of packaging. This move did not go down well with some who thought it would be a "logistical nightmare" for farmers because it meant removing all stocks from the market – down to farm level – with many months passing before replacement packs become available (NOAH 1999b). MAFF has now devised an action- plan to improve OP containers; to develop best practices; and to revise the system of certification for the manufacture and packaging of the substances, and for the

supervised training of sheep dip operators (a certificate of competence) (MAFF 1999). An immediate programme of further research based on the COT report recommendations was also announced.

In March 2000, DEFRA, DoH and HSE jointly announced a programme of research 'designed to address further questions into the effects of OPs on human health' (DEFRA 2001), and announced funding for an analytical survey of health complaints among sheep dippers to be undertaken by the London School of Hygiene and Tropical Medicine. At the same time, the HSE announced new advice for GPs, regarding monitoring and prevention of occupational illness caused by OPs (HSE 2000). Shortly after this, the House of Commons Agriculture Select Committee made certain recommendations regarding the labelling of OP concentrates. In particular, they recommended a form of wording on labels that stressed the circumstances under which OPs could be used and the risks associated with concentrates. They further suggested that a laminated sheet setting out in plain language the dangers of handling sheep dip should be distributed at the point of sale and that this should be a legal requirement.

4.4. Scientific Evidence and Expert Advice

4.4.1. SCIENTIFIC EVIDENCE ON OPs

There are three main sources of information on the effects of OPs. First, there are epidemiological studies of people involved in the use of OPs. Second, there are clinical reports on patients with histories of OP exposure, which entail experiments to establish the likely extent of exposure. Third, there are studies on the effects of OPs on the central nervous system of animals. Among the criteria by which studies can be judged are:

- *Adequacy of control* – does the study include an appropriate control (unexposed) group?
- *Sample size/statistical power* - does the study include sufficient people to give statistically meaningful results?
- *Selection bias* – are the people selected for study representative of the population under study, or has the selection process introduced some form of bias?
- *Overall study design* – did the study involve very small number, or was it a large cross-sectional study?

The problems for researchers are the difficulties in developing a hypothesis on the toxicity of OP intoxication, and in establishing causal links. Establishing causal links would need:

- reliable evidence that illness is more common in farmers/dippers who have been exposed to OPs than is likely to be explained by other known causes of illness;

- a toxic mechanism through which OPs could cause illness.

Studies are hindered by a range of factors, such as difficulty in measuring actual exposure levels, the variety of OPs on the market; the length of time between exposure and the appearance of the symptoms; and the diverse nature of the symptoms. There is no alternative but to base studies on people who have been unintentionally exposed to OPs, paying careful attention to sampling, bias, confounding, quantification of dose exposure and verification that the psychological tests used are valid for toxicity studies (*Lancet* 1998:499). All of the above considerations are standard features of normal science, as described in Chapter 2.

The problem seems to be that there is no general agreement on the effects of lower doses, and there are no studies of long-term and multiple exposures to OPs. The toxic effects of OPs as a class of substance are classified into three categories:

- Acute (short-term) effects - inhibition of the enzyme acetylcholinesterase
- Intermediate syndrome – delayed effects following inhibition of acetylcholinesterase
- Chronic (long-term) effects – OP induced delayed polyneuropathologies

(Mutch 2004: personal interview).

The postulated long-term effects of OPs following long-term low-level exposure have resulted in some studies that have shown subtle effects (e.g. slower reaction times) in tests for neurological function. The problem for researchers is that the alleged theories and mechanisms are sometimes not related to acetylcholinesterase activity. (PSD 2002: 2). One academic research scientist, Elaine Mutch, in the field of OP substances explained that 'it is common for humans to want an explanation for an illness, and if they experience symptoms after sheep dipping, whether or not it is connected, they like the idea of something to blame.' Dips contain substances other than OPs that could cause some of the symptoms experienced, and Mutch has talked to farmers who claim they feel sick just smelling the dip (Mutch 2004: personal interview). Industry based researchers suggest that the answer to the problem is that certain individuals are vulnerable because they have weak immune systems (Walker 2001).

In some cases, it is necessary to carry out experiments to establish the likely extent of exposure and this is often in the form of a mathematical model that is based on representative measurements. When an exposure has been estimated, it is compared with the acceptable operator exposure level (AOEL) that defines a level of daily exposure that would not cause adverse affects in operators who work with a pesticide regularly over a period of days, weeks or months. (DEFRA 2000a: 10).

The government has a voluntary scheme for reporting suspected adverse reactions to veterinary medicines. This is known as the Suspected Adverse Reactions Surveillance Scheme (SARSS) and is run by the VMD. The idea is that a vet or farmer may report to the VMD any case of harmful and unintended reaction to a veterinary medicine administered to an animal. VMD can react to these reports by recalling a product, revoking a market authorization or recommending changes to labeling of products. However, this system has been criticized because it is said that the questionnaires have not been constructed in a way that would elicit meaningful information, and there are no medical follow-up procedures, which means the scheme does not produce much factual evidence for scientists (Sigmund 2003a: personal communication). Moreover, according to DEFRA, 'the precautionary principle is applied as routine in the investigation of new pesticides' (DEFRA 2000a: 15). DEFRA also claims that over the years, the regulation of pesticides has become more precautionary with constant reviews of products that are already approved (DEFRA 2000a: 14). However, this does not mean that, when reviewing existing products, the ACP will make explicit precautionary decisions. 'Rather it aims to give due weight to all uncertainties in the risk assessment, whether they relate to risks from continuing or withdrawing approval.' (DEFRA 2000a:16). This includes any risks associated with withdrawal as well as continuing use.

Since the emergence of reported problems with sheep dip, a number of scientific studies have been carried out. The first study to pin down the health effects of using OPs was carried out by the UK Institute of Occupational Health, Birmingham in 1995 at the request of the Health and Safety Executive (HSE). This report 'compared the performance of 146 sheep farmers with 143 quarry workers in tests on cognitive functioning and mental health.' (Stephens et al 1995: 1135). Farmers were recruited from the Wool Marketing Board registration lists for Devon, Cumbria and north Wales by selecting every tenth name on the lists. The quarry workers were recruited in the same geographical areas. The study was carried out at a time when farmers were not involved in sheep dipping in order to avoid any observed effects that were of recent exposure (Stephens et al 1995:1135). The study concluded that it is reasonable to accept 'that chronic long-term effects on

the nervous system have occurred in this group of farmers and that these effects are likely to be associated with long-term exposure to organophosphates' (Stephens et al 1995:1138).

The VPC met to consider this report, and whilst accepting that it contributed to the body of knowledge, it was not considered to be a definitive study, and the committee did not find sufficient evidence to support a ban on OPs. Indeed, the VPC concluded that chronic ill-health in sheep farmers was not due to long-term, low-level exposure to OPs in sheep dip (*Pesticide News* 1995). The later COT examination of this study concluded that it was limited by the small sample size, and that examinations were not fully blinded (Woods 1999: 196). The then Agriculture Minister, William Waldgrave, told the Agriculture Select Committee that "we are doing a range of further work", and that "if it shifts the balance of probabilities, we will ban the products". (*Pesticide News* 1995).

On 11th November 1998, the Royal College of Physicians and Psychiatrists issued a joint report: *Clinical Aspects of OP Sheep Dip Exposure.* This report concluded that farmers were 10,000 times more likely to suffer from mental disorders if exposed to OPs (*BBC News Online* 1999b). COT did not agree with this report, stating: 'the evidence relating psychiatric illnesses to OPs is insufficient to allow useful conclusions' (Woods 1999: 92).

In 1999, a major study was carried out at a cost of £500,000, conducted by teams at the Institute of Occupational Medicine (IOM), Edinburgh University, and the Institute of Neurological Sciences, Glasgow. The aim was to study whether cumulative exposure to sheep dip OPs is related to clinically detectable measures of polyneuropathy (Sewell et al 1999). The subjects of the study were farmers and dippers (not self selected sickness sufferers) from the Scottish borders. An important observation in the study was '...that the most important source of exposure to OPs was contact with the dip concentrate....larger flock sizes tended to result in more replenishment of the dip bath and hence more handling of the concentrate containers'. The report linked long term ill health, 'including dizziness, impotence, muscle problems, and pins and needles in the hands, to repeated exposure to OPs, particularly in concentrated form before they were diluted in the dips.' (Meikle 1999). The study found that up to 20% of farmers who have used OP sheep dip could have nerve damage and that those with disease of the nervous system could also suffer anxiety and depression (Sewell et al 1999). The report suggested that the greatest hazard arose when handling the *concentrated dip.*

The question of whether or not some dippers are more susceptible than others to OPs, has been considered in a study conducted by members of a team of scientists from the Centre for Occupational and Environmental Health, Manchester University, whose report was published in *Lancet*, March 1 2002. This was a clinical study funded by HSE, and looked at genetic differences in OP exposed people, and showed that people who have dipped sheep and become ill are more likely to have a variant in their genes that make them less able to break down OPs once they get into the human body. However, the study could not rule out the possibility either that ill health was due to exposure even in those whose genes appear to put them at low risk, or that for those at higher risk, ill health was due to exposure to other toxins. (Cherry 2002). In summary, all of the studies into exposure to sheep dip discussed above appear to have one important conclusion in common: that there is a hazard attached to working with OP substances. The problems of proving any firm link between the OPs and farmers' symptoms are challenging when investigations are conducted on the basis of null hypothesis – the idea of trying to disprove something. An occupational and environmental health professional, Andrew Watterson, believes that the data reviewed by policy-makers has increased over the years, is of good quality, and the findings are consistent in suggesting dangers in the use of OP sheep dip, and concludes that there is a compelling argument for the application of the precautionary principle (quoted in Fairclough 2003: 436).

4.4.2. EXPERT ADVICE ON OPs

In Britain, the regulation of pesticides is covered by an Act of Parliament. The Food and Environment Protection Act 1985 (FEPA) has the following aims:

- To protect the health of human beings, creatures and plants;
- To safeguard the environment;
- To secure safe, effective and humane methods of controlling pests;
- To make information on pesticides available to the public.

The Control of Pesticides Regulations 1986 (COPR) provides the mechanism for the implementation of the aims of FEPA. They prohibit the sale, supply, storage, advertisement or use of pesticides unless Ministers approve them. Ministers are advised on approvals by the Advisory Committee on Pesticides (ACP), a committee of scientific experts in this area.

This legislation, which promotes worker health and safety in pesticides use, does not apply to sheep dip because dip is classed as veterinary medicine rather than pesticides. The Control of Substances Hazardous to Health Regulations 1988 (COSHH) apply to the mixing of dip, but not the dipping process, on the basis that when the dip is diluted it is not hazardous to health (PAN UK nd). Therefore, although FEPA governs pesticide use, it does not apply to veterinary medicines. The Veterinary Medicines Directorate (VMD), an executive agency of DEFRA, is responsible for approving animal products and medicines which includes OP dips and SP dips. The VPC gives advice on safety, quality and efficacy in relation to the veterinary use of substances not included in the Medicines Act. (see a summary of this organization in figure 4.2). The control of OP sheep dip is also covered in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1988. MAFF jointly with HSC, have issued two codes of practice: a Code of Practice for the safe use of Pesticides on Farms and Holdings, and Code of Practice for Suppliers of Pesticides to Agriculture, Horticulture and Forestry.

4.2: Table 4.2: ANDPBs Involved with Pesticide Regulation

Advisory Body	Sponsoring Department	Advice to
Pesticide Safety Directorate (PSD)	DEFRA	DEFRA Ministers
Veterinary Medicines Directorate (VMD)	DEFRA	DEFRA Ministers
Veterinary Products Committee (VPC) *Advises on safety, quality & efficacy Of veterinary substances*	DEFRA (through VMD	Licensing authorities
Advisory Committee on Pesticides (ACP) *Approval for sale of pesticides used on animals or involving humans*	DEFRA (through VMD)	advises Ministers in the regulatory departments & FSA
Pesticide Residue Committee (PRC)	DEFRA (through PSD)	PSD
Committee on the Safety of Medicines (CSM) – *advises on the safety & quality of substances for human use*	Department of Health (DoH)	DH/DEFRA Chief Medical Officer
Committee on Toxicity of Chemicals in Food (COT)	FSA	FSA/Chief Medical Officer

The regulatory committees involved in advisory science listed above are all NDPBs and are sponsored by two different government departments: the VCP is a DEFRA advisory committee; CSM is a DoH advisory committee and COT advises the Food Standards Agency (FSA). HSE has the role of ensuring the safe use and disposal of veterinary medicines.

A new pesticide has to be approved for sale by the ACP, and this committee will require evidence of the product's efficacy and assurance that it does not pose an unacceptable risk to human health or to the environment. To this end, companies must seek approval by submitting a package of scientific data on a new product. On the basis of these data, a decision is made as to whether the new product requires labeling as a hazard and on possible effects to operators.

However, there is some evidence that the system for regulating pesticides in agriculture is not transparent and is not open to proper public scrutiny. Recent research into pesticide regulation suggests that current regulation and risk assessment of OPs lacks rigour and draws conclusions about low-level risk that is not justified by the literature, and indeed there is often a lack of literature (Fairclough 2003). Moreover, there is evidence that the way the VCP operates favours the interests of industry at the expense of the public: Fairclough's study found that in the current regulatory system, there is a lack of 'formal oversight of the evaluations of scientific data '...as trust was placed in the ...pesticide industry to protect public safety' (Fairclough 2003: 104). Fairclough's research found that of the 21 members of the VCP in 1993/94, 'nine declared they had undertaken consultancy work for pharmaceutical companies and nearly half of the Committee declared that they had received some form of research funding from pharmaceutical companies. (Fairclough 2003:110). One Professor of Occupational Health concurs with this view and believes there are indirect pressures from industry, pointing out that a number of members of advisory committees have share-holdings in chemical companies: '...it's only recently that we've known what the shareholdings were - of the representatives on these committees, and if you look at the Pesticide committees, some of them have shareholdings in chemical companies' (Watterson 2003: personal interview). Moreover, the system of authorizing OP products is flawed. The method of obtaining advice on the OP products is based on paying a fee to the chemical companies for advice on their own products. This is based on the imperative that market research should not be done by Government (Harvey 2004: 12). While this conflict of interest does not necessarily mean that decisions will be biased, it increases the risk of bias. Fairclough also found that the evaluation and interpretation of scientific data and the details of decisions on approvals are not fully available to the public: her own attempts to access such information from

the ACP met with continuous refusals (Fairclough 2003:115). The independence of the committees involved in pesticide regulation is questionable. Members of committees rarely had time to digest the huge amounts of data contained in applications for approval or reviews and it has been suggested that toxicological evidence presented at meetings could have their meanings changed after being interpreted and recorded by civil servants (Fairclough 2003:110).

4.4.3. DISAGREEMENTS OVER THE EVIDENCE

NOAH, the umbrella organization that represents the agro-chemical industry, 'congratulated the COT working party for the open and thorough way in which it conducted its enquiry and the trouble it took to ensure all interested parties had the opportunity to provide evidence' (Sketchley 2003). But the report has been highly criticized by many organisations. OPIN proclaimed their disappointment that the working group did not answer the question of whether there existed scientific proof that low-level exposure to OPs could cause chronic neurological and neuropsychiatric damage. They asserted that many of the recent studies considered by COT in their report had already answered this question (OPIN nd b). They also questioned the *validity* of the report in view of the group's admission that they had found the existing sources of clinical data of limited value. PAN also made a similar point when they claimed the report was a paper exercise, because no clinical examinations of sick people had been carried out; there were no clinical databases; and the report highlighted institutional failure, in that the VMD SARSS scheme was unable to contribute any useful data (*Pesticide News* 2000a). A further OPIN criticism was that the report did not give clear definitions of such terms as "acute" and "chronic" effects when used in considering "acute" exposure and "chronic" effects. Nor did the report clarify what is meant by "dippers' flu".

COT's call for research which quantifies and measures precisely the amount of OP exposure a victim has had, was rejected by Emeritus Professor Malcolm Hooper, a medicinal chemist, at Sunderland University, who said that OPs are now so widely dispersed in the environment that only in a laboratory would it be possible to measure such quantities, and this would be of little practical value. (PAN UK nd). At a scientific workshop organized by the government's Central Science Laboratory, the IOM, represented by Dr Adele Pilkington, described its own study, which appeared to contradict COT conclusions, in that it found '...up to a fifth of the sheep farmers who used OP dips, are suffering, or will suffer, peripheral neuropathy or chronic ill-health' (PAN UK 2000).

OPIN's conclusion was that COT's report, 'from a group selected and supported by a government department, once again leaves the scientific community with a huge question mark over the political use of science and medicine.' OPIN nd b). They argued that their reading of the report gave the impression that there had been disagreement between members of the Working Group:

> ...there obviously were sharp differences between members coming from conflicting positions, either of previous experience or strongly voiced opinions, and that an attempted synthesis, built upon basic contradictions and deliberate implicit denial of the validity of preceding scientific studies, is no way to produce a scientifically respectable report about a serious matter of public and occupational health. (OPINnd a).

I put these remarks to Dr Mike Joffe, a member of the Working Group, who replied that 'there was a lot of methodological discussion and you could say disagreement, and that is what scientists are for – to disagree until consensus is reached." He admitted that he could think of one or two people who were 'vehement and didn't shift their position but they were genuinely trying to learn from other people' (Joffe 2004: personal interview).

4.5. Discussion

In terms of our theoretical options in Chapter 3, the facts of the OP issue suggest a sound science approach rather than a precautionary one. There has been much research into the problem – all soundly based on scientific method with some fairly obvious conclusions: that OP substances are dangerous but can be safely used; and that some users of the OP products are more likely to be affected than others. Features of the precautionary approach are absent, such as the recognition that there is relevant knowledge other than specialized scientific knowledge, which seems to have been ignored. Let me explore the evidence for my interpretation, in accordance with the models of sound science and the precautionary principle, as set out in Chapter 3.

The authority of science/scientists

The empirical evidence of this case seems to indicate that the research carried out to establish a causal link between the OP dips and ill health in users was done between government expert committees and the industries concerned. MAFF operated as a closed policy community: because of the regulatory system in place, the licensing and information on OP dips remained with government and the chemical industries concerned. This approach meant that peer review was inclusive to government experts and industry experts. The decision-making on approvals and reviews of OP sheep dip products were made in a consensual way 'between the regulator and

those being regulated without formal scientific analysis' (Fairclough 2003: 105). These are all signs of a sound science approach.

Definitions of hazard

The investigations into the potential problems of using OP sheep dip was focused on the direct effects of the products. That is, Government expert bodies looked for direct and measurable impacts on individuals. That is a typical approach to toxicological studies, in which risk assessment was confined to reviewing existing human data relating to neurotoxicity, and reviewing information from the Government's adverse reaction surveillance scheme. This is a sound science approach – there is no evidence that the Government study looked to any wider, social context: on the contrary, the COT report dismisses any social aspects from its deliberations: 'Individual case reports were informative but could not be used to make any assessment of cause and effect' (Woods 1999: 2). The comments of the then Agriculture Minister, William Waldgrave (*Pesticide News* 1995, *op cite*), are an example of this – he was waiting for a shift in the balance of probabilities before placing a ban on OPs.

Evidence and Data

The scientific advisory bodies, (ACP, COT and VPC), reviewed 29 existing studies by professional and academic institutions, which contained published data on sources and routes of exposure, the metabolic pathways of OPs in the body, and mechanisms of toxicity (Woods 1999), without being convinced by this evidence, yet have not conducted any clinical studies of their own with which to make comparisons. For its part, the Woods report ignored any data that was not empirically verifiable and quantitative. On the recommendations of the COT study, DEFRA commissioned yet more research and took steps to tighten up safety regulations on packaging, storage and handling of the dip solutions, in the hope that strict adherence to this would eliminate the risks to dippers' health.

Burden of Proof

The report produced by the Government's own expert committee, COT, is perhaps a classic example of the use of the false negative, i.e. concluding that it is better to claim their research found no link than to claim there was a link. As Barrett and Raffensperger have noted, it is better for science to erroneously claim there is no effect, than to erroneously claim there is an effect (Barrett and Raffensperger 1999: 112). In terms of OP sheep dip, this means it is better for scientists to claim that there is no effect and, therefore, there requires much more experimentation

to prove there is an effect. This seems to be what has happened in this case. A sound science approach of this type helps government justify doing nothing about the substance on the basis that because it has found no conclusions that point to any certainty, then it can proceed to regulate the use of sheep dip.

Uncertainty

There were two areas of uncertainty about the use of OPs: whether or not the dip causes chronic health problems in users, and whether PPE is an effective protection for users of dip solutions. The controversy was over scientific evidence: while it has been accepted by the Government and its scientific advisers that exposure to OP dip solutions causes acute effects, such as headache and fever, there was no agreement on the long-term effects of constant low-dose exposure, such as depression or psychiatric illnesses. The studies commissioned by HSE and considered by the Government's expert committees were epidemiological studies. This type of study is useful as it deals with human situations, however, as these studies are not conducted under laboratory condition, data obtained on exposures to OPs cannot be accurate, and moreover, subjects may have been exposed to more than one toxin. Thus conclusions are uncertain. Under Wynne's typology, uncertainty represents knowledge of the parameters of a system, which was the case with OP research. However, what does not seem to be present in OP research is Wynne's category of indeterminacy: the conditional nature of knowledge and locating it in social contexts – in the OP case, an ignorance of how sheep dippers work, and failing to incorporate farmers' knowledge into their scientific deliberations.

In addition, given the physical differences in individuals it is difficult for science to develop a suitable hypothesis that will help establish causal links. First, sheep dip contains many chemical substances other than OPs, all of which could affect human health. Second, as levels of enzymes and other aspects of human physiology differ between individuals, deciding on what is a toxic dose is very difficult. Third, in the research that used individual respondents (farmers) to questionnaires, it is difficult to decide whether a person simply 'thinks' his/her symptoms are the result of OP poisoning; whether the symptoms are caused by OPs; or whether they are the result of a host of other possible explanations. And fourth, there is a problem of deciding whether there exists a sub-group of people who have levels of certain enzymes that make them more susceptible to illness from OP dips than is the general population. Therefore, this leads to indeterminacy, a position where scientific knowledge is conditional and there is a need to include social behaviour in the policy process.

4.5.1. SUMMARY

As one farmer's support group observed on the COT report: 'This is the language of many previous reports to Government on the subject and is a tried and tested method of taking the heat off while the issue gets pushed around the table to yet another committee.' (OPIN nd b). All of this suggests a sound science approach; that the Government is confident about the advice it has been given, and asserts that the burden of proof is with dippers and their supporters. Moreover, in deciding whether or not certain chemicals can cause particular effects, government advisory bodies do not consult farmers, or anyone else involved in the practical job of actually using sheep dip (*Pesticide News* 1995).

4.6. Conclusions

This chapter has dealt with the problem of a dangerous chemical substance in the workplace. The issue here was health problems suffered by sheep dippers, their families, and other workers peripheral to this activity. There was controversy over scientific evidence: while it has been accepted by the Government and its scientific advisers that exposure to OP dip solutions causes acute effects, such as headache and fever, there was no agreement on the long-term effects of constant low-dose exposure, such as depression or psychiatric illnesses. After each piece of research on OPs has been considered, government advisory bodies have noted uncertainties in the research, or have quibbled over the methodologies used and called for more research. The government's own advisers, therefore, do not accept the evidence of proof on this issue, and, according to one pressure group, do not even agree on the most recent research findings (OPIN nd b). No new data has since been found to change this situation. COT appear to have used the sound science approach and simply looked at the chemical properties of OPs; accepted that they are toxic; found no causal links; and insisted that any problems can be avoided by the wearing of PPE as a preventive measure. The burden of proof remains with the farmers affected by OPs, and this is why there is a constant revisiting of research findings, a continuous cycle of research with conclusions that suggest even more research. Moreover, the Government's own regulations on the handling of hazardous substances (COSSH) puts PPE as the last line of defence – there are three prior guidelines before PPE:

1. elimination – should you use the substance?
2. substitution – use the least toxic option
3. reduce exposure by technical controls
4. if exposure cannot be avoided, use PPE.

The Government's advisory body on toxicity, COT, and the ACP, were not convinced that low-level regular exposure to OP sheep dip solutions could cause long-term physical health problems or psychiatric illnesses. This illustrates the approach used by advisory scientists discussed in the previous chapter, that is, the tendency to use established scientific method that focuses on looking for a causal link between a potentially harmful substance and the alleged effects on human health. An occupational and environmental health professional with knowledge of the sheep dip problem told me that he had hoped

> that the Woods Committee would have adopted the precautionary principle and said the data that we have got is not adequate for us to say it is safe' But of course that goes against the grain – where you have a null hypothesis, and the idea is that you need to prove that something is unsafe, and I think the argument that you should make is that [safety] counts, and there is a real problem for scientists in terms of dealing with this because it doesn't fit in with their way of thinking, their experimental approaches, and so on (Watterson 2003 – personal interview).

All this suggests that the system for the regulation of pesticides used in sheep dipping does not appear to be satisfactory. The regulatory system appears to display a lack of transparency. The expert bodies concerned, PSD and VMD, do not explain why they have accepted some research papers that indicate OP safety, while they fail to act on papers that provided evidence about human health problems from OP use (OPIN 2004, quoting from the *Farmers Guardian*). The case study demonstrates the uncertainties encountered, raising the question of whether some of those who claim that their illness is the result of involvement in sheep dipping are affected by some other condition, even a psychosomatic condition; and whether it is only a small sub-group of people who are susceptible to OP substances. But what alternative approach is open to Government? In terms of precaution, if the Government and its advisers accept there is uncertainty as to the effects of OPs on workers' health (and the Woods Report does recommend more research), then some precautionary measures other than those relating to information and PPE for workers needs to be devised. One idea, suggested to me, is that the Government could encourage better animal husbandry, with farmers using very low levels of SPs in place of OPs (Watterson 2003 – personal interview). One problem for Government, suggested by Fairclough, is that to accept the findings of, for example, the Institute of Occupational Health study (Stephens et al 1995), would be to admit they were not safe, and 'would have meant that MAFF could be sued for compensation, not just for the ill-health of farmers using OP sheep dips, but all OP pesticides' (Fairclough 2003: 123). This suggests a policy based on the kind of sound science discussed in Chapter 3 – that publicly commissioned scientific evidence (for example, the Woods

Report), was used by policy makers to justify the decision not to withdraw the sheep dips, with no real efforts to find an alternative substance. As Fairclough and others (Fairclough 2003; Brown 2000) suggest, to admit the dangers inherent in OP sheep dipping would be to leave the Government open to claims for compensation.

The next chapter presents my second case study, that of GM crops, which is similar in that it focuses on the government's efforts to ensure the safety of the development of biotechnology, but is dissimilar in that it is not simply a pollution problem, but deals with attempts to regulate a novel technology.

CHAPTER FIVE

CASE STUDY 2: Public Pressure for a Precautionary Policy? The Problems Surrounding the Commercialization of Genetically Modified Crops

Government regulations stipulate that we will not permit any commercial growing of GM crops in the UK unless we are confident that they present no significant risk to human health or the environment. We must continually bear in mind that Genetic Modification is a new technology, and that therefore our approach must be based on the precautionary principle. We must ensure that our decisions are guided by sound science and based on independent advice (Meacher 2003)

5.1. Introduction and Background

5.1.1. INTRODUCTION

In contrast to organophosphorus pesticides, the genetic modification of plants is a relatively novel area for science, farming and government policy-making. Therefore the regulatory framework needs to be carefully considered from the beginning. In the early to mid-1990s, before GM crops became controversial, it seemed that commercialization of these products would follow a straightforward course ' from precautionary measures, to more credible claims for predictability, to public acceptability, and thus to commercialization as normal products' (Levidow, et al 2000: 193). But resistance from NGOs, food retailers, consumer environmental groups and the concern of members of the public, have forced the Government to delay commercial approvals and rethink its regulatory strategy. This issue has therefore become, in effect, a testing ground for the interpretation of the precautionary idea.

The debate on GM crops has focused attention on modern highly intensive farming methods that have encouraged monocultures, thus endangering biodiversity. Consequently the arguments for and against GM crops have centred on the issue of sustainable development in agriculture and worries about biodiversity.

This chapter will explain the issues and controversies surrounding the British Government's eagerness to introduce GM crops into the country in the face of much public anxiety; describe recent advances in biotechnology; discuss the various potential risks to biodiversity consequent

upon the commercialization of GM crops; survey the debate on sustainable agriculture and GM crops; examine the regulatory regime in place; and evaluate the government's strategy for allaying public fears about GM crops and foods.

5.2. What is the Issue?

Biotechnology is a way of applying scientific and engineering techniques to the processing of materials by microorganisms to create previously existing products in different ways. During the mid 1950s, cytologists, (biologists who study the workings of cells), were beginning to experiment with ways of separating chromosomes from the rest of a cell's makeup and to analyze them under a microscope. By this technique, geneticists could relate abnormalities in human chromosomes to genetic disease, and thus began the science of medical genetics. This method of isolating, identifying and storing genes led to a number of new techniques to manipulate and transform genes. The most important new tool, from the point of view of this case study, was recombinant DNA, developed by Stanley Cohen of Stanford University, and Herbert Boyes of the University of California. These researchers took 'two unrelated organisms that could not mate in nature, isolating a piece of DNA from each, and then recombining the two pieces of genetic material' (Rifkin 1998: 11). This technique allows scientists to 'engineer' new food crops with improved nutritional values, in-built resistance to herbicides, and the capacity to adapt to dry or salty terrains.

GM techniques allow movement of heritable traits *between species* for the first time, finally moving away from any "natural" process. Therefore, genetic engineering is different from earlier breeding techniques and despite the enthusiasm of biotechnology companies, government and many scientists, it has run into serious public relations problems, because many NGOs and consumers believe it is not safe, and in response to this, many supermarkets have refused to stock any foodstuffs containing GM ingredients. The reaction of the public caused the Government to delay commercial development of GM food and crops and conduct a series of field trials. Around the summer of 1999, the EU Commission imposed a de facto moratorium on new approvals of GM products.

The global trade in biotechnology-related products is enormous. The market within the EU alone was expected to be worth $100 billion by 2005 (*Guardian* 2002). Biotechnology companies in the UK employ around 20,000 people, contributing approximately £2 billion to the British economy. Worldwide, there are about 35 million hectares of land producing commercial GM crops. The government is, therefore naturally keen to see the British biotechnology industry

retain its lead in Europe. Prime Minister Tony Blair, in a speech to the Royal Society on 23rd May 2002, said that biotechnology is at the forefront of modern scientific research. With our 'excellent science base, sophisticated capital markets and venture capital industry, the large number of skilled scientists and managers in our pharmaceutical sector, and the investment in research....Britain is well placed to keep and extend its lead.' (*Guardian* 2002). Since the early 1990s, these industries have done considerable research into the creation of GMOs in crops, animals and fish.

A major concern of environmental NGOs and consumer organizations was the fear that genetic modification to crops to make them insect or herbicide resistant might escape into the wild and endanger biodiversity – the geneflow problem. It is also feared that herbicide resistance will work against biodiversity if it gets into weed populations: the weeds may out-compete other weeds if there is no suitable control available. However, the industrialized farming that has become the norm since the end of World War II has also compromised biodiversity by encouraging monocultures. The decline in farmland bird populations and the destruction of complex and diverse niches such as hedgerows is a demonstration of this. Of course, even if these altered traits do not escape into the wild, biodiversity can still be compromised. The decline in the number of insects feeding on crops has an impact on bird and other predator populations, and if, as a result, insect-eating bird numbers fall, then predatory birds and animals such as hedgehogs, which eat eggs, are also affected.

5.2.1. THE WIDER CONTEXT

The development of a regulatory regime for GM food and crops has international implications. The US biotechnology industry dominates the development of GM technologies and their application to food, and together with Canada and Argentina, produces large quantities of GM crops, such as maize and soybean. However, there is a difference in attitude towards GM food between the United States and countries of the EU. The US Administration regards GM food in the same way as non-GM food and regulates its safety in the same way. US research has generally shown that GM food crops does not cause health problems, nor has it caused much controversy because American people eat it every day. EU countries, on the other hand, have been more sceptical about the application of GM technology to food. Moreover, the environmental movement in Europe appears to be more powerful. In the past, the EU has permitted the import of GM soybeans from the USA, but since 1999 there has been a *de facto* moratorium on new approvals for GM products. This was imposed because of widespread public

unease about the technology, and in recent years the EU has strengthened regulation for authorizing releases of GM seeds and also on labeling of GM products. This has meant refusing the admission of US GM products.

The US Administration and agricultural industry view the EU policy as protectionism because US companies dominate the biotechnology industry, and would make much more profit without the European ban. The issue has caused much ill will between the EU and the USA. In March 2003, the Speaker of the US House of Representatives, Dennis Hastert, speaking before an agricultural committee, said:

> Over the past few years, we have seen country after country implementing protectionist, discriminatory trade policies under the cloak of food safety, each one brought on by emotion, culture, or their own poor history of food safety regulation (quoted in Rowell 2003: vii).

The issue resulted in a trade dispute between the USA and the EU, with the US, Canada and Argentina challenging the EU in the WTO over its *de facto* moratorium, and a dispute settlement panel has been set up to decide on the issue. In February 2006, the WTO dispute panel considered the complaint and issued an interim report (WTO 2006). The panel found that there was a moratorium and that this was not a measure under WTO agreements (rules that protect human health and the environment). Moreover, it also found that member state bans violated WTO rules because they were not based on risk assessments (WTO 2006: 330). The US, Canada and Argentina have claimed 'victory' over this, although the implications are limited, and does not provide any basis for challenging other countries regulating GMOs (GeneWatch 2006), because this ruling is very narrow and specific.

The final outcome of this case will have serious ramifications for the development of the environmental, social and health aspects of trade policy word-wide. For the EU, if the case is lost, it is felt that they will be unable to implement appropriate measures to protect the health of people and the environment from GM products, and the WTO will be seen as the enforcer of the interests of global corporations at the expense of human health and the environment.

5.3. Debates about Sustainable Agriculture

During the 1990s, when GM crops were nearing the commercialization stage, governments were increasingly accepting the concept of sustainable development. This idea, as noted in Chapter 3, originated in the Brundtland Report and rests on the principle that we must meet the

needs of the present without compromising the ability of future generations to meet their needs: in other words, the importance of the stewardship of both natural and human resources. In Britain, the negative effects of intensive farming was now a concern, particularly after the BSE crisis, when GM crops 'became a focus for more general concerns about intensive agriculture' Levidow et al, 1999: 6). GM crops became a sustainability issue in the EU and therefore the issue of the regulation of this new technology should be evaluated in terms of the wider debate about sustainable development.

5.3.1. THE ISSUE OF BIODIVERSITY

The problem with judging the issue of GM crops by the criteria of sustainable development is that sustainable development is a contested concept: 'The "environment" has become a terrain of contested social values' (Levidow 2000:2). The concept of sustainable development is flexible enough for there to emerge a number of varying forms of 'sustainability' according to the agendas of the actors/groups involved in the GM crops debate. Levidow shows how three views emerged in Europe: the neo-liberal view; the global environmental management view; and the people-centred view (Levidow 2000:3).

(1). The neo-liberal view of sustainability is that nature is an asset in which to invest capital and that inefficiencies in agriculture should be addressed by market liberalization and self-regulation, the process being led by multinational corporations (Levidow 2000). The biotechnology industry promotes the idea that GM agricultural products are environmentally friendly because they say farmers will use fewer chemicals and obtain greater yields, resulting in more efficiency and competitiveness. The biotechnology industry story line is the sound science one, that the genetic engineering of a plant to get a better plant is no different in principle from earlier conventional methods of plant breeding, and the technology is being sold as being a part of a 'green' or sustainable agriculture. Industry representatives extol the virtues of the new technologies by referring to the possibilities of more nutritious foods, bigger yields, lower labour costs and a more secure supply of food (Marantelli 2002). One prominent scientist, Professor Vivian Moses, who is a spokesman for CROPGEN, a lobbying organisation funded by the biotech industry, gave a presentation at a GeneWatch conference, in which he asserted that 'sooner or later, transgenic crops will be accepted and become a non-issue, just as vaccination, pasteurization and many other technologies.' He was critical of the way GM crops had been received by the UK public which had:

> been assailed with threats of health hazards from transgenic foods and damage to the environment from transgenic crops. But nothing has happened: there have been no health effects that anyone anywhere has been able to determine, nor any substantiated detrimental effects to the environment (Moses 2002).

A similar argument was put in a presentation by Professor Janet Bainbridge, a scientist, and at the time holding the Chair of the Advisory Committee on Novel Foods and Processes (ACNFP). Professor Bainbridge said that:

> experimentation with plants has had a long history before genetic engineering came along and there have been few problems, and moreover, scientific assessment was made on a case-by-case basis with no blanket approvals, and besides there was always peer review (Bainbridge 2003).

The multinational corporations involved in transgenic crops have advanced considerably over the last few years. Between 1996 and 2000, there was a 25-fold increase in the global area of transgenic crops to 44.2 million hectares. This is equivalent to an area twice the size of the UK (Nottingham 2003: ix). Over this time, many of the companies involved have merged, becoming global conglomerates, rapidly acquiring many of the existing traditional seed companies, biotechnology start-up companies, pharmaceutical and medicinal businesses and food processing companies, and in the process creating huge 'life science' corporations. Monsanto was an example of the 'life science' corporations in the 1990s that merged with Pharmacia and Upjohn in 2000, with its biotechnology division alone keeping the name Monsanto. Today, in an impressive concentration of power, there are four life science corporations: the American companies, Monsanto and Dupont; the Anglo Swiss Syngenta; and the German Bayer. These corporations have patented genetically modified genes and the processes of genetic manipulation, and they control the sale of all transgenic seeds (Nottingham 2003: xi). It is this factor that drives transgenic crop development (Nottingham 2003: xx).

One social critic noted that the world's gene pool has become a source of increasing monetary value:

> Multinational corporations are already scouting the continents in search of the new "green gold", hoping to locate microbes, plants, animals, and humans with rare genetic traits that might have future market potential. Once having located the desired traits, biotech companies are modifying them and then seeking patent protection for their new "inventions". (Rifkin 1998: 37).

This has led some commentators to believe that the unpopularity of GMOs with the public has been created, at least in part, by the actions of biotechnology companies. The environmental journalist George Monbiot, for example, has observed that by patenting genes, seeds and associated technologies, the biotechnology companies have 'placed a padlock' on the food chain and effectively they are in a position from which they can exercise complete control over what we eat. He claimed that a survey in 1999 showed that for GM crops and their associated technologies, 81 percent were then in the hands of just 13 companies (Monbiot 2000: 253). This number has since reduced to four as described above. These big players have the capacity to influence international trade regimes. For example, in the early 1990s, Monsanto and other biotechnology companies lobbied governments to request the General Agreement on Tariffs and Trade (GATT) to create a worldwide patent regime to protect what the company claims were inventions. The biotechnology conglomerates can also exert considerable power over farmers who have shown reluctance to use engineered seeds, and have been dealt with ruthlessly by companies who have 'rediscovered the old ways of dealing with reluctant customers: if persuasion doesn't work, use force.' Companies such as Monsanto have used the threat of litigation to ensure farmers buy their seed (Monbiot 2000: 252). Research by the US Center for Food Safety reveals that up to the end of 2004, Monsanto had filed 90 lawsuits against American farmers. The company had 'used heavy-handed investigations and ruthless prosecutions that have fundamentally changed the way many American farmers farm' (US Center for Food Safety 2005: 4).

Table 5.1. Corporate Lobbying Organisations

Agricultural Biotechnology in Europe (ABE)	Aims to address misconceptions, meet the public and answer questions about GM crops. (Bernard Marantelli, formerly of Monsanto, organizes their PR campaigns.
CROPGEN *An industry initiative, sponsored by Bayer, Dow, Agri-sciences, Monsanto and Syngenta*	Aims to make the case for crop biotechnology to achieve a more balanced debate about GM crops in the UK. Consists of a panel of pro-GM scientists, including Prof. V Moses.
Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) *(membership includes NFA, British Sugar Beet Seed Producers, British Agrochemical Association, British Society of Plant Breeders).*	This is the main lobbying body for the GM crop industry. It is responsible for the selection of sites for the UK Government FSEs
British Society of Plant Breeders (BSPB). *(Bayer, Crop-Sciences, Monsanto, Dupont, Syngenta, are all members).*	Represent seed industry. Lobbying for reforms in UK seed certification process to reduce cost to plant breeders and lobbying both UK government and EU for the acceptance of traces of GM material in supplies of non-GM seed.

Moreover, since the events of 1998-9, when the NGO and media campaign against GM foods began, supported by most supermarkets, the biotechnology industry has fought back by using opinion-forming measures and lobbying groups to apply pressure to government. Table 5.1 lists a number of the more prominent groups.

(2). The global environmental management view emphasizes the delicate balance that is necessary to maintain biodiversity. After the Second World War, farming changed dramatically with improved seeds, the use of chemical fertilizers and pesticides, water irrigation projects, and mechanization, maximizing yields for a minimum of land, leading to the increase of monocultures. The global environmental management story-line is that genetic modification poses unknown risks to the environment; it reduces biodiversity of plant cultivars, commercial pressure to use GM technology forces selection pressure for resistant pests which further promotes industrialization of agriculture; herbicide-tolerant crops are a threat to sustainable agriculture by harming habitats; and GM crops threaten diverse crop varieties developed by farmers. All of this has a negative effect on habitats and biodiversity. Therefore this view recommends that sustainable development should be led by regulatory agencies to minimize these adverse consequences of GM crops.

Table 5.2. Some of the Pressure Groups that Lobby Government over GM Technology

GeneWatch	A not for profit public interest group which was formed to secure public, academic, media, investing, regulatory, parliamentary, local, national and international government support for a programme to ensure genetic technologies are developed and used in an ethical and safe manner
ISIS *(Institute for Science in Society)*	A not for profit organization founded to work for social responsibility and a sustainable approach to science.
Soil Association	A membership only charity that campaigns for organic food and farming in the UK. It aims to influence the public, government and industry on wildlife threats, GM crops intensive farming and pesticides
Elm Farm Research Centre	Founded as an educational charity to develop and promote organic agriculture
GM Watch *(including Norfolk Genetic Engineering Information Network (INGIN)*	A news and research service which aims to report on the concerns about genetic engineering and release of GM crops and food into the environment in the absence of social or scientific consensus on their safety

A number of organizations, including English Nature, the Royal Society for the Protection of Birds (RSPB), Friends of the Earth (FOE) and Gene Watch called for a moratorium on the growing of GMOs for a period of up to five years. The government's response was to refuse to consider a moratorium but to establish a Cabinet Committee to deal with biotechnology matters and, in collaboration with the biotechnology industries concerned, it decided informally to halt the commercial growing of herbicide resistant GM crops until scientifically controlled field trials had been completed. As a result of all this resistance, instead of the straightforward progression from regulation to commercialization, governments in Europe have come under pressure to delay or restrict commercialization of GM crops. In addition to prominent international NGOs, such as FOE and Greenpeace, there are a number of homegrown pressure groups that have a place in this story, and some of the more high profile groups are listed in Table 5.2.

(3). For those holding the people-centred or community view on sustainable development, the problem is the profit driven nature of agricultural innovation and undemocratic institutions involved (Levidow 2000). This storyline holds that in nature there has to be a harmonious balance and that agricultural production should be small-scale, using the expertise and resources of local communities. This group is in favour of less intensive farming methods and recommends this as a model and a baseline for evaluating the effects of GM crops (Levidow 2000: 12). Many of the smaller campaigning groups such as Five Year Freeze, Elm Farm, GeneWatch and ISIS campaign along these lines. These groups include a growing organic food sector in Britain that sees GM crops as a threat to their livelihood. Organic farming is based on the certification of the system of production rather than the end product. This means that GMOs (as well as some artificial fertilizers and pesticides) cannot be used in organic production. The proposed commercialization of GM crops is a threat to this sector and this has caused much debate over the establishment of separation distances between organic farms and GM crops.

Other groups, perhaps typified by the Institute for Science in Society (ISIS), call for a non-GM sustainable agriculture, where organic farming and land management techniques can increase yields and rehabilitate degraded environments (ISIS 2004:2). English Nature, who claim to be neither for nor against GM technology, believe that we need better agriculture, not more. In a conference speech, English Nature's Head of Agricultural Technologies Group, Brian Johnson, accepted that transgenic technology could help to develop plants with certain traits (resistance to cold; salinity; drought, and weed control), but he believes that research should emphasize sustainability rather than just risk assessment (Johnson 2003). Through this threefold typology it is possible to see the different stances taken by the groups involved in the debate on GM crops.

Given this climate of controversy over the proposed commercialization of GM products, what options does the British Government have?

5.4. Policy Options and Government Decisions

5.4.1. POLICY OPTIONS

At the stage when the biotechnology industry had decided that the technology had advanced sufficiently that they wished to commercialize the resulting GM seeds, it seemed that the Government would follow the traditional process of risk assessment, followed by licensing of GM seeds. However, Green campaigners highlighted potential problems with the technology and this caused public disquiet. There were fears of harm to human health, although it may be that the unpopularity of GMOs with the public is more to do with revulsion at the idea of scientists meddling with nature than any real fear of being poisoned. The general public in Britain and Europe has been fed stories by the media of mad cow disease, salmonella in chicken, *listeria* in cheese and *escherichia coli* poisoning, for several years, and in such a climate, news of GM or 'Frankenstein' food development is hardly welcome. As an American writer puts it: 'for a consumer, there is perhaps nothing more offensive than to be kept in the dark about something so personal as the food we choose carefully at the grocery store.' (Pringle 2003: 5). Whatever the reason, products made in this way are unpopular with consumers and environmentalists, while farmers are becoming increasingly unhappy with the problems that have arisen and, according to one source '...the companies that developed GMOs are either imploding or offloading their GMO subsidiaries as fast as they can find anyone to buy them.' (*Economist* 2000: 119).

In this climate, the Government had only one option: to delay commercialization and carry out tests on GM crops over a long period of time in order to build up some solid evidence that they were not harmful to human health or the environment. The British Government claims to be neither pro-or anti-GM crops. 'It recognizes that they have both the potential risks and benefits. ...and that the Government's first priority is to protect human health and the environment...'(DEFRA 2002a). Michael Meacher, the then Minister of State for the Environment, publicly stated that there would be no commercial growing of GM crops in Britain until the Government was satisfied that there will be no unacceptable effects on the environment. He announced this in his keynote speech at a conference, Gene Futures, held at the Royal Society of Arts, and sponsored by the Guardian and GeneWatch. The government however, recognizing the wealth-creating potential of GM food and agriculture, is keen to remain a leading player in biotechnology, positively supporting British biotechnology firms. However, the Government has

had to contend with considerable resistance from environmental groups, food retailers, the media and the general public. In the summer of 1997, several environmental groups campaigned for a moratorium on the commercial growing of GM crops in the UK.

5.4.2. GOVERNMENT DECISIONS

In reaction to this campaign, there was a major policy shift when the Government announced a set of field trials into the impact of GM crops on wildlife, called Farm Scale Evaluations (FSE), of which more will be said later. These trials were set up to run for four years, but in the meantime, the government still had to deal with public disquiet and campaigns by groups such as FOE, GeneWatch and many others. On July 26 2002, the Secretary of State, Mrs Margaret Beckett, announced that there would be a public debate on GM issues, creating a dialogue between all strands of opinion on GM. One part of the public debate, the science review, for example 'involved taking popular concerns and questions about GM crops and foods and considering the evidence for the salient scientific issues they raise' (DTI 2003a: 28).

Therefore, in addition to the field trials, in 2002, the Secretary of State at DEFRA, Margaret Beckett, taking the advice of AEBC, organized an extensive review of the technology. It was to consist of three strands: (1) a review of GM science; (2) an economic review; and (3) a public consultation exercise. The public consultation programme, named *GM Nation?*, used strands (1) and (2) to achieve the following aims:

- To allow ready access to scientific evidence concerning GMOs, including the potential introduction of commercially grown crops in the UK;
- To allow access to the opinions of a variety of people and organizations on the scientific evidence;
- To allow the concerns of the public to drive the review and to contribute and participate in it.

The methodology for this exercise was organized in three separate but linked parts. First, was the organization of nine foundation workshops, consisting of twenty people in each, chosen by random sample, and representing different age and socio-economic groups. These workshops identified the broad issues for subsequent public debate. Second, the Steering Group compiled a 'toolkit' consisting of a booklet, CD-ROM and a film – all based on the workshop findings. The third and final stage was a series of public deliberative events, where participants watched the

film and discussed the issues in small groups, guided by the booklet, and reporting back to plenium sessions. All participants in the events were asked to return feedback questionnaires.

5.4.3. THE REGULATORY REGIME

The EU believes that genetic engineering is sufficiently novel to justify independent regulation and Britain's membership of the EU means that its regulatory approach is influenced by this legislation. The main legislation that authorizes experimental releases and the marketing of GMOs in the EU, from 17th October 2002, is Directive 2001/18/EC, which repeals and replaces Directives 90/219/EEC and 90/220/EEC. The new directive establishes a step-by-step approval process for a case-by-case assessment of the risk to human health and the environment, before authorizing the marketing or release into the environment of any GMO or product containing GMOs. For a GM food product to gain market authorization, the Member State concerned must submit a case to the EU Commission, while at the same time the relevant advisory committees in the Member State must carry out a preliminary risk assessment. This assessment, together with the submission to the Commission, is then circulated to the other Member States. Any objections are made to the Commission which makes the final decision. The main thrust of this new Directive is that if new information on risk comes to light after a consent has been issued, it can be revoked.

In the UK, the main source of scientific advice for the regulation of GMOs is the Advisory Committee on Releases to the Environment (ACRE), a committee that was set up by the Secretary of State for the Environment in 1990. In February 1993, when the Genetically Modified Organisms (Deliberate Releases) Regulations 1992 (amended in 1995) came into force, ACRE became a statutory advisory committee under the Environmental Protection Act 1990 (EP90). Thus in the UK, Part VI of the EP90, and the Deliberate Release Regulations implement the EU Directive 2001/18/EC on the deliberate release into the environment of GMOs. These parallel regulatory controls give a EU-wide safety regime for the release and marketing of GMOs.

All decisions on applications for release and marketing of GMOs are considered by ACRE. Applications for projects involving GM plants are passed to ACRE, which scrutinizes the Environmental Risk Assessment supplied with the application. Applications to place animal feeds derived from GM crops on the market are reviewed by the Advisory Committee on Animal Feeding Stuffs. A risk assessment would identify the intrinsic properties of a substance or

organism that may cause harmful effects to humans, animals, or the environment; estimate the likelihood of those effects occurring under the conditions of the proposed release; estimate the magnitude of the harm that may arise; and, on this basis, evaluate the overall risk (DEFRA 2000c). Once ACRE is satisfied they have all the necessary information, they advise Ministers. In the case of proposed GMO research trials, ministers then decide whether to grant or refuse authorization. In the case of proposed commercial releases, ACRE's advice informs the UK's position at EU-level collective decision-making. ACRE has developed guidelines for the risk assessment of GM products. This scientific advisory body's approach to risk assessment has been to 'identify the intrinsic properties of an activity, substance or organism that may cause harmful effects to humans or the environment;' to then 'estimate the likelihood of those effects occurring under the conditions of the proposed release or use,' then 'estimate the magnitude of the harm that may arise, assuming that the effects occur;' and on the basis of these steps, 'evaluate the overall risk' (DEFRA 2001).

In providing expert advice on GMOs, ACRE is complemented by three other Government advisory bodies, which give advice on different aspects of GMOs. The Advisory Committee on Genetic Modification (ACGM) provides advice on the contained use of GMOs; the Advisory Committee on Novel Foods and Processes (ACNFP) provides advice on novel foods by novel processes and the use of GMOs as foods and animal feeds; and the Gene Therapy Advisory Committee provides advice on proposals for gene therapy research on humans. There is some cross-membership and the same Government assessors attend committee meetings, which may produce a useful exchange of information between different committees (ACRE 1998). However, ACRE is the most important committee of scientific experts to consider GMOs.

In the USA, the regulatory framework for the development and experimental growth and release of GM crops is designed to regulate the *product* rather than the *process*, and therefore regulation is through a number of existing agencies working in cooperation, namely the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). However, there is no statutory provision dealing specifically with GM food as such, because it has been decided that, in accordance with the principle of *substantial equivalence*, foods developed through genetic modification are not inherently dangerous; rather they are seen as a logical extension of conventional techniques and therefore do not need pre-market testing and regulation (Hester & Harrison 2001: 7). In the US, GM crops with pesticidal genes are regulated by the EPA under the Federal Insecticide,

Fungicide, and Rodenticide Act (FIFRA). The assessment and evaluation of these cases are done by Scientific Advisory Panels chosen from academia, corporations and administrative scientific personnel. In this regulatory framework, there is an underlying assumption that GM products are safe, and that contrary evidence that has been claimed is unsound (Ho & Cummins 2003).

5.5. Scientific Evidence and Expert Advice

5.5.1. SCIENTIFIC EVIDENCE

Since the late 1990s, the main thrust of scientific research into GM crops has been to evaluate them for how 'their associated agricultural methods may affect biodiversity and sustainability' (Levidow, *et al* 2000:195). Most research on GM crops has been reviews of current literature, laboratory experiments, and, more recently, some field trials. MAFF/DEFRA funding has gone to the John Innes Centre for Plant Science Research (JICPSR), the Rothamstead Experimental Station (RES), the Institute for Arable Crop Research (IACR), the Scottish Crop Research Institute (SCRI), and the National institute of Agricultural Botany (NIAB) (Levidow, et al 1999:20). Important issues that are frequently considered are: a search for evidence that is predictive of effects; whether new scientific knowledge creates more certainty, or increases uncertainty; and deciding on which adverse effects should be prevented. Some of the main potential hazards that are at the centre of the research are:

- Herbicide resistance and agricultural practice. One of the perennial problems of agriculture is control of weeds that compete with crops for water and nutrients. If weeds are not controlled efficiently, the farmer can expect lower crop yields. But herbicide treatments that are very effective against many weeds can also kill the crops the farmer is trying to protect against weeds. Genetic engineering has solved this problem, by modifying the crops to be resistant to herbicides, and also by reducing pesticide use. Resistance by genetic modification is to a single group of herbicides which means resistance to one herbicide will not be resistant to another. Resistance has been developed to several groups of standard modern herbicides. This situation raises questions of what effect herbicide use will have on agricultural practices. Manufacturers claim their products will result in reduced herbicide use. However, as one study noted, there is a tendency for farmers to over-spray because they are confident that it will have no adverse effect on the herbicide-tolerant plant. Also, from a commercial point of view, to claim that it will encourage reduced use is difficult to sustain, as the aim is to sell more herbicides. (Nottingham 2003: 43). Some recent research in the US suggests that for

herbicide-tolerant crops such as GM corn, soybeans and cotton planted since 1996, pesticide use has increased. Furthermore, the report states that some farmers have had to spray more herbicides on GM crops in order to keep up with shifts in weeds towards tougher-to-control species and to deal with the emergence of genetic resistance in certain weed populations (Benbrook 2003, quoted in ISIS 2003a). A major concern for regulators therefore, is whether or not herbicide-tolerant crops are a threat to sustainable agriculture. The then MAFF funded a SCRI field study of movements of transgenes in oilseed rape.

- Gene transfer to other (non-target) plants. A point of major concern is that herbicide-tolerant crops may become invasive, and that genes may be transferred to wild relatives and the ensuing offspring will in some way be detrimental to existing flora and fauna. GM rape pollen, for example, can fertilize many types of brassica (they are closely related). So the problems for science is how great is pollen flow and the possibility of hybridization. DEFRA has provided funding for NIAB to carry out trials on the 'frequency and viability of hybrids, especially oilseed rape: they found that oilseed rape pollen remains fertile over greater distances than previously thought' (Levidow, et al 1999: 21). This 'gene flow' problem was of particular concern to organic farmers and there was an anxious debate about what constitutes safe distances between GM planted fields and neigbouring fields planted with conventional crops. ACRE had discounted these views, arguing that gene flow was a farm management issue, rather than an ecological issue, and that 'cross pollination could be avoided by voluntary agreements on management practices rather than regulation' (Toke 2004: 69).

- Insect resistance. The development of insect resistant plants allows for crop protection with reduced insecticide use. Using soil bacteria, scientists have been able to isolate genes expressing insecticidal proteins from bacteria and transfer them to crops. All commercial, insect-resistant crops have been engineered with genes from the bacterium *Bacillus thuringiensis (Bt).* However, according to some critics, insect pests could rapidly evolve resistance to *Bt* toxins, what one scientist described as: 'the natural evolutionary "arms race" between insects and plants: plants evolving new defences escape insect attack, until the insects evolve counter-adaptations (Nottingham 2003: 55). This happens in the same way as in the development of resistance to conventional insecticides. An insect with a genetic predisposition that enables it to survive on a toxin-

containing plant will be selected for in preference to susceptible insects, causing the resistance gene to spread in the population (Nottingham 2003: 55). Critics have said that risk assessments do not review for this risk.

- Antibiotic resistance marker genes. Insect resistant maize also contains gene coding for an antibiotic resistant gene *(ampicillin)*. The Antibiotic resistant gene was included to simplify seed production and there was no need to include it in the final plant, but it has been accepted by the regulatory authorities as it is (Mayer 1998: 28). There is, however, concern for the possible development of *ampicillin* resistance in flora, fauna and humans, which could lead to problems with resistance in disease-causing organisms. Science advice on this issue is that marker genes should not be used. Unfortunately these genes cannot be removed from plants, which were developed some years ago.

5.5.2. SUBSTANTIAL EQUIVALENCE

The concept of *substantial equivalence* has been widely used outside the USA to decide whether or not GM foods are safe for human consumption. The concept is designed to show that a genetically modified food is chemically similar to its natural counterpart. Not everyone agrees that this testing method is adequate to ensure that the product tested will be safe for human consumption. Critics argue that this particular test, which is for chemical composition, is not predictive of biological effects, and that therefore the concept of substantial equivalence has not been defined properly. Its poor definition makes it useful for industry, but not acceptable to the consumer (Millstone et al 1999: 525).

The concept of substantial equivalence has been contested by NGOs and consumer organizations. Media debates on the safety or acceptability of GM food and crops means that:

> Substantial equivalence became more difficult to defend as a basis for risk assessment of GM foods. In public debate, critics easily ridiculed the concept for downplaying genetic novelty. The concept became a problem for restoring consumer confidence and public trust in regulation. (Levidow and Murphy 2002: 7).

There are some who believe that GM foods should be treated in the same way as novel chemical compounds, such as pharmaceuticals and pesticides, which would require companies to conduct a range of toxicological tests which would produce evidence to set acceptable daily intakes (Mayer 1999: 525). The Royal Society of Canada, for example, has publicly stated that: '(t)he use of 'substantial equivalence' as a decision threshold by regulatory agencies is

scientifically unjustifiable when used to exempt new products from full scientific scrutiny.' (Royal Society of Canada 2001). As Levidow and Murphy note: '...the concept became an easy target for criticism and thus politically risky, undermining the credibility of regulatory authorities' (Levidow and Murphy 2002: 17).

However, regulatory science has since moved towards a wider idea of what constitutes safety. The EU Commission eventually abandoned the concept after pressures from Member States. In Britain, a Royal Society Report suggested that 'safety assessments should be made explicit and objective and that differences in the application of substantial equivalence, for example in different Member States of the European Union, need to be resolved.' (Royal Society 2002: 10).

5.5.3. THE FARM SCALE EVALUATIONS

The UK government launched a number of GM crop trials in the spring of 1999. Although the Government funded the research, the evaluations were carried out by a consortium of independent researchers. The first year was a pilot study, followed by three years of trials. The government appointed an independent group, the Scientific Steering Committee, drawn from the AEBC, with a secretariat provided by DEFRA, to oversee the conduct of the trials, which were designed to assess the impact upon biodiversity of the herbicide under its particular regime, and not of the GM herbicide tolerant crop itself, but they did not include potential human health impacts. The tests evaluated whether weeds and insects fared better in fields of conventional crops or in fields of crops that had been genetically altered to be resistant to a single herbicide. In particular the researchers looked at how weeds grew around the crops. The trials consisted of growing a GM crop and a non-GM equivalent, and comparing the number and diversity of insects, plants and seeds remaining in the soil (GeneWatch 1999: 3). The farms were selected to represent the varied agriculture in Britain in terms of soil, climate and agrochemicals used, and involved three crops: maize, which is tolerant to the herbicide glufosinate (Liberty); oilseed rape, also tolerant to glufosinate; and sugar beet, tolerant to glyphosate (Roundup). Plants would be grown under a range of conditions, thus allowing different biological properties to be expressed.

The report on the results of the FSE was published in *Philosophical Transactions of the Royal Society* in October 2003 (Royal Society 2003). The main conclusions were that two of the three GM crops grown in the trials, oilseed rape and sugar beet, appear more harmful to the environment than conventional crops and should not be grown in the UK, whereas the third crop, GM maize, allows the survival of more weeds and insects than did non-GM maize and might be recommended for approval, though some scientists still have reservations. (Royal Society 2003).

The results had some supporters and many critics. ACRE considered the results of the FSEs, and published its advice on 13th January 2004. It held that the FSEs provided 'important and robust evidence concerning the impact of the herbicide regimes associated with the three GM crops studies' (ACRE 2004.1), and it accepted the FSE report's conclusions. ACRE emphasized that their conclusions only apply to the management regime used in the FSEs and that alternative management regimes may have different impacts, which could be either beneficial or adverse. Given the divergent views of the various groups involved in this issue, it is not surprising that there were some arguments over the interpretation of the results.

Predictably, the biotechnology industry was enthusiastic about the results of the trials. CROPGEN, a high profile corporate lobbing organization, issued a statement on its website on the results of the FSEs:

> The Farm Scale Evaluations show that contrary to what campaigners have been asserting for years, GM technology, if managed properly, can benefit the environment as well as farmers and consumers. Today is a momentous one for UK agriculture. The implications are clear: GM maize is good for farmers! (CROPGEN 2003).

This statement was made despite the fact that the FSE report approved only one of the three crops on test.

The House of Commons Environmental Audit Committee (EAC), considered the report and their deliberations on the trials cast doubt on the usefulness of the research. Among other observations their report showed concern over the GM maize trials, which they thought were based on an invalid comparison because it had used the chemical atrazine, use of which is being phased out. (House of Commons 2003: 1). This particular criticism was also expressed by the former Environment Minister, Michael Meacher, ISIS and FOE. The EAC was also concerned about the biotechnology industry's role in the operation of the trials. Their report stated: 'Even if these inputs had not cumulative effect upon the results of the trials, they were sufficiently integral to raise significant concerns as to the extent to which the industry was in practice capable of influencing the results' (House of Commons 2003:).

Some critics, such as GeneWatch, Greenpeace and FOE, believe these trials had expectations placed on them that were unrealistic and unscientific, because the trials lasted for four years but the GM crop was only grown for one growing season in any one field, so small incremental impacts of repeated growing could not be detected (Mayer 1999), nor could the issue of geneflow

from GM crops to non-GM or organic crops and native flora, or the issue of the possible creation of 'superweeds' and 'superpests', be resolved. GeneWatch held that the message coming from these trials that 'GM herbicide tolerant crops do not harm the environment misrepresents the results of a complex four-year study and do an injustice to scientists who have undertaken the research' Rather, 'the trials should be seen as a small piece in a large jigsaw puzzle aimed at understanding potential effects of introducing GM technology into British farming systems' (GeneWatch 2005:20). In summary, the critics of the FSEs felt that 'the FSEs provided only limited data and not a definitive risk assessment' (Oreszczyn 2004: 10).

5.5.4. OTHER GOVERNMENT STRATEGIES

The three strands of DEFRA's public debate produced four reports The *GM Science Review, First Report* (DTI 2003a), was released in July 2003, followed closely by a report for the Prime Minister's Strategy Unit on the economic impact of GM crops: *Weighing up the Costs and Benefits of GM Crops* (Cabinet Office 2003). In September 2003, the report on the public debate, *GM Nation? The Findings of the Public Debate,* was published (DTI 2003b). And finally, the *GM Science Review, Second Report* was published in January 2004 (DTI 2004).

There was not much comfort for the Government in the conclusions of any of these exercises. The science panel's first review found no scientific case for ruling out GM crops, but nor does it give them blanket approval. The panel scientists admitted gaps in their knowledge and emphasized that products for approval need to be considered on a case-by-case basis. They also stressed the importance of regulation keeping up with new developments. The second report from the science panel considered the FSE results, which had not been available earlier, but did not substantially alter the panel's overall considerations on GM crops.

The economic review report concluded that while existing GM crops could offer some benefits to farmers, any economic benefit to the UK is limited because of the narrow range of crops currently suited to UK conditions. The report also recognizes that future costs and benefits depend on public attitudes, and on the ability of the regulatory system to manage uncertainties.

The public debate, *GM Nation?,* which had began in June 2003, was overseen by a steering board chaired by Professor Malcolm Grant, Chairman of AEBC. The findings concluded that the public is generally uneasy about GM products, and that the more people engage in GM issues, the more their attitude hardens, as they become uneasier about the risks involved. Furthermore, there is little support among the public for the early commercialization of GM crops.

However, the public debate exercise was criticized by both anti-and pro-GM groups. It was said, on the one hand, to be run by pro-GM scientists, many of whom were supported by biotechnology corporations. The Institute for Science in Society (ISIS) for example, observed that it produced no critical evidence on the problems and hazards of GM crops as opposed to the potential benefits (Ho 2003). On the other hand, some scientists criticized this debate because they believed it was dominated by NGOs. An example of this criticism is a letter signed by 114 British scientists, many of them members of the Royal Society, sent to the Prime Minister complaining about the lack of government support for GM crops during the debate, and describing the public meetings as 'rallies by the green groups' (Charter 2003).

5.5.5. EXPERT ADVICE

In the debate on the safety of GM crops there was criticism of the composition of the main regulatory advisory committee, ACRE. As one academic noted, as the controversy over GM crops became more intense during 1998-9, ACRE was criticized for the narrowness of its membership. It was alleged that the membership was skewed towards biotechnology interests (Toke 2004: 75). *The Guardian* reported in April 1999 that 'ten out of sixteen members of ACRE are either directly employed by, or receive funding for research or other work, from the companies which want to market genetically modified crops' (Brown 1999).

However, ACRE's membership was changed in 1999 and is now organized 'on the basis that members are recruited because they possess certain required disciplinary skills rather than because they represented particular interests' (Toke 2004: 75). These skills now include farmland systems and wildlife biodiversity. ACRE, during the mid-1990s, saw its role simply as that of providing risk assessment as to the safety of GMOs through scientific method. As the former Chairman, Professor John Beringer, stated in his annual report for 1996/7:

> The responsibility of advisory committees, such as ACRE, is to develop scientific procedures for assessing risks, consider risk assessment and advise whether GMOs are at least as safe as the parents from which they are derived. Social, ethical and other issues arising from this technology should be debated elsewhere by those with the appropriate competence (ACRE 1998).

The biotechnology industry and its supporters had initially assumed that GM products would follow a straightforward course of risk assessment and acceptance by the regulatory authorities. However, due to the public outcry that arose in the late 1990s the safety assessment of GM crops

and food began to be questioned, in particular at the point at which the GM products had been approved for commercialization. The environmental and consumer groups who oppose GM produce have successfully challenged this basis for safety approvals and governments in Europe have had to review their risk assessment methods, to include social, economic and ethical issues.

Also, the Government perceived a need for a source of new strategic advice about genetic modification, and in May 1999, set up the Agricultural and Environmental Biotechnology Commission (AEBC). The commission was one of three new institutions created in a review of the government's regulatory framework at a time when it was felt that there was a need to recapture public confidence in scientists and scientific advice and its remit was to offer strategic advice to Government on biotechnology issues which impact on agriculture and the environment, and is expected to identify gaps in the regulatory regime. The proposed public debate mentioned earlier is based on advice put forward by the AEBC. The other two new institutions were the Food Standards Agency (FSA) and the Human Genetics Commission (HGC). The FSA was felt to be necessary after the BSE crisis in the mid-1990s; while the HGC was needed to consolidate fragmented sources of strategic advice on genetics and public health (Grove-White 2001: 466).

There has been has been some criticism of the science review, with some people maintaining that it lacks independence and disinterested research (ISIS 2003b), and claims in the media reveal that many of the review panel members have links with biotechnology companies. One member, Professor Carlo Leifert, an agricultural ecologist, resigned from the science review panel before it reported, because, he claimed, someone employed by Monsanto was writing the chapter on safety, and they omitted too many potential risks 'I think they have left out too many potential risks in that review, for me to sign up to...there were too many issues suppressed in the discussions' (Leifert 2003: personal interview). His fears were widely reported in the media: 'Studies that disagreed with the GM experiment were strongly criticized for problems in procedure or gaps in knowledge and then discarded rather than explored further or commissioning more research' (Crooks 2003.5).

Another member of the science review panel, Dr Andy Stirling, a social scientist specializing in risk management, had a similar experience to that of Professor Leifert. Dr Stirling was a member of the Science Review Panel and was nominated for a place on it by a consortium of NGOs. Stirling claimed that a senior British academic and regulator of GM food had got in touch with a major research funding organization and urged that they drop him from a current research

project (Stirling 2003: personal interview). Although Stirling has not named his objector, and has not given any reason for the objection to his membership of the Panel, press reports suggest that it was because he had concerns about GM crops (Townsend 2003: 4). A list of the members of the Science Review Panel is at Figure 5.3.

Table 5.3. Members of GM Science Review Panel

Professor Sir David King, Chairman	Civil Servant (Chief Scientific Officer to the Government)
Professor Howard Dalton, Deputy Chairman	Civil Servant (Chief Scientific Adviser to DEFRA)
Dr Mark Avery	Director of Conservation, RSPB
Professor Janet Bainbridge	Director, Science/Technology, University of Teeside; Chair, ACNFP
Dr Chitra Bharucha	Consultant Haematologist; Chair, Advisory Committee on Animal Feedstuffs
Professor Dianna Bowles	Dept of Biology, University of York
Dr Simon Bright	Syngenta, Jealott's Hill International Research Centre
Dr Andrew Cockburn	Monsanto, Cambridge
Professor Mick Crawley	Imperial College
Professor Phil Dale	John Innes Centre, Norwich
Professor Mike Gale	Deputy Director, John Innes Centre
Professor Mike Gasson	Food Research Institute, Norwich
Professor Alan Gray	Dept Plant Science, University of Cambridge
Professor Pat Heslop-Harrison	Dept Biology, University of Leicester
Ms Julie Hill	Programme Adviser, Green Alliance; Dep Chair AEBC
Dr Brian Johnson	Head of Agricultural Technology, English Nature
Professor Chris Leaver	Head of Dept of Plant Sciences Oxford University
Professor Jules Pretty	Director of Centre for Environment & Society, University of Sussex
Revd Professor Michael Reiss	Institute of Education, University of London
Professor Bertus Rima	Medical and Biological Centre, Queens University, Belfast
Professor Bernard Silverman	Institute of Advanced Studies, University of Bristol
Dr Andy Stirling	SPRU, University of Sussex
Professor William Sutherland	University of East Anglia
Professor Michael Wilson	Chief Executive, Horticultural Research International
Professor Peter Young	Professor of Molecular Ecology, Dept of Biology, University of York

5.5.6. DISAGREEMENTS ABOUT THE EVIDENCE

Some scientific research has raised questions that have been uncomfortable for the pro-GM lobby. For example, the Rowett Institute for Agriculture in Aberdeen obtained public funds to conduct safety tests on experimental genetically modified potatoes. The idea was to attempt to make potatoes resistant to aphids. The researcher, Dr Arpad Pusztai, engineered genes for a certain class of protein into potatoes and then fed them to rats. The potatoes were engineered to produce a molecule called *Galanthus nivalis* agglutinin (GNA) which is a natural insecticide found in snowdrops, and proven in peer review research to be harmless to mammals. Pusztai claimed that the GM potatoes affected the growth of rats and depressed their immune systems (Ewan & Pusztai 1999). The publication of the results of this experiment in *The Lancet* cause a furore amongst the scientific community and the mass media, some scientists severely criticizing Pusztai's methodology. Pusztai's work was grossly misrepresented in the newspaper media, along the lines that he had 'fed harmful lectins inserted in potatoes to rats' (Burke 1999). Furthermore, the editor of *Lancet*, Richard Horton, claimed he was threatened by a pro-GM scientist and member of the Royal Society, who told him that in publishing the Pusztai paper, his position as editor was in doubt (Flynn & Gillard 1999). Since then, a number of scientists have scrutinized Pusztai's work and appear willing to concede that it is interesting enough for further experimentation. It does not seem likely that this will be carried out since Pusztai has lost his job at Rowett Institute because of the outcry.

A further example of research that was not received well by the biotech industry involves the story of Mexican maize. Maize originated in Mexico about 10,000 years ago and is an important crop for farming communities, being the main ingredient in tortillas, a mainstay of the local diet. This native maize, or landrace, while not being pure, was at least GM free, and, moreover, the Mexican government had imposed a moratorium on growing of GM crops in 1998.

Inacio Chapala, a microbial ecologist and an assistant professor at the University of California at Berkely, was helping peasant farmers in Oaxaca, southern Mexico, with a sustainable agriculture project. It was common in this area for farmers to buy imported seeds from subsidized government seed stores. What was noticeable was the differences between the seed kernels of the native maize and those imported maize seeds. Chapala's PhD student, David Quist, set out to test the seeds to 'see if there was any geneflow from transgenic varieties in order to see whether the government's ban was working.' (Pringle 2003: 164). Initial tests showed the presence of *Bt* genes. Further research was done in the laboratories of Berkeley and the results

were published in *Nature* (Quist & Chapala 2001). This showed that the local maize had been contaminated with GM maize. The researchers further claimed that the GM DNA seemed to be randomly fragmented in the genome of the Oaxaca maize.

The reaction from both Berkeley and the biotech industry was negative and hostile. Chapala and Quist's colleagues at the University accused them of 'misinterpreting the result', and of 'bad science'. Representatives of the biotechnology companies said the paper was 'junk science that shouldn't have made it past rudimentary peer review process.' The reaction from Berkeley was perhaps more predictable, because the University had received research funding from the biotechnology company Novatis (now part of Syngenta). The row over this research was so vicious that *Nature*, in an unprecedented move, withdrew support for the article. Moreover, in Mexico, Chapala claimed he was threatened by an official from the Mexican Biosafety Commission (BBC 2003). Both this case and the Pusztai case show how the biotechnology industry spends huge sums of money discrediting research findings that question the safety of GM crops, and how questions of safety are not addressed.

There is much unease in some quarters, including among some individual scientists, about the way some of the research is carried out. For example, Professor Carlo Leifert, while he was a member of the Science Review Panel, noted that there were disagreements among panellists from the beginning, with differences in approach between those who were keen to commercialize GM crops, and those who were more cautious. Leifert said that:

> ...disagreement started from the beginning, about procedures, and certainly some people felt the whole thing should be done as a standard risk assessment. But I think the majority of people felt it should follow more the form of a literature review...there seemed to be a fundamental difference in approach between the sort of people who promoted GM crops and want them commercialized, and the people who are cautious about them (Leifert 2003: personal interview).

All of these potential dangers and conflicting scientific points of view have meant that governments have had to give serious consideration as to how GM foods and crops would be regulated.

5.6. Discussion

As GM products have approached the licensing and market stage, the Government has found decision-making difficult because of resistance from a variety of sources. However, the Government has put considerable efforts into reassuring doubters with its field trials and public consultation. How does the policy arrived at fit with our two models of sound science and precaution?

The Authority of Science/Scientists

In the early days of regulating GM crops it appears that the authority of science featured very highly. This can be seen from the ACRE chairman's remarks that conventional scientific method was considered to be the only way of assessing risk in GM products (ACRE 1998, *op cite*). However, from the late 1990s, with public hostility about biotechnology bringing pressure to bear on the Government, questions of harm or safety factors that had not been examined in any serious way now had to be reconsidered: the Government had, perhaps, against its instincts, become more precautionary on this issue. The debate on GM crops and food widened to include other disciplines on Government committees and expert panels, in other words, a more inclusive peer review. For example, changes in ACRE membership to reflect wider issues; the creation of the AEBC, with a membership that included a farmer, a lawyer and social scientists, with a deputy chair from Green Alliance, an environmental pressure group; the creation of a Science Review Panel that included a lay member, an academic specialist in organic agriculture, and two social scientists; and the initiating of a public debate. All of these initiatives go further than a narrow science-based approach, and towards a weak precautionary approach.

Definitions of Hazard

The early use of the conventional mechanistic approach to hazard attempted to directly measure harm, as is the case in toxicological studies. To follow this approach in the assessment risk of GM crops means the hazard has to be limited to a well-defined "event", such as, for instance, the possibility of a *bt* crop being toxic to insects. In this case, the problem is simplified and limited to the introduction of a new gene, and the hazard is only what can be foreseen. GeneWatch have highlighted the narrowness of the approach by referring to the way in which requests for releases to the environment are considered on a step-by-step, case-by-case basis. According to GeneWatch, this approach does not take account of 'cumulative impacts.' For example, a crop containing a toxin that kills insects may seem straightforward enough, but 'if

many such crops are authorized, the toxin could affect the whole food web either by killing beneficial insect life or by removing an important food source for higher species' (GeneWatch 1998: 3). The risk debate on GM crops from the late 1990s onwards, has focused attention on potential risks to the agricultural environment from the use of herbicides, its danger to wildlife and biodiversity, and this has been much more precautionary than hitherto.

Error, evidence, data, and Burden of Proof

The initial ACRE approach used in the investigation of the safety of GM crops was to minimize Type I errors – i.e. claims that GM crops are on the side of 'no effect'. 'The argument is that science has not proven harm, therefore, we can legitimately charge ahead' (Barrett and Raffensperger 1999: 112). According to one study, 'Since the 1980s, scientific and policy literature on GEOs [Genetically Modified Organisms] has emphasized the need for accurate measures of probability and empirical evidence of 'an event' (Barrett and Raffensperger 1999: 112). It has frequently been stated that no hazard has been observed in early field trials; therefore, negative evidence is used to support the hypothesis that GM crops are safe. A more precautionary approach to the validity of data would suggest the need to look more closely at simple attempts to prove causality by examining indirect relationships such as correlations, patterns and associations, and by examining the experiences and practices of farmers. The decision to implement field trials on three GM crops is an example of where this has been done, as is public consultation in the issue. With the pressure on Government to widen its approach to risk assessment, and increasing scientific evidence that suggested that earlier scientific knowledge did not create the certainties expected, the burden of proof of safety has moved to the biotechnology industry, which is a precautionary move.

Uncertainty

Uncertainty seen as a *temporary* lack of data, is a sound science characteristic, i.e., in a world that is perceived as determinate, uncertainties can be accounted for: this is a manageable scientific problem. In GM crops research, this can be seen as a step- by-step approach to problem solving. "Each step provides more (negative) scientific evidence to rationalize proceeding to the next step' (Barrett and Raffensperger 1999: 114). This may seem like a precautionary approach, to seek out adverse effects and take remedial action, but does not in any firm way, question the assumptions that are fundamental to sound science, and 'therefore fails to anticipate unknown and uncontrollable effects' (Barrett and Raffensperger 1999: 115). This is a cost-benefit approach that is based on a narrow range of expertise. However, uncertainty seen as *indeterminacy*, in

Wynne's definition, is a more open-ended approach that examines the complexity of the issues, the social and ecological contexts. In the Government's handling of the uncertainties inherent in the GM crops issue, its instincts seem to have been to accept *scientific* evidence that supports commercialization, given its support for the biotechnology industry, but at the same time, to demonstrate its commitment to the precautionary idea because of the resistance from the public, supermarkets and NGOs. Hence, its setting up and commitment to making decisions resulting from the FSEs, scientific and economic reviews and public consultation exercise.

5.6.1. SUMMARY

The introduction of GM crops into the UK has been accompanied by considerable public disquiet, and in the ensuring debate, the various participating groups - seed and biotech industries, government, agricultural interests - have claimed the concept of sustainability to justify their positions on the issue of GM crops. Pro-GM groups have been hampered by the regulatory authorities', perhaps, late, concern to present evidence with which to make scientifically sound, yet at the same time, precautionary decisions on the commercialization of GM products. To answer the question: is it a precautionary policy? - one could say that if left to make its own decision, the Government would use the sound science approach, that is, accept the scientific evidence from conventional risk assessment to justify decisions on licensing, but because of the public controversy, it has been forced to adopt what it claims is a precautionary approach. The existence of the advisory system on GMOs, in particular, ACRE, to assess proposed GMO release into the environment, seems proof of a precautionary approach. However, ACRE operates 'under the cloak of science....and their "science" is limited by the belief systems, the discourses, underpinning the scientific communities which comprise the committees dealing with GM food and crops regulation' (Toke 2004: 65).

Scientists admit there are gaps in their knowledge of GM crops and that many uncertainties still exist; the public appears not to be particularly enthusiastic about GM technology; poor economic prospects are on offer; and the field trials suggest some GM may threaten wildlife. Moreover, the public perception of GM technology may have been influenced by the attitude and actions of biotechnology companies, with their handling of PR problems sometimes showing clumsiness. Also, according to a recent press report, in Britain, plant scientists have given up attempts to grow new varieties of GM crops because of the activities of extremists who dig up newly planted fields (McKie 2005: 16).

5.7. Conclusions

In the early years of the attempts to regulate GM products, the Government approached the introduction of these untried technologies by accepting the conventional risk assessment procedures familiar in the sound science approach, but also appear to have been caught between pressure from, on the one hand, the US Government and biotechnology multinational corporations, urging a sound science approach to risk assessment, and, on the other, the vociferous campaigns of the green lobby and elements of the media, urging in some cases, a GM-free Britain, or at least, a more precautionary policy in the regulation of GM crops. This debate caused Government to set in motion a number of precautionary strategies and also to increase the burden of evidence of safety of GM products. These strategies demonstrate a weak precautionary approach to the issue, in that the Government has attempted to balance the risks to the environment by, on the one hand, delaying commercialization pending clarification of potential harm, and product safety, against, on the other hand, the risk to the environment of taking no action. By contrast, anti-GM groups demand decisions based on the precautionary principle (strong precaution), urging the Government to forbid commercialization until the biotechnology industry has demonstrated that GM crops will not damage the environment.

The case study shows how the Government used risk assessment process to reduce uncertainties and reassure the public about the safety of GM products, but found itself in a position where some research, for instance, some of the Government funded experiments cited earlier in this chapter, only served to heighten public uncertainty, because they cast doubt on safety conclusions of earlier positions.

This chapter has demonstrated the problems faced by policy-makers in their efforts to frame adequate regulations for a novel technology, using scientific advice, and in the face of the competing pressures from a number of opposing groups. It illustrates how a new technology, genetic modification of plants, was developing faster than government regulation could keep pace with. It also highlights the problems facing scientists responsible for providing the advice to these policy-makers on potential harmful consequences of introducing GMOs into the environment, and the uncertainties that remain to be resolved. This issue is an example of where pressure from the biotechnology industry, combined with a government eager to reap the rewards from a sector that could produce high-skill jobs, produced, at times, an intolerance of dissenting science.

The issue of GM crops is different from that of OPs in that it gained high political salience very quickly, and was the subject of much media attention. Also, unlike OPs, which have been in general use for a long time, the problem could not be put off with the excuse that more research was needed, because of pressure from the biotech industry to license crops being developed, on the one hand, and public concerns on the other.

The next chapter presents the case of BSE in Britain during the 1980s and 1990s. It is similar to the GM crops case in the previous chapter (the frontiers of science) in that the Government was faced with a problem: a new disease, which, at the time, could not be explained by science.

CHAPTER SIX

CASE STUDY 3: 'Mad Cow' Disease and the Beef Crisis - The BSE Problem 1985 – 1998

The UK BSE Crisis is one of the best opportunities we have to explore the link between science and politics. (Seguin 2000: 293)

6.1. Introduction

Unlike the previous two case studies, which are ongoing policy problems, this chapter will investigate a specific set of past events. The BSE crisis led to what is generally viewed as a policy disaster, and certainly the events of the affair during 1996 fit one definition of a policy disaster: '...a negative event, that is perceived by a socially and politically significant group of people in the community to be at least partially caused by avoidable and blameworthy failure of public policy-makers' (Bovens & 't Hart 1996: 15). The BSE saga is a historical example of a policy problem, and my analysis of it relies mainly on government and parliamentary archives - in particular, the Phillips Report on the events of the years 1985 – 1998, (Phillips et al 2000) - and some scholarly studies. It is an example of how the scientific aspects of risk management were misused by ministers and officials while attempting to regulate a novel hazard. In the early days in particular, during the emergence of BSE in cattle herds there was a reluctance by MAFF officials to take a true precautionary stance, relying, instead, on science to provide evidence with which to make decisions, yet manipulating that evidence to suit the political priorities of the Government.

During, and immediately after, the BSE crisis of the late 1990s, the media made much of the issues surrounding BSE and CJD, and yet for all the contemporaneous articles and news reports, not much light was shed on the subject. In the aftermath of this affair, there was an opportunity for social scientists to look for explanations of the crisis: some viewed the crisis as poor risk communication; others believed it was a manifestation of an unsatisfactory statutory advisory system; while yet others say it is an example of how the economic imperatives of the government can badly skew decision-making.

This case study begins in 1985, when BSE first began to appear in herds in Britain, and ends in 1998, the year the EU Commission allowed the resumption of exports of British beef, though,

of course, the aftermath of this crisis remains today. There is still scientific controversy over the origins of the disease, and whether or not it can be transferred to humans in the form of CJD, and in Europe and other parts of the world, cases of BSE still appear.

The case study begins with the origins of the disease, and considers why it became a salient political issue for the Government of the day, describing the Government's policy options and decisions on measures to cope with the disease. It then examines the scientific evidence on BSE, and the expert bodies set up to advise ministers on the problems. The study concludes with a discussion of the empirical evidence presented in the case study.

6.2. What was the issue?

6.2.1. BSE, A NEW DISEASE

BSE is one of a group of neurological diseases known as transmissible spongiform encephalopathies (TSEs), which also include scrapie in sheep, Creutzfeldt-Jacob disease (CJD) and kuru in humans. In its scrapie form, it is endemic in the UK sheep population. CJD normally occurs in approximately one case in two million persons per year throughout the world (Oldstone 1998: 165). The disease mostly strikes people over 65, and is rare in people under thirty, and because of the randomness of where in the world it appears, and because of its unknown origin, it is called sporadic CJD. Kuru appears to be restricted to tribes people in New Guinea. The symptoms of TSEs were found in cattle in the UK from 1985, and after research conducted by the Central Veterinary Laboratory (CVL) of the then Ministry of Agriculture, Fisheries and Food (MAFF), it was confirmed in November 1986 that a new strain, BSE, did exist. Within two years, over 2000 cases emerged in over 200 herds (Oldstone 1998: 163). The first account of this epidemic appeared in the journal *Veterinary Record* in October 1987 (Wells et al 1987). Initially, MAFF scientists believed that BSE had been caught from sheep infected with scrapie and was being transmitted through contaminated feedstuff.

6.2.2. INITIAL RESPONSE TO THE PROBLEM

The media began increasingly to report the disease, and eventually there was a crisis of confidence in British beef. Ministers and officials of MAFF continually denied that BSE posed a health risk for humans: in November 1988, Keith Meldrum, Chief Veterinary Officer at MAFF, stated that 'we don't believe that there are any implications for humans at this time', and in May 1990, the Chief Medical Officer, Donald Acheson, said: 'There is no risk associated with eating British beef' (Weir & Beetham 1999: 283). On 7th December 1995, during Prime Minister's

Question Time in the House of Commons, John Major stated: '...I have sought and received advice that there is currently no scientific evidence that BSE can be transmitted to humans or that eating beef causes CJD.' (Dealler 1996: 242). Lord Souslby of Swaffam Prior, a Conservative and a veterinarian, blamed the crisis on 'media hyperbole' and pressed the government for 'positive steps' to generate public confidence by more 'aggressive' information: "The British public will believe the science of the situation if it was put to them in a more effective way' (quoted in Powell and Leiss 1997: 13). The Phillips report subsequently noted that while the government thought the likelihood that BSE posed a risk was remote,

> 'they did not trust the public to adopt as sanguine an attitude. Ministers, official and scientific advisory committee members alike were all apprehensive that the public would react irrationally to BSE' (Phillips et al 2000, volume 1: 233).

On 19th March 1996, the government's new advisory committee on BSE, Spongiform Encephalopathies Advisory Committee (SEAC), informed the Secretary of State for Health, Stephen Dorrell, of their latest findings: that a distinct variant of CJD had occurred in ten people in Britain over the previous 14 months and that a link between BSE and CJD could not be ruled out. Mr Dorrell told the House of Commons this the following day. A month later, the medical journal *Lancet* published a report of ten cases of a new variant of CJD in Britain. The unusual feature of these cases was that the patients' ages ranged from nineteen to thirty-nine. The brain-wave pathologies of these patients were found to be different from other patients with sporadic CJD. The CJD Surveillance Units decided that Britain had a new variant CJD: vCJD (Oldstone 1998: 166).

For almost 10 years, the British Government and its scientific advisers had insisted there was no risk, or that any risk was so small that it could be said that there was no risk (Powell & Leiss 1997:4). This message contributed to the so-called BSE crisis during which the beef market collapsed, there was a mass slaughter of cattle and a number of people in Britain died of vCJD. What had begun as an animal health problem escalated first into a critical economic issue with serious consequences for European farming and food industries, and then into a human health-scare. It also caused a diplomatic crisis when Britain began a non-cooperation policy designed to paralyze EU business.

The burning question that needed to be urgently answered was, can BSE jump the species barrier? In other words, can humans develop CJD after eating beef from cattle infected with BSE?

6.3. Policy Options and Government Decisions

By 1987, the disease had become a significant problem in British herds. Scientists at MAFF suspected that BSE was likely to have been caused by a scrapie-like agent passed from sheep to cattle via feedstuffs containing animal protein in meat and bone meal (MBM).

6.3.1. POLICY OPTIONS OPEN TO THE GOVERNMENT

As the crisis escalated, there were a number of policy options available to agricultural ministers that may have reduced the risks from BSE. These ranged from imposing controls on the animal feed chain to slaughter of all the UK's cattle herds. Less contentious options were:

- A ban on the use of MBM for ruminants, pigs and poultry.
- The slaughter of cattle known or suspected of having consumed MBM.
- A ban on the use of animals from affected herds.
- A ban on bovine tissue from animals suspected of harbouring the pathogenic agent.
- A ban on clinically affected animals as human food.

The important point about all of these options is that under the conditions of scientific uncertainty that prevailed at that time, any decisions would necessarily be of a political nature. As one study of the BSE affair noted: 'Policy-makers had to make political judgements about which actions to take, and how the costs should be distributed between public and private sources' (van Zwanenberg and Millstone 2002: 173).

6.3.2. GOVERNMENT DECISIONS ON BSE

MAFF was the lead department on issues related to BSE. This raised two problems: first, MAFF was not only responsible for promoting the economic interests of farmers, but also responsible for the interests of the food industry in general, and for the protection of public health from food-borne hazards. MAFF had been structured in a particular ideological way, to incorporate the shared beliefs of farmers and officials in the common goals of agricultural policy that had been formed after the Second World War. Over time, this developed into a closed policy

community, with MAFF maintaining a strong relationship with the National Farmers Union (NFU) and agricultural officials, which set 'the rules of the game' that determined how the various interest groups should act in order to obtain access to the policy community (Smith 1992: 20).

Second, scientific integrity was in danger of being compromised by politics. There is evidence that the BSE crisis demonstrates that increasing demands for scientific advice undermined the credibility of scientists, because their objectivity was questioned (Weingart 1999). In a recent analysis of the BSE crisis, two academics believe that

> the BSE saga demonstrates that in UK policy-making there is too little clarity about how the scientific aspects of risk assessment and the political aspects of risk management can, and should be, both differentiated from each other and coupled together (Millstone and van Zwanenberg 2001: 109).

These authors posit a model of decision-making where risk assessment (scientific considerations) is separate from risk evaluation and risk management (non-scientific considerations). (Millstone and van Zwanenberg 2001). This is a linear model: risk assessment – risk evaluation - risk management (outcome and regulation) which, is supposed to be a socially and politically neutral process. But, as Millstone and van Zwanenberg show, there is another model at work. This second model is one in which scientific data is embedded in a socially derived framing of assumptions (e.g. goals and parameters of policy). In this model scientific considerations are sandwiched between two sets of non-scientific considerations; both upstream, where there is a framing of assumptions, i.e. what is harmful? - and a baseline for evaluating impacts; and downstream, where evaluations consider technical, economic and social aspects of the issue in hand (such as the costs of accepting or diminishing the risks). (Millstone and van Zwanenberg 2001). The study examines the workings of the expert body set up to give advice during the BSE crisis (the Southwood Committee) and concludes that this body was established to provide political support for the introduction of regulations which would not have been otherwise acceptable to MAFF and the Treasury.

Millstone and van Zwanenberg demonstrate how the expert body set up to consider the scientific issues of BSE was pressurized by the prevailing assumptions of public policy. This was, concern for public expenditure (spend as little as possible, and don't scare the public), a thesis also posited by Weir and Beetham (1999) Seguin (2000) and Dressel (2000); and judgments about the acceptability of risk (are the proposed regulations of the risks too hard on the

industries concerned? - that is, how to sustain the meat and dairy industries in the face of these risks) (Millstone and van Zwanenberg 2001).). Millstone and van Zwanenberg study shows how, bending under these pressures, Southwood 'began to acquiesce with the Government's risk communication priorities' (Millstone and van Zwanenberg 2001: 104), quoting from the Working Party's report that they were mindful of disastrous consequences of an alarmist report. The Phillips report covers the role played by the Southwood Working Party in great detail.

One particular issue examined by Phillips illustrates how the scientific aspects of risk assessment were manipulated by political considerations. Phillips notes how the Southwood Working Party was concerned that the continuing practice of feeding MBM to pigs and poultry might pose some risk to human health and in a report they recommended extending the ban on feeding MBM to ruminants to all herbivores (Phillips et al 2000, volume 4, paragraph 9.21). This was of concern to MAFF officials who were sensitive to the effects of regulation on the beef trade and meat processing industry. The officials attempted to gain access to the Working Party's next meeting to explain their anxieties. Sir Richard Southwood refused to allow this, but the officials nevertheless managed to persuade two members of the committee of their viewpoint before the meeting, and one of those members, Bill Martin, wrote to Sir Richard Southwood to argue that "I think we have to be restrained in the view we express in the report, on the subject' (Phillips et al 2000, volume 4, paragraph 9.26). The recommendation was, therefore, dropped and, this absence of expert advice to extend the feed ban to other animals, allowed MAFF to report that the lack of discussion of pigs was 'scientific' proof explaining why the Working Party had not recommended an extension of the ban.

6.3.3. REGULATORY MEASURES

When BSE became a concern, the problem for MAFF in devising regulatory measures to control the disease, was that any admission that the consumption of beef or dairy products might be harmful would undermine confidence in the farming industry. As BSE was a new phenomenon with no scientific information or research on its potential as a human health risk, the Government's professed policy was "let science be the guide", on the basis that scientific research on BSE would be duly initiated (Maxwell 1997: 55). Yet from the early days of the crisis, without any research on which to make informed decisions, government ministers and officials continued a policy of denying there was any risk repeatedly reassuring the public that "British beef was safe." Dr Bernard Williams, Head of Veterinary Investigations at MAFF, told the Phillips Inquiry that this policy of reassurance was adopted 'because of the nature of the

disorder, its political implications and possible effects on exports' (Phillips et al 2000, vol 3: 51). Because of this fear of bad publicity, the Government 'took no regulatory measures whatsoever' (Millstone and van Zwanenberg 2001: 103). At an early stage, the decision to make the disease notifiable was rejected because, as one official stated, this '...might imply to the general public we know something they don't, like the meat or milk is a source of danger for humans' (Phillips 2000, vol 3: 44).

Moreover, there was a deliberate policy of restricting dissemination of information about BSE to research institutes and Universities, because any sharing of information with bodies outside MAFF was seen as undermining confidence in the beef industry. An example of secrecy is to be found in a SEAC draft document on the safety of beef prepared for the Chief Medical Officer in which it was revealed that ' some of the edible offal ...that have on rare occasions demonstrated low titres [measures of concentration] of infectivity are not included in the offal ban' and 'there are some who insist on nothing less than an absolute guarantee of safety. No scientist is in a position to do that at present for British beef' (Phillips et al 2000, volume 11: 68). This draft document was circulated within the Department of Health (DoH) and MAFF. The final document was sent to ministers with the comments from officials that 'the most inflammatory pieces [including those above] have been edited out' (Phillips 2000 et al, volume 11: 67)

However, in the face of a growing epidemic which was increasingly being reported in the media, senior officials at MAFF were concerned that difficult questions would sooner or later be asked in Parliament, and that if some action was not taken by Government they may be held responsible if it later emerged that BSE was transmissible to humans (Phillips et al 2000, volume 3, paragraph 5.41c). In February 1988, therefore, these officials advised the Minister of Agriculture, John McGregor, that he should authorize a slaughter and compensation policy (Phillips 2000 et al, volume 3, para 192). But this advice was rejected on the grounds that it was not consistent with the Government's policy that industry should pay the costs of eradicating animal and plant diseases (Phillips et al 2000, volume 3, paragraphs 5.58). The Minister of Agriculture's approach to the proposed slaughter policy was that there was no evidence that the disease was transmissible to humans and its cause was uncertain, and that 'more positive evidence of risk to humans was required before the expense of government compensation could be recommended' (Phillips et al 2000, volume 3, paragraph 5.193).

More persistently, MAFF officials recommended to the Minister that he should enlist support from the DoH Chief Medical Officer (CMO) (Phillips 2000, volume 3, paragraph 5.195). At a

subsequent meeting of DoH and MAFF officials, they concluded that as there was a complete absence of evidence of risk to humans with which to support their slaughter and compensation proposals, the only way forward was to appoint an expert committee to advise MAFF and DoH Ministers on the disposal of affected animals and on the safety of pharmaceutical products derived from cattle. The Southwood Working Party was set up as a result of this decision and it met for the first time on 20 June 1988. Its early advice was that infected cattle should be not be allowed into the human and animal food chains; that farmers should be compensated; and that BSE be made a notifiable disease. The committee also made clear the risks of the use of potentially contaminated MBM to ruminants, and recommended a ban on the feeding of cattle with this foodstuff. Although this last recommendation was too controversial for the Animal Health Division of MAFF who complained that it would have serious consequences for the rendering industry, a ban on the use of MBM was put in place.

Regulatory measures were not introduced until June 1988, when BSE became a notifiable disease, followed in July by a decision on the slaughter of affected cattle and a ban on ruminant derived MBM came into force. This policy was later followed by the introduction of a Compensation Order, which was set at 50% of the value of each confirmed case. However, it was not until the following year that a ban was imposed on specified bovine offals (SBO): brains, spinal cord and other organs and in the human food chain, and it was not until February 1990 that full compensation payments were made. In November 1995, acting on the advice of a new advisory committee, SEAC, the Government announced its decision to stop the use of bovine vertebral column in the manufacture of mechanically recovered meat. 1996 saw the introduction of the 30-month Slaughter Scheme, whereby all cattle over 30-months at the time of slaughter do not enter either the human or animal food chain. These measures were, according to one commentator, 'not designed to eradicate the BSE agent, ... but only to diminish the risk.' (van Zwanenberg & Millstone 2002: 175).

Some scholars believe that many precautionary measures were not introduced early enough, 'not because of their immediate costs, but because of their liability to undermine the government's reassurance message'. (Van Zwanenberg & Millstone 2002: 177). The result was that regulatory control was slow to develop, and implemented with little rigour or enthusiasm.

6.4. Scientific Evidence and Expert Advice

6.4.1. THE SCIENTIFIC EVIDENCE ON BSE

The spread of BSE in cattle herds was the result of feeding them MBM. The MBM was infective because it had been manufactured by rendering infective offal from cattle suffering from, or incubating the disease, and as little as 1 gram of this infective material could cause death in cattle fed on the material (Phillips, *et at* 2000, volume 1, 1122). Initially, veterinary officials had believed that the disease originated from the rendering of sheep carcasses infected with scrapie, although this hypothesis was found to be implausible. Phillips believed that there might have been earlier cycles of BSE in the 1970s and early 1980s that had gone undetected because tissue from 'recycled' animals were incubating the disease but not showing any signs of disease (Phillips, *et al* 2000, volume 1, 1122). The rendering of animal waste to produce tallow is an industry that originated in the 1920s. It is a more recent practice for the rendering industry to process the solid material remaining after the removal of water and fat from the waste, using chemical solvents at high temperatures. The resulting substance was ground down to produce MBM and added to cattle feed: 'feeding herbivores boiled animals' (*Economist* 1996: 25). From 1981, a new system of rendering animal material was introduced which resulted in the material being rendered at a lower temperature.

Almost all research into BSE was financed by MAFF and carried out by either by the CVL or the Neuropathegenesis Unit (NPU), with priorities set by the Tyrrell Committee. BSE emerged at the unfortunate time when Ministers believed that expenditure on research into animal disease was disproportionate and was reduced by twenty percent. This resulted in staff cuts at research establishments (Phillips, *et al* 2000, volume 1, 1126).

In the late 1980s and early 1990s virtually nothing was known about the origins of the disease, and importantly, whether or not it could cross the species barrier to humans. At that time there were several theories to explain the origins of the disease. Early opinion was that it was a virus, because of scrapie's transmission from sheep to sheep and from sheep to mouse. Some evidence that BSE exhibited distinct transmission characteristics from scrapie emerged in the early 1990s, and this indicated that BSE had an 'unknown and unpredictable host range' (van Zwanenberg and Millstone 2002: 172). Experiments to see how scrapie could transmit to cattle were begun in 1997, and as Phillips noted, it would have been useful if this test had been carried out ten years earlier (Phillips, *et al* 2000, volume 1, 1133). The true explanation, when it was discovered, was a challenge to basic biological beliefs. Stanley Prusiner, a neurologist at the University of

California, had studied scrapie and identified an infectious protein in the brains of sheep with scrapie. This infectious agent contained no DNA (compounds that are vital constituents of all living cells). He called this agent a protein prion (PrP) and the discovery was known as the "protein only" or prion hypothesis (Pattison & Almond 1997). It was at first ridiculed, but it is now generally accepted, that prions are the infectious agent that cause TSEs. There are some scientists, however, who consider that while PrP is 'an essential component of the infectious agent, additional (possibly non-host) informational molecules such as nucleic acids are required to explain strain diversity, but none have been identified.' (Hester & Harrison 2001: 81). Most scientists believe that the most likely route of exposure to vCJD was through eating beef products that included offal before it was banned from human consumption.

There was also a theory that it was an autoimmune disease of the central nervous system, but this theory is not viable because experimentation has shown that mouse-adapted BSE can be transmitted by intracerebral inoculation to mice lacking a functional immune system. Moreover, the theory is incompatible with what has been established about the central role of the protein prion in TSEs (Phillips, et al 2000, volume 1, 1124). One other alternative theory of the origins of BSE - that it was the result of the use of an organo-phosphate pesticide Phosmet, to control warble fly in cattle herds. This theory has not been supported by research.

In 1995, several cases of an unusual variant of CJD were discovered in exceptionally young people, which provided temporal and geographical association between the two diseases, if not evidence of causality. By 1996-7, some direct evidence that indicated a causal relationship between BSE and CJD was found in studies where the 'pathological and clinical features of BSE and vCJD were identical whilst both differed from the distinctive features of scrapie and sporadic CJD' (van Zwanenbereg and Millstone 2002: 172).

Against this background of scientific research and the uncertainties it generated, there were disagreements between those involved in policy formulation in the Department of Health and in MAFF, over which department was responsible for risk assessment to human health and the management of that risk (Phillips et al 2000, vol 1:29). It is noticeable that although MAFF appears to have made all of the decisions on regulating such issues as MBM and SBOs, it was the Secretary of State for Health, Stephen Dorrell, who made the critical announcement to the House of Commons in March 1996. Possibly as a result of this blurring of responsibility, during the period when the disease was appearing in more and more cattle, efforts to investigate a disease that had been identified in 1985 were very slow. Some research into the causes of transmission of

the disease took place in 1987 at the NPU and CVL. These investigations were into infectivity of placental and uterine tissue, and oral infectivity of foetal membranes in calves. Neither piece of research found positive signs of transmission of BSE. One important area of research was to look for evidence of direct transmission from dams to offspring (maternal transmission) that might be detected by careful recording the development of cases in herds. This kind of study depended on the purchase of 300 offspring and 300 controls. The was first recommended by Southwood and formally proposed by the Tyrrell Committee on 13 March 1989, and forwarded to the Permanent Secretary at MAFF. The proposed research was subjected to a series of delays over funding arrangements. A case-control study of maternal transmission that examined the management of calving in herds, eventually got under way in 1993. The results, reported in 1995, found no significant increase in the incidence of BSE in herds where calves were born to BSE-affected dams, compared to controls, but a statistically significant risk for animals born between one and three days after an affected dam had given birth, though there was no convincing evidence of causal association (Phillips, *et al* 2000, volume 2, 3.121).

Throughout this period, the Government continued to reassure the public by claiming there was an absence of evidence of harm, when no convincing evidence either way was available. As one study noted: 'This was a classic example of "no evidence of harm" being misinterpreted as "evidence of no harm"' (Harremoes, et al 2002: 191). Steven Dealler, an independent researcher, similarly noted that '....direct information about BSE was not reaching the medical literature and that what we were hearing was what MAFF was allowing us to hear.' (Dealler 1996: 35).

6.4.2. EXPERT ADVICE ON BSE

As already noted, MAFF and DoH jointly made the decision to set up a small expert working party to advise agriculture and health ministers on BSE. This expert body was chaired by Sir Richard Southwood, a professor of zoology at Oxford University. (see membership of this body at Table 6.1.). However, according to one study 'the committee was established primarily to provide MAFF and DoH officials with a political resource with which to push for regulations which they believed agricultural ministers and the Treasury would not otherwise accept' (Millstone and van Zwanenberg 2001: 103).

Table 6.1. Membership of the Southwood Working Party

Professor Sir Richard Southwood	Professor of Zoology, Oxford University
Professor M.M. Epstein	Emeritus Professor of Pathology

Dr W.B. Martin	A veterinarian and formerly Director of the Moredun Research Institute, Edinburgh
Sir John Walton	Formerly Professor of Neurology, University of Newcastle
Mr J. Wilesmith	MAFF civil servant and veterinary epidemiologist
Mr A.J. Lawrence	MAFF civil servant
Dr H. Pickles	DoH civil servant

This Working Party was carefully selected by MAFF and DoH. None of its members had experience of the epidemiology of TSEs and, according to Dr Steven Dealler, a microbiologist, 'Major researchers on scrapie and BSE in the UK were not asked for their opinion on the subject and much of the information on spongiform encephalopathies were taken out of good text books' (Dealler 1996: 41). Southwood himself is reported to have had concerns about the controversy over the BSE pathogen, and is reported to have said that he did not wish to have any experts who were 'almost too close to the front line to take the slightly broader view that we needed' (Phillips 2000, volume 5, paragraph 1.12). Missing from membership of this committee were several obvious candidates; such as Dr Richard Kimberlin, who had recently been Acting Head of the NPU in Edinburgh, Dr Alan Dickinson, a leading expert on scrapie and the current Director of the NPU, and Kenton Morgan, a research veterinarian interested in scrapie. The Working Party's terms of reference were:

> To advise on the implications of Bovine Spongiform Encephalopathies and matters relating thereto (Phillips et al 2000, volume 1: 48).

This advisory committee reported in February 1989, but it was not published immediately. One study of information management during the BSE crisis suggests that the report was apparently written by a civil servant, with the members having to approve or alter the draft. MAFF officials intervened until they were satisfied with the result, and the report was finally published in November 1989 (Miller 1999: 1245). Whether or not this is an accurate assessment, MAFF officials did, '...exert as much control as possible over the sensitive political functions of risk evaluation and risk management' (Millstone and van Zwanenberg 2001: 104). Another writer echoes similar views: '....civil servants and politicians have a naively uncritical approach to scientific evidence, failing to recognize that their opinions and political sensitivities might

influence the presentation of conclusions which they assume can be based on objective science' (Winter 1996: 562).

One major criticism of the Working Party was that, while it had been set up to advise Ministers, its report failed to convey to MAFF and DoH that its advice was based on deduction rather than scientific data, even though a caveat inserted in the General Conclusions stated that if the Working Party were wrong the implications were serious (Phillips, *et al* 2000, volume 4, 68). The rather serious consequence of this was that Government minister and officials quoted the *Southwood Report* as if it demonstrated scientific certainty, rather than provisional opinion. The Food Safety Minister at MAFF, David Maclean, for example, is reported as saying:

> **I regard Southwood as our bible...we had the *Southwood Report*. There was no better or more learned scientific body (Phillips, et al 2000, volume 4, 11.7).**

The Southwood Working Party admitted its lack of expertise in TSEs, and their report recommended the establishment of an advisory committee on *research* into BSE. The Working Party was duly replaced in January 1990 by the Consultative Committee on Research into Spongiform Encephelopathies under Dr David Tyrell, (the "Tyrrell Committee"), which included experts in the field of TSEs and focused its efforts on research rather than policy advice. This Committee was later chaired by Dr John Pattison and renamed the Spongiform Encephalopathies Advisory Committee (SEAC), and still exists today. Pattison not only revised the committee's membership, doubling its size and including scientists involved in experimentation on both human and animal TSEs, but, as Dressel notes, this committee 'became much more present in political decision-making and much more visible in public' (Dressel 2000: 50). SEAC's first report concluded that because scrapie around the world had not been linked to CJD, BSE was not likely to affect human health. It also recommended that cases of CJD should be monitored over 20 years.

This information gave the government assurance that its experts had matters in hand (Lacey 1997: 247). However, concerned that BSE may pose a human health problem, the Government set up a national CJD surveillance unit to monitor changes in the disease pattern of CJD that might indicate transmission of BSE to humans (Oldstone 1998: 164).

6.4.3. DISAGREEMENTS OVER THE EVIDENCE

The problem here is not so much of dissent among scientists over evidence from the research projects, which was mostly conducted at two Government institutions, NPU and CVL. Rather, it

was a case of the exclusivity of the research community and its attitude towards those not part of that community. The Government's regulatory policy on BSE was said to be based on science but this would suggest decision-makers were making a choice strictly from several scientific knowledge claims. Yet what happened, according to two analysts was that the government, or at least MAFF, as the lead department, created an in-group and an out-group of scientific claimsmakers. Certain groups of scientists were declared to be [politically] sound, and, by inference, so were their scientific claims; but others, such as Lacey, Dealler and Narang, were declared [politically] unsound and, therefore, so was their science (Jacob & Hellstrom 2000). Professor Lacey, for example, had experience of serving on the MAFF Veterinary Products Committee and had been a consultant to WHO since 1984. He was convinced from the beginning that BSE could be passed on to humans. After appearing before the House of Commons Select Committee on Agriculture, his evidence was dismissed as being "sensationalist" and having "lost touch with the real world". His evidence was discarded as a mixture of "science and science fiction" (Rowell 2003: 42). Dr Dealler had a conversation with scientists at the Edinburgh University Neuropathogenesis Unit, and he is reported as saying: 'MAFF is made up of vets who have connections throughout the farming world. Farmers are their friends, and they think Lacey is mad' (Dealler 1996: 49).

Dr Narang was similarly ridiculed and marginalized. Narang's contribution to the BSE debate was to develop diagnostic tests for BSE and vCJD. This test system (blind touch technique) claimed to distinguish infected meat from non-infected meat, and was originally developed for scrapie and was modified by Narang for BSE (Narang 1997: 146). Narang offered this test to MAFF in 1988 but it was rejected. According to Dressel, the test was rejected 'because it would be too costly for the government, for once you apply the test and you find positives, you have to destroy the animals and prevent them from going into the human food chain. Therefore, it was "pretended" by the government that there was no such test'. (Dressel 2000: 23). MAFF's internal correspondence reveals that there were 'political sensitivities in producing a diagnostic test for BSE and the pressure this may bring, e.g. for major screening programmes.' (Rowell 2003: 49). Narang was prevented from continuing with experimental work on BSE and was suspended and finally sacked from his job at the Newcastle Public Health Laboratory. The situation was further exacerbated by MAFF's monopoly over dead cows' brains and other organs access to which was denied to these out-groups. This meant that the workings of science and views on risk were one-sided. In the words of the Phillips report:

> The official line that the risk of transmissibility [of BSE] was remote and that beef was safe did not recognize the possible validity of any other view. Dissident scientists tended to be treated with derision, and driven into the arms of the media and to exaggerated statements of risk. Thus views expressed on risk became polarised. Dispute replaced debate (Phillips et al 2000, volume 1: 234).

Dressel came to a similar conclusion when she argued that research funding was a 'closed job'. Her study of BSE revealed that when, in 1990, the agriculture minister announced that he would make additional money available for research, an independent researcher the next day enquired about the conditions for applications, and was told that 'this money has already been spoken for, the minister has already allocated this money to people and there is no more available for *outsiders*' (Dressel 2000: 9 italics in original).

The issue of the integrity of the government's decision-making approach is addressed by Sheila Jasanoff (1997), who argues that the central feature of the crisis was the 'civic dislocation' that followed the March 1996 announcement in Parliament that a link between BSE and vCJD could not be ruled out (Jasanoff 1997: 223) – an announcement that was contrary to the message put out by MAFF that 'British beef is safe'. This dislocation, a mismatch between what government institutions were supposed to do for the public and what they actually did, was a result of the characteristics of British policy institutions where expert advice is managed through consensual advisory committees, meeting in private, with a membership consisting of the 'great and the good' (Jasanoff 1997: 227-8). Professor Richard Lacey, a former member of the VCP, commenting on his earlier recruitment to that committee said: 'prospective members are to a varying degree vetted on their general views and philosophy of life' (quoted in Miller 1999:1244). This seems to be an accurate description of the BSE advisory committees (MAFF, DoH), which dealt with the BSE situation. All of the successive BSE committees were staffed by 'respectable scientists', while those scientists who held more radical views, such as Lacey, a clinical microbiologist at Leeds University; Dealler, a highly experienced microbiologist: Dr Harash Narang, a microbiologist with over thirty years experience working with TSEs; and Dr Helen Grant, a consultant neuropathologist at the Charing Cross Hospital, were excluded.

6.5. Discussion

How, then does the BSE saga fit the models of sound science and precaution? From the outset, the government of the day claimed to 'let science be the guide', yet the research done, such as it was, did not demonstrate any scientific certainty, and government ministers and

officials continued to assure the public that British beef was safe. The lack of 'evidence' or 'proof' of the causes of the disease, or of any causal link between BSE and vCJD, was used as justification for limited or lack of action. Moreover, early advisory bodies established to look into the disease did not include in their membership the appropriate type of scientific expertise, while much of the precautionary advice given to government was not introduced or was introduced very late, in case it undermined the government's reassuring message to the public. Van Zwanenberg and Millstone conclude that 'the government's policy was not precautionary. Its primary objective was rather one of trying to diminish, as far as possible, the short-term adverse impact of BSE on the profitability of the food industry and the level of public expenditure'. (Van Zwanenberg & Millstone 2002: 174). Moreover, the various expert bodies involved in the BSE problem did not really adopt a precautionary approach when assessing risks; rather they confined themselves to searching for causal evidence of the likelihood of BSE crossing the species barrier from cattle to humans. Can further analysis of the empirical evidence of this case study identify any of the characteristics of the two models outlined in Chapter 3?

The authority of science/scientists

The *Southwood Report* was repeatedly cited as if it demonstrated scientific certainty, even after it was no longer the most authoritative assessment of the risk posed by BSE. It was this scientific authority that was used by Government Ministers and officials as the reason for its regulatory decisions, although there is evidence that the Government was hiding behind science. It is difficult to maintain the fiction that the specialized scientific knowledge needed to deal with the crisis was separate from the political context, given that the Government used scientific recommendations to suit their own agenda: to protect the beef and meat processing industries.

Moreover, the elitist nature of the policy community led by MAFF, which prevented researchers who were not funded or employed by MAFF, from having access to diseased organs or in-house information and data, is an example of the exclusive peer-review system at work. Another example is the action of the Southwood Working Group chairman in selecting his members so as to exclude anyone involved in the controversy surrounding the causes of the disease (Phillips 2000, *op cit*).

Definition of Hazard

This case was an example of trans-science, where there was no existing scientific knowledge to decide whether or not BSE was a hazard. It is possible in such cases, where a problem presents technical difficulty, that experts, such as epidemiologists or statisticians, can use their expertise and judgment to decide whether a risk exists. But this was not the case with BSE. The proper assessment of risk was undermined by considerations of whether the proposed remedies would be too hard on the beef and meat processing industries. In deciding what was harmful, the assumptions in the BSE case were that nothing was scientifically proven as to whether the BSE pathogens could be transmitted from cattle to humans. Ministers and MAFF officials continued to reassure the public that eating beef posed no hazard to human health. This can be seen as a sound science characteristic – using science in a way that suited the Government's policy purposes. The potential of this hazard was never fully faced by the Government in its need to protect industry.

Error and the burden of proof

During the early years of the BSE saga there was scant evidence on which to make policy decisions. Therefore, the sound science procedure of following false negatives to establish that there was no likely harm is not present in the early years of the BSE crisis. However, the possibility that BSE might transmit to humans was recognized by MAFF veterinary officials in 1986 after the disease was first diagnosed. Moreover, in 1996 direct evidence of a causal relationship between BSE and vCJD was discovered. Yet up to that time MAFF had steadfastly kept the burden of proof with those who had warned that there was the likelihood of the disease jumping the species barrier.

Evidence and data

As noted in the previous section, there was little scientific evidence beyond the early research that identified BSE as a TSE that could be transmissible to mice, sheep and goats. Therefore, early advice of the Southwood Working Party to Ministers was based on deduction rather than scientific data. Despite this, policy-makers at MAFF did not seriously consider potential public safety issues when making decisions: rather, Ministers and officials were too eager to use what little evidence there was to justify policy positions – concern for public expenditure and possible damage to the beef and meat processing industries. The fact that there was no hard evidence of harm seems to have reassured MAFF that what evidence was at hand meant there was no evidence of harm.

Uncertainty

The fact that BSE, unlike OPs, was a new problem puts it in the realm of Weinberg's trans-science, a phenomenon with no known scientific answer. There were a number of theories floated at the beginning: that it was a virus, or an auto-immune disease of the central nervous system, and that it resulted from the use of OP pesticide to control warble fly in cattle herds. From the scientific experts' point of view, conventional scientific method was absolutely necessary - there was a need to study the disease in solid scientific fashion, using quantitative data from animal and epidemiological studies, and searching for causal links of some kind. But in the beginning, there was no scientific knowledge that would suggest there was any risk to human health, and here lies the uncertainty. It was a sound science conclusion that because there was no data to suggest a possible threat to human health, then it was not necessary to do anything. As the Phillips report noted, Ministers happily quoted the Southwood Working Party report as if it demonstrated scientific certainty, rather than the provisional opinion of the group. A precautionary approach to this problem would have 'involved producing and disseminating far more information and evidence' (van Zwanenberg and Millstone 2002: 179).

6.5.1. SUMMARY

It is easy to sum up the BSE crisis as an example of where a precautionary policy was not followed. That much is straightforward, and certainly two academics who analysed this issue have said as much (van Zwanenberg & Millstone 2002: 170): that it is a good example of sound science at work. Many of the characteristics of the model of sound science are present. These are: the way the authority of science was used to justify Government decisions that ignored public health considerations; the inclusiveness of the scientific community, both in the composition and recruitment method of the early expert body (the Southwood Committee), the continuous citing of the Southwood Report to justify its decisions when this report was only the provisional opinions of scientists; the way credible experts were excluded from the policy community; where risk assessment was undermined by pressure from industry; and where research priorities appeared to be geared towards establishing that there was no likely harm. The government's handling of scientific advice was central to the BSE crisis: all of the official or ministerial pronouncements during the crisis emphasized the scientific evidence used in their decision-making. However, ministers and officials made public pronouncements about the safety of beef without any scientific evidence. Therefore, the "scientific" case the government was relying upon was as much a political as a scientific construct:

> ...the nature of this process of scientific assessment was clearly of considerable importance. The problem is, of course, that any assessment has to be made based on criteria that must inevitably be political in the sense that scientists on the committee worked under the guidance of civil servants (Winter 1996: 562-3).

The events of the BSE affair thus demonstrate the blurring of the boundaries between scientific risk assessment and political considerations. As Millstone and van Zwanenberg explain, a balance must be struck between complete separation, and complete integration between politics and science:

> On the one hand, it is crucial to ensure that analysis and representations of risks are not subordinated to the prior decisions of risk managers, and that ministers do not hide behind their officials and advisors, pretending that they are merely following the advice of scientific experts and not responsible for any of the key judgements or decisions. On the other hand a complete separation of science and policy would not be desirable or feasible: scientific decision-making cannot operate in a policy vacuum and policy decision-making cannot operate in a scientific vacuum (Millstone and van Zwanenberg 2001: 109).

But on the BSE issue, the Government struck this balance too much in the direction of integration, manipulating the science for political reasons. This was because the government did not trust the public. In risk communication terms, the Government's strategy was, according to the Phillips Enquiry 'shaped by a consuming fear of provoking an irrational debate' (Phillips et al 2000, volume 1, paragraph 1294). Some academics believe that the risk communication strategy went beyond the idea that 'if the public only understood the science (or a simplified version of the science) they would comprehend technical risks in the same way as do technical risk assessors' (Frewer and Salter 2002: 139). This is the 'deficit model', but rather it went a step further by assuming that the public 'was unable to conceptualise uncertainty because of a lack of insight and understanding regarding scientific processes, risk assessment and risk management (Frewer and Salter 2002: 139). But this strategy did not create a culture of trust in official pronouncements on BSE, and as the then CSO, Sir Robert May told the Phillips Enquiry, forming a consensus on the facts and reducing it to a simple message must be resisted His view was 'that the full messy process whereby scientific understanding is arrived at with all its problems has to be spilled out into the open' (Phillips et al 2000, volume 1, paragraph 1297).

6.6. Conclusions

This chapter has described a policy disaster involving the use of specialized scientific advice. At the heart of this crisis is the problem of how to handle a hazard - a previously unknown disease in animals - and how to deal with its possible consequences for humans (Phillips 2000, vol 1: xvii). It demonstrates how policy-makers claimed to be listening, but did not always act speedily on the advice given by its own experts. Moreover, political pressures had influenced scientific advice.

The BSE saga demonstrates many of the hallmarks of the sound science approach as outlined in Chapter 3. Scientific uncertainties are present, but not addressed by government in a rational way; a reluctance to follow sensible precautionary regulatory measures to lessen the effects of the disease; and placing the burden of proof with those who were thought of as alarmist for making claims about the hazards of the disease. Rather, the science seems to have been misused as a political resource to further the priorities of Government.

The way the government handled risk communication over the BSE issue, caused so many problems during the late 1980s and throughout the 1990s, that many current debates on food safety end up referring back to this problem. BSE resulted in new institutions, such as the Food Standards Agency and the Agricultural and Environmental Biotechnology Commission, being set up in an attempt to improve the regulatory framework and recapture public confidence in the government's advisory system.

CHAPTER SEVEN

CASE STUDY 4 - Scare Stories: The MMR Vaccine and a Possible Link with Autism

What I would find helpful is a calculation of how many cases of autism would have to be caused by MMR – if there were a causal association – for the risks of vaccinating to outweigh the risks of not vaccinating (Altman 2000: 409).

7.1. Introduction

This case study, unlike the previous three case studies, is an example of a public health issue, to the exclusion of the general environment, and which concerns a small part of the population: children between 18 months and two years. It focuses on a research paper that, when made public, caused a problem for UK Government policy on vaccination for some serious childhood diseases, and a dilemma for parents of small children. This case highlights what happens when scientists differ over matters that affect the general public, the ensuing media hysteria, and the problems this poses for Government policy, and demonstrates how difficult it is to apply a straightforward precautionary policy to a complex problem.

I begin the study with the events that sparked off the controversy and describe the reasons for inoculation against mumps, measles and rubella (MMR) and its proposed relation with autism. I then set out Government policy on vaccinations, and in particular, its response to the opinions of some medical scientists, that the triple vaccination is dangerous to children, and review the scientific research into the subject of autism, bowel disease and MMR. I conclude with a consideration of whether the Government made a sound science or a precautionary response to the new research.

7.2. The Issue

Dr Andrew Wakefield, Reader in Experimental Gastroenterology, and Head of the Inflammatory Bowel Disease Study Group at the Royal Free Hospital, London, had for many years been involved in research into bowel disease in children, and, from about the mid-1990s, began to consider whether there was a link between the multiple - (MMR) vaccine, autism and bowel disease. In February 1998, he and a group of research associates at the Royal Free Hospital, published a paper giving the results of a research project that records twelve possible cases of bowel disease associated with pervasive child developmental disorders, including loss of acquired skills. (Wakefield et al 1998). The paper noted that

parents of eight of the twelve children studied, associated onset of these behavioral symptoms with the MMR vaccine, though it stopped short of claiming that a link between the MMR vaccine and autism was proven. However, at a press conference at the hospital before the paper was published, Wakefield (but not his colleagues), gave a different message. He told the assembled journalists that the risk of autism developing is related to the combined MMR vaccine, and he advised that until further research was published, single vaccines would be a sensible (i.e. precautionary) policy.

Reports of this message in the media prompted many parents to decide against having their children inoculated with the MMR vaccine, with some parents opting for the alternative of having their children vaccinated using single vaccines for each disease. Some parents were scared off the idea of any kind of vaccination at all. At the beginning of 2004, it was estimated that the inoculation rates had fallen to 79%, when 95% is needed to confer 'herd immunity' (Deer 2004). The Government was fearful that the 'herd immunity' that is produced by inoculating the whole population, would be weakened by this reaction, and in future that there might be an epidemic of measles. The Health Protection Agency (HPA), using computer models, have predicted that the poor uptake of the MMR vaccine makes an outbreak of measles in London very likely, followed by countrywide incidence (HPA 2003).

Dr Wakefield was criticized by some medical authorities, and his campaign against MMR has been vigorously opposed by various professional bodies, and more recently, he has been the subject of criticism by some journalists. The Chairman of the Parliamentary Select Committee on Science and Technology told me, when describing his work on monitoring the kind of subjects that find their way into academic and scientific journals, that [what gets published] affects policy by affecting people's concepts, and [the likes of Wakefield's paper] 'can turn the world over, whether it was right or wrong, it still has an effect' (Gibson 2004 – personal interview).

7.2.1. THE PUBLIC AND THE MMR VACCINE

The press conference held before publication of the 1998 Royal Free research caused considerable anxiety among the public, particularly those with small children, and Wakefield continued to publicize his view, in the media, that parents should go for the single measles vaccine. The DH repeatedly dismissed concerns about the safety of MMR, but there was increasing pressure for the government to supply the NHS with sufficient supplies of the single measles vaccine, which they refused to do. It seems that ever since the BSE scare, where the Government first claimed that beef was completely safe, then announced that it wasn't, the public have been ready to disbelieve the government's claim that the MMR

vaccine is safe. 'In a climate highly sensitive to health risks and increasingly distrustful of expert opinion, many – including prominent journalists and politicians – wanted to believe Dr Wakefield' (Fitzpatrick 2004: xiii).

Uptake of the MMR vaccine has since fallen, and the Chief Medical Office (CMO) believes it had, by 2001, stabilized at 88%, which is too low to maintain sufficient levels of protection in the population, especially against measles, where 95% is needed (Donaldson et al 2001: 9). A number of information and parents advocacy groups, such as Justice, Awareness and Basic Support (Jabs); the Vaccine Information Service, Allergy Induced Autism; and Child Vaccine Injury; Concerned Parents for Vaccine Safety, have become active since the Royal Free research was published, and in Britain, around 700 parents of children who have developed autism have pursued claims against manufacturers of the vaccine. Many of these pressure groups support a parent's right to choose to use the alternative of single inoculation, and there has been a spate of advertising of the single vaccine on the internet by private clinics. According to the journalist, Brian Deer, 'legal cases have proliferated...legal aid for those suing the vaccine companies has reached £15 million...and about £4 million has gone to doctors, some of them earning £100 an hour to study reports' (Deer 2004: 7). In addition, some journalists have reported that anti-MMR campaigners, in response to the Government's Medical Research Council (MRC) report, *Review of Autism Research* (2001), note that two of the expert panel of researchers who compiled the report have shares in Glaxo-Wellcome, one of the pharmaceutical companies that manufactures the MMR vaccine (Dixon 2001; Mills 2002).

7.3. Policy Options and Government Decisions

7.3.1. POLICY OPTIONS

After the media and public reaction to Wakefield's views on the MMR vaccine, the Government had three options:

- Cease the vaccination programme (the highest risk)
- Revert to the three separate inoculations (next highest risk)
- Maintain the combined vaccination programme (lowest risk)

Ceasing the vaccination programme posed a very high risk that 'herd' immunity would drastically lessen, with a likely outbreak of one or more of the diseases that the vaccination was designed to control. Reverting to separate inoculations for each disease may be a less effective option because it requires six separate inoculations with gaps in between that may leave children open to infections, thus eroding herd immunity. The DoH took the lowest risk

option of maintaining its policy of using the MMR vaccination. This had the advantage of maintaining the current status of around a 95% herd immunity.

7.3.2. GOVERNMENT DECISIONS ON MMR

The Government and its experts could not dismiss quickly the advice to abandon the MMR vaccine, because there was no large body of data about its safety on which to draw. However, the MRC held an ad hoc meeting of experts (Dr Wakefield and two of his associates also attended), to examine evidence relating measles vaccine to chronic gastrointestinal inflammation. One of the main conclusions of this meeting was that there was no reason for a change in the current MMR vaccination policy (MRC 2000).

But the Chief Medical Officer at the DH was concerned enough at calls for single vaccinations to replace the MMR programme, to make public announcements in the subject. He is reported as stating that a single vaccine programme would not work because children would be unprotected for longer periods: "We would be playing Russian roulette with our children's health and that, in my view, would be an irresponsible and ineffective way to run a programme which is meant to protect children's health" (Duckworth and Grice 2002). The DH has spent £3 million on a TV campaign urging the take up of the triple vaccine, and a series of educational road shows and advice sessions targeted at areas of the country with low take-up of MMR began in the summer of 2003.

7.4. Scientific Evidence and Expert Advice

7.4.1. THE MMR VACCINE

The MMR vaccine is a combined three-in-one vaccination against measles, mumps and rubella (German measles), three common infectious diseases of childhood. There are two combined measles, mumps and rubella vaccines licensed in the UK (Priorix and MMRII), and both were approved after clinical trials over a number of years (Donaldson et al 2001:8). The vaccine was introduced into the UK in 1988 to replace single vaccines for each disease and is used in 90 countries throughout the world, and more than 500 million doses have been given. Trials conducted in 1987 on the new vaccine, in which 11,000 families took part, showed no apparent ill effects (Donaldson et al 2001:8). The vaccine is given by injection at around 12 – 15 months, with a second dose as a pre-school booster. Some anti-immunization campaigners claim that a child's immune system cannot cope with three vaccinations at once. However, there is no published evidence for this claim – the human immune systems are constantly being challenged and there is no reason to think that MMR overloads it (Donaldson et al 2001: 9).

All three diseases can have serious and even fatal consequences, and they are still common on a worldwide basis. The incidence of these diseases will reduce, once a certain percentage of the population has been inoculated. This is called 'herd immunity'. The triple vaccine is a freeze-dried preparation that contains live virus particles of the three viruses, which are modified to stop them from producing the full effects of the disease. . Vaccines, like medicines, can cause side effects, but vaccines, including MMR, are considered among the safest in the world. Official advice is that anyone who has had a life-threatening allergic reaction to gelatin or the antibiotic neomycin should not have the MMR vaccination. MMR can produce a side effect that is a mild version of one of the viruses involved, but is not very different from the single measles vaccine, which was previously used.

The alternative to the MMR vaccine, single vaccines for each disease, are said to be less effective in maintaining herd immunity because they require six acts of vaccination and the recommended gaps between vaccinations may leave children open to infections and therefore at risk (Donaldson et al 2001: 8). However, there are some GPs who believe the single vaccine is safer, and medical practices have been inundated with requests for the single vaccine. Many private GP clinics are charging £300 to give children individual vaccinations. Licenses for the single vaccine do exist in the UK, but no licensed measles or mumps vaccines are manufactured for, or in the UK market, and the MCA has restricted the importation of single measles and mumps vaccines on the grounds that under law, unlicensed medicines should not be imported when a safe and effective alternative which meets patients' needs (such as, MMR), is available (Donaldson et al 2001: 9). Dr Wakefield has claimed that MMR was licensed too early because some of the trials missed or ignored evidence that the vaccine causes gastrointestinal symptoms. He also claims that adverse effects of immunization are specific to MMR rather than to a single measles vaccine because of biological interference between the different viral components.

7.4.2. WHAT IS AUTISM?

Autism is 'a set of neurodevelopmental disorders in which the way that a person communicates and interacts with other people is impaired' (MRC 2001: 7). The disorder typically presents itself in the form of delayed speech communication and intellectual impairment that is usually diagnosed in the second year of life. However, in recent times autism is considered to be one of a number of related developmental disorders, which includes Asperger disorder, childhood disintegrative disorder, and Rett's disorder. These are generally known as autism spectrum disorders (ASDs).

ASDs result from a range of causes, and most evidence seems to suggest that there is a genetic component, whereby several genes interact to create susceptibility to the disorder. There are also a number of theories about environmental risk factors such as diet, drugs, toxins and infections. During the 1990s, there was considerable research into inflammatory bowel disorders (IBDs) in some children with autism. IBD is a term used to cover Crohn's Disease and Ulcerative Colitis. The average age of MMR vaccination is 18 months to two years, which is also the typical age for the diagnosis of autism. However, the problem of hypothesizing a link between autism and the MMR vaccine is that, while autism has indeed increased in recent years, this increase pre-dates the introduction of the MMR vaccine by about a decade (Lingham et al 2003: 666). The problem is further complicated by the recognition today of many more childhood disorders that are classed as autism.

7.4.3. THE EVIDENCE

Research into possible links between measles virus and inflammatory bowel disease had been conducted for many years before the Royal Free research paper was published in 1998 (Mazure et al 1994; Lewin et al 1995; Wakefield et al 1995 and Daszak et al 1997). However, this earlier research had not become a public issue. Wakefield, with his associates at the Royal Free Hospital, conducted research on twelve children who had been referred to the hospital for gastro-intestinal problems. The children had all been normal before their illnesses and all twelve children had been vaccinated with MMR. All twelve children had intestinal abnormalities ranging from enlarged lymph nodes to ulcers, and chronic inflammation was present in the colon in eleven children. Nine of them were diagnosed with autism, and one with post-viral or vaccination encephalitis (inflammation of the brain). The resulting paper was peer-reviewed and published in the *Lancet* in February 1998 (Wakefield 1998). The paper purported to show that children with autism and gut disorders frequently have the measles virus in their gut. Wakefield argued that, in some children, the MMR inoculation provoked inflammation of the bowel, and this causes toxins to leak into the blood stream. These toxins then pass into the brain, causing damage that is manifest as autism. However, the paper stopped short of concluding that there was a direct link between measles, bowel disorder and autism.

In March of the same year, an *ad hoc* group of experts set up by the MRC to consider this hypothesis, concluded that there was no evidence of any link between the MMR vaccine and bowel disease or autism (MRC 2000). This study was a review of existing virology and epidemiological evidence. The subgroup that was set up to research this issue consisted of experts from leading universities, specializing in gastro-enteritis, colitis, Crohn's disease,

cognitive neuroscience, epidemiology, virology, immunology and autistic diagnostics assessment.

Shortly after this, a study conducted over fourteen years in Finland, and studying 31 children, concluded that they could 'find no data supporting that [MMR] would cause pervasive developmental disorder or inflammatory bowel disease' (Peltola et al 1998: 1327). In 2002, the *New England Journal of Medicine* published a paper detailing an epidemiological study conducted in Denmark, covering over 500,000 children born over an eight year period, and concluded that there was no link between children given an MMR injection and the onset of autism (Madsen et al 2002).

Also in 2002, a group of researchers at Trinity College, Dublin, (including Andrew Wakefield) published a paper that details a novel methodology for detecting various strains of measles virus, and claims to have detected the strain of measles virus in tissue samples from children with developmental disorder, provided by the Royal Free Hospital, (Uhlmann et al 2002). This research used new measuring technology developed by Professor John O'Leary. He used TaqMan RT-PCR, a viral detector sensitive enough to pick up minute traces of measles virus DNA in tissue from autistic children with bowel disorders (Uhlmann et al 2002). The authors believed the study showed, for the first time, 'an association between MV [measles] infection and ileocolonic lymphonodular hyperplasia and ileocolitis in children with developmental disorder' (Uhlmann et al 2002: 5). However, this paper does not indicate whether the children studied had received the MMR vaccine, or whether the virus particles were the same as those in MMR (Fitzpatrick 2002: 2). The results of this research was released in précis form to the public before a scientific presentation to a meeting of the Pathological Society of Great Britain and Ireland, and created more anxiety among parents groups.

The methodology described in the paper has since been criticized. Measles is a highly infectious agent, and in the tests, some materials were intentionally infected as a positive control: it is thought by those who have tried to replicate the experiment that this may have caused contamination of other tissue. Although Wakefield has continued to state his theory with sympathetic press coverage, including a special edition of *Panorama* in February 2002, and a long campaign in *Private Eye* (Mills 2002), he has appeared to have abandoned his original hypothesis that in some children an inflammation of the bowel causes toxins to leak into the bloodstream and eventually the brain, to renew his claims about the MMR vaccine safety (which is not his field of expertise). For instance, in a review of MMR vaccine safety, published in a medical journal, he wrote that the original safety checks on the MMR vaccine were poorly conducted and only lasted for four weeks (Wakefield and Montgomery 2001).

This claim was rejected by the CMO. It was thought that the Wakefield and Montgomery article, which generated much media interest, merely reviewed a number of published papers and did not mention studies that did not support the authors' views (Donaldson et al 2001:7).

Two researchers at St Georges Hospital, London, and the Institute for Child Health examined all of the current studies into MMR and found no reason for concern. Indeed, their report asserted that Wakefield's review was 'mistaken in some facts, but was also highly selective, ignoring important recent findings' (Elliman and Bedford 2001: 271). The MRC has produced two further reports on this issue, and other studies have been conducted by the American Medical Association, the Institute of Medicine, the World Health Organization, and the American Academy of Paediatrics, the Canadian Public Health Body and the Irish Department of Child Health. All of these reviews were, according to the MRC, 'unanimous in their conclusions that a causal link between the MMR vaccine and "autistic colitis" and autistic spectrum disorders was not proven and that current epidemiological evidence did not support this proposed link' (MRC 2001: 28).

In March 2004, ten of the original authors (but not Wakefield) involved in the 1998 research at the Royal Free Hospital, published a retraction of their original interpretation of the research. They wished 'to make it clear that in this paper no causal link was established between MMR vaccine and autism as the data was insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health' (*Lancet* 2004b: 750). In later correspondence, Dr Simon Murch, one of these authors, has emphasized that a 'subtle form of intestinal inflammation had been confirmed, but this does not mean that MMR is the cause of either this lesion or of autism' (*Lancet* 2004a: 568). He went further by saying that if the measles virus actually does persist abnormally in autism, it is more likely to be the *result* of immunological abnormality, than its *cause* (*Lancet* 2004a: 569).

Two recent studies dispel any remaining concern of a link between autism and the MMR vaccine. One was a study in Japan by researchers at the Institute of Psychiatry in London. The MMR vaccine had been withdrawn in Japan in 1993 after fears that its mumps component was causing meningitis. This study found that the number of children in Japan with autism continued to rise after the MMR vaccine was replaced with the single vaccine (Honda et al 2005). The second study, published in the Journal of Medical Virology in 2006, sought detectable measles virus genome sequence in blood of autistic children who have had the MMR vaccine. This research failed to substantiate reports of the persistence of measles virus in autistic children (Afzal, M.A. (2006).

7.4.4. PROBLEMS WITH THE RESEARCH

Studies that attempt to demonstrate causal links between the measles virus and autism are fraught with difficulties. The criteria for appraising such studies are similar to criteria used in my OP case study, attempting to show causal links between OPs and illness in farmers. These criteria are: adequacy of control; sample size/statistical power; selection bias; and the robustness of the study design.

The research carried out on the MMR issue shows the difficulties in attempting to draw conclusions from clinical studies involving the small number of participants (children) of the research described above, (except the Danish and Japanese studies, which were larger in scale but epidemiological in nature). As autism occurs at a rate of about five children in 10,000, the ideal experiment would require both a test group and a control group of enormous size. This is both distressing and unethical, as it means conducting uncomfortable and invasive tests and also withholding the vaccine from the control group.

Moreover, if molecular pathology data (of the type produced by Wakefield and his associates) over a number of years shows that vaccine strain measles virus is present in children with autism, then although there is an association, it is not necessarily causal. It may be that an underlying immune disorder is present in those children, which would permit measles virus to persist if exposed through the injected pathway. This immune disorder may be caused by pathogens such as yeast, anerobic bacteria, viruses, influenza in pregnancy and toxins such as mercury (a component of the MMR vaccine). Therefore, it may turn out that there is only a small sub-group of the child population for which the vaccine is not safe.

One of the main difficulties in assessing the various research papers is in their differences in methodologies. For example, Wakefield and his associates used clinical methods, involving subjecting children to rectal examinations using a 4 feet fibre-optic endoscope, pushed deep into the bowel. They also carried out lumbar puncture to extract tissue for examination; electro-encephalography (EEG); and magnetic-resonance imaging (MRI) (Wakefield et at 1998: 637). By contrast, subsequent research projects responding to Wakefield's claims, were epidemiological studies and involved inspecting GP records and sending questionnaires to parents, In other words, it has been a situation of clinical case studies versus statistics, which is not comparing like with like. (See Table 7.1 for examples of the two contrasting methods). As one reader of *Lancet* observed:

> Increasingly, it has become a battle between the crude science of epidemiology and the forensic science of clinical examination. The cause of those who seek to shore up public confidence in childhood immunisation by placing all their faith in epidemiology, much of

it based on children's medical records that probably contain little of relevance to the issue, will be more than ill served if they are eventually proved wrong (Thrower 2002:2113).

Table 7.1. Some Examples of MMR and Autism Research Methods

Reference	Statistical/epidemiological studies	Clinical Studies
Daszak et al (1997)		Testing of intestinal tissues from patients with Crohn's Disease
Wakefield et at (1998)		Ileocolonoscopy & biopsy sampling, MRI scans, Lumbar punctures of children with developmental disorders and bowel problems
Taylor et al (1999)	Children with autism identified from disability register & special school records. Information from clinical records examined for evidence of a changing trend at diagnosis associated with introduction of MMR vaccine	
Wakefield & Montgomery (2001)	Literature review of MMR safety studies	
Elliman & Bedford (2001)	Overview of current evidence	
Madsen et al (2002)	Cohort study of more than 500,000 children in Denmark between 1991 and 1998.	
Uhlmann et al (2002)		Examination of tissue samples using TaqMan RT-PCR measuring technology
Fombonne et al (1997)	Epidemiological study of 6,100 school-aged French children	
Chadwick et al (1998)		Development of method for the detection of measles virus RNA in clinical samples

7.4.5. EXPERT ADVICE

Up to the time of the controversy over the Wakefield research, Government policy on vaccination against MMR was a settled one. The subject of vaccination had, for many years, been based on sound science involving expertise in epidemiology, immunology and virology. The DH has an expert body, the Joint Committee on Vaccination and Immunisation (JCVI), which is an independent advisory committee, whose responsibility is to 'advice the Secretaries of State for Health, Scotland Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation' (DoH 2004). As one GP and medical writer notes, 'The object of immunisation policy is not to provide a 'pick and mix' selection to the public, but to provide a coherent programme for the prevention of infectious diseases' (Fitzpatrick 2004: 6). This system appears to have worked well and creates the herd immunity required to eradicate disease. A more liberal policy of

say, simply making the vaccines available, could lead those parents loath to use the MMR vaccine, to 'free-ride' on vaccinations dispensed to other children, thus prompting an epidemic. The Government can also call on the resources of the Medical Research Council (MRC), which is a body appointed and funded by the DTI. The MRC has a College of Experts from which it can provide a wide range of medical and medical related expertise.

7.4.6. DISAGREEMENTS ABOUT THE EVIDENCE

One medical practitioner, a GP, medical writer and father of an autistic son, believes that many of the medical authorities have been feeble in their response to what he calls 'Dr Wakefield's junk science', and applauds a small number of doctors 'who have taken a consistent and robust stand in defence of the interests of child health in general and of children with autism in particular' (Fitzpatrick 2004: 3). Fitzpatrick also notes that 'while Dr Wakefield has been lionized in the press and on television, these doctors have been subjected to scurrilous personal abuse, particularly through the internet' (Fitzpatrick 2004: 3). Similar sentiments were expressed in the *Lancet*: '...a balanced scientific debate has given way to personal attacks and unreasoned demands for single vaccines' (*Lancet* 2002: 637).

One revelation that affected the standing of Wakefield's original research paper was the discovery that before his 1998 research project, he had applied to the Legal Aid Board for a research grant of £55,000 to investigate a possible link between MMR and autism in respect of ten named children. Of the eight of these ten children whose parents associated the MMR inoculation with autism in their children, five of them were covered by the legal aid contract. These parents had an interest in establishing a link between MMR and autism, and Wakefield knew this. When this discovery was revealed in the *Sunday Times*, the editor of *Lancet*, Richard Horton, is reported to have said that Wakefield's paper would not have been published had he known about the way in which it was funded – it was a clear conflict of interest (Deer 2004).

A more recent revelation came from Brian Deer, a *Sunday Times* reporter, who, in a series of articles and a Channel 4 (C4) Dispatches TV programme, suggested that Wakefield had commercial interests in discrediting the MMR vaccine because he had patented a rival vaccine for measles, and also collaborated with 'charlatans and quacks' in the development of unproven treatments and 'cures' for autism (C4 2004).

Meanwhile, in the correspondence pages of the *Lancet,* the debate goes on, over whether there is a link between childhood disintegrative disorders and symptoms of gastrointestinal disease, and whether or not it is caused by a measles virus or by the MMR vaccine, with

contributors continuing to argue the merits of the case against the MMR vaccine, many of whom support Wakefield's original hypothesis.

7.5. Discussion

The crux of the issue here is about one piece of scientific research that questions a government policy, namely its vaccination policy, a policy that was considered to be scientifically soundly-based, and where a change in policy, to administering single inoculations to children over a period of time, may jeopardize children's health. A *prima facie* appraisal of this issue suggests that Wakefield is an example of the way dissenting experts have been vilified by the policy community. However, this is not the case. Whereas the scientists in the BSE and GM crops cases were 'outside' scientists who were attempting to contribute to problems of already known uncertainty in specific issues, Wakefield intervened in a settled national health policy area, where no problems were previously being debated. He created the issue of uncertainty.

The Authority of Science/Scientists

This issue can be viewed in two different ways. First, is the idea of the separation of medical science and its processes from the social and cultural sphere. On this view, there are clear boundaries between the Government medical researchers whose expert knowledge on the complicated medical specialties of immunology and virology seem to be beyond challenge from the lay public. Second, is the viewpoint that to change government policy on vaccinations on the strength of narrow research by these medical experts may have undesirable results because it overlooks the social and cultural aspects – that parents are scared off having their children vaccinated. However irrational that may seem, it is a consequence of not looking beyond the research conclusions, and weakens the herd immunity at the heart of the vaccination policy. In terms of peer review, this case shows the traditional British Government fondness for the closed policy communities of the previous case studies, although in this case the policy at issue was an established, settled one.

Definitions of Hazard

Wakefield's (limited) research purported to demonstrate that the MMR vaccine was present in some children with ASDs, an association that has not proved to be causal. The subsequent research into his hypothesis was therefore of the traditional medical scientific kind, the hazard in this case being the likelihood that the MMR vaccine would cause autism, and this was measured as the probability of this happening, and its magnitude. The risk assessment carried out by expert bodies and discussed above did just that – using mainly

epidemiological methods. This can be seen as straightforward sound science in policy as described in Chapter 3 – accepting the scientific evidence produced by pharmaceutical companies.

Evidence and Data

The original research findings triggered off more research, mostly of the epidemiological or statistical analysis type, but no single research finding was conclusive; on the contrary, all findings resulted in scientific disputes. It is also notable that the official response to Wakefield's hypothesis has been remarkably restrained, with ministers preferring not to address the issue in any great detail, and making bland reassurances, such as the one made by the Secretary of State for Health, John Reid, on GMTV in November 2003: 'It is unequivocal that there is no evidence at all that MMR is linked to autism'. It is however, understandable that the Government does not wish to rekindle this debate because the media publicity it generates only rebounds on vaccination rates. Research funding does not seem to have been considered urgently: according to one journalist, the MRC was awarded £2.75 million by the DH in 2002 for new research, but by December 2003, none of the money had been allocated to any specific projects (Sandall 2003: 11). This only confused those members of the public most concerned – parents of small children.

Burden of Proof

The Government's stance, while based on sound science, did include an immediate review of the available evidence on autism and MMR (MRC 2000 and MRC 2001). However, reviewing evidence is not necessarily being precautionary. And, moreover, unlike the previous case studies, on OPs and GMOs and BSE, applying the precautionary principle – that is, ceasing MMR vaccinations - was not a safer option. In recommending precautionary action (withdrawal of the MMR vaccine), Wakefield was using an extreme level of precaution that would deter preventive or therapeutic intervention: '...there must always be a limit to vigilance; otherwise we allow the damage against which we are vigilant to become oppressive' (Fitzpatrick 2004: 133). What this case study reveals is that the Government persisted with a sound science approach, despite a minority scientific dissenting voice, supported by media hysteria and some public anxiety. So, in response to these attacks from the media and a maverick scientist's opinions, the government reviewed the evidence in favour of the precautionary idea, but stuck to its sound science guns. As to the burden of proof, in this affair, a characteristic of the sound science approach is that the burden of proof is with those who make the allegation of harm (see Table 3.1). The allegation that the triple

vaccine causes autism therefore places the burden of proof on Dr Wakefield – because it is impossible to prove a negative – that MMR cannot cause autism.

Uncertainty

The MMR scare raises two points of scientific uncertainty. One was Dr Wakefield's idea that the MMR vaccine could cause autism, and most medical authorities believe this was highly speculative. It nevertheless caused a rush of research and review of the current research, both by British Government expert bodies and by child health research institutes around the world. While most of the results of these research projects concluded that there was no link between MMR and autism, there were some research scientists in the Royal Free Hospital and in the US who persisted in their belief that there was a link, and recommended that, as a measure the single vaccine for measles should be given to all children. The second cause of scientific uncertainty was the choice between the multiple jab and the single jab: whether the series of single jabs were a safer alternative, given that it was a long drawn out process that could mean parents miss appointments at clinics and also that time lapse between jabs could allow children to become open to infection. Even today, seven years after the original theory was publicised, some medical practitioners still recommend the single inoculation for each disease, despite the fact that Wakefield's hypothesis has not been proven, and that it is contrary to the CMOs advice, which was distributed to GP clinics and hospitals (Donaldson et al 2001).

7.5.1. SUMMARY

In the face of so much scientific uncertainty, and confusion amongst the public, the DoH could have been more honest in its public pronouncements. Instead of stating, as many ministers and officials did, that MMR was absolutely safe, they could have acknowledged that there was no guarantee of absolute safety and listed the three options open to government: the high risk one of not inoculating children; the next highest risk option of giving children three separate inoculations; and the low risk option of the universal use of MMR. This would have been a much more open and honest way of communicating risk and uncertainty to the public.

It is notable that in the three previous case studies, using the precautionary idea could be criticized because it hampered economic development: chemical companies' profits in the OP case; developing and selling GM seeds by biotechnology companies in the GMO case; and damage to the meat processing industry in the BSE case. But the use of the vaccines discussed in this chapter do not appear to impinge in any tangible way on pharmaceutical companies' business.

7.6. Conclusions

The issue here was that vaccination policy for three childhood diseases, measles, mumps and rubella, which had been relatively uncontroversial since their introduction in 1988, became a cause of anxiety for parents of small children, and for the Government, as a result of the publication of a research paper describing a novel syndrome combining gut inflammation and forms of autism and linking it to the MMR inoculation – a link that was publicized by the lead author at a news conference at the time the paper was published, at which Dr Wakefield also advocated the discontinuance of the MMR vaccine. Here was some not well-grounded scientific speculation about MMR that called into question a national vaccination policy which sparked off a media campaign supporting Wakefield's speculative research and, in many cases, favoured the single vaccine over the MMR vaccine. This was a difficult situation for the Government, because the obvious precautionary action would be to discontinue the multiple vaccines, and, in future, use only the single vaccine, but this was not possible because there was no scientific agreement that the single vaccine was a safer option. The Government's decision to continue using the MMR vaccine has been controversial, with Wakefield and some of his research associates, some GPs and other medical practitioners campaigning for single jabs, and the Chief Medical Officer and the JCVI insisting that the multiple vaccine is safe. The MMR case study demonstrates the Government's defence of sound science, yet adopting a weak version of the precautionary idea (the precautionary approach) in re-reviewing the evidence, though not succumbing to the strong version of the precautionary idea (the precautionary principle), which would entail withdrawal of the MMR vaccine. Conversely, it could be said that the Government's decision to continue with the multiple vaccine was itself a precautionary measure – to prevent a drop in take-up of the vaccine, in the light of uncertainty about its impact on autism. In other words, it weighed up the risks and benefits of continuing with the multiple vaccine, thereby exemplifying the precautionary approach, rather than the precautionary principle.

This chapter has dealt with the problem of a settled medical policy position being undermined by research findings that were extensively reported in the media and given an importance that was not warranted. The policy area itself was informed by sound science and which the Government felt, after several reviews, could not be changed without profound consequences for child health. This case study is different to the previous three studies in that challenges to the vaccination policy did not automatically need recourse to the precautionary principle, but its policy can be still characterized as precautionary in a weak sense.

The following, concluding, chapter will summarize all four case studies, comparing the issues in the case studies in terms of the role of science and precaution, changes in political context and what influenced those changes or differences across the cases.

CHAPTER EIGHT

Conclusions – A Comparative Analysis of the Case Studies

...political decisions will rarely be based on the expertise of scientists alone and not while innovation and entrepreneurship still dominate in the current political environment sweeping aside all principled arguments before them. (Gibson 2002: 49).

8.1. Introduction

This concluding chapter will draw together themes that have been identified in the preceding case studies. These themes - the use of scientific evidence and experts advice; disagreements about scientific method, evidence, and scientific uncertainty; and relations between sound science and precaution - will be analysed by comparing the case study evidence in the light of changes in political context, changes over time, and what influenced such changes. However, we will first recapitulate our two theoretical concepts, sound science and the precautionary principle.

8.2. Sound Science and the Precautionary Principle revisited

Chapter 3 outlined two models of science that appear in environmental and public health policy. These are: sound science and the precautionary idea. The distinction between these concepts is that one view of policy-making (sound science), involves the use of science and scientists with particular expertise to develop risk assessment procedures based on conventional scientific method. This focuses on finding causal links between hazards allegedly found in new products and processes being introduced commercially, with this process ignoring social, political and ethical issues. On the other hand, an approach that utilizes the precautionary principle, which, while still accepting conventional scientific method, is also aware of the conditional nature of scientific knowledge, finds ways to encompass the views of a wider body of experts and in some cases, the general public.

In Chapter 3, sound science was defined as science used to make public policy, that is, research conducted in accordance with conventional scientific method, and used by policy-makers to justify their decisions. Two problems were noted. First, is that utilizing science in this way often leads to inconclusive results that create endless debate and fudged decision-

making. Second, was that scientific research commissioned by Government, although conducted by universally accepted scientific method is not always value-free, and this subjective element colours expert judgement, allowing governments to claim their policy decisions are based on rational value free, science.

The precautionary idea, we found, was an ambiguous and controversial concept and quite difficult to define precisely. In its stronger formulation - termed 'the precautionary principle' - it was noted for example, that internationally accepted definitions of the precautionary principle are inflexible when applied to environmental problems and cause some people to see the concept as an obstacle to scientific innovation. A weaker version, on the other hand, is a useful tool for managing technological risk because it balances the costs and benefits of intervention and non-intervention. This weaker version – termed 'the precautionary approach' - uses the idea of proportionality: weighing up the level of uncertainty before proceeding with remedial action. I shall now return to the analysis of the case studies.

8.3. Analyses of case studies

8.3.1. My main conclusions are twofold: *First,* that while the UK Government is institutionally wedded to sound science, it is sometimes forced by political pressures to modify its sound science stance in the direction of the precautionary idea, though when it does so, it usually chooses the precautionary approach rather than the precautionary principle. *Second,* that the government's shifts/non-shifts in the precautionary direction reflected deep-rooted disagreements over scientific methodology. The first conclusion has been reached as a result of the following findings:

a). *In all four cases (OPs, GM crops, BSE and MMR), the government began by taking a sound science stance, but later modified these stances in the first three cases .*

Of our four case studies, the GM crops issue shows the clearest change in policy-makers' stance from a narrow science based risk assessment, to a wider, more precautionary policy over time. An early, narrow, risk assessment-based approach led researchers to focus on a restricted range of potential effects or harm. However, regulation that has been developed since the late 1990s, reflects the Government's reaction to public concern on the issue, and acknowledges some uncertainties with regard to the potential effects of GM crops on the environment. Thus, since the late 1990s, Government strategies have taken a precautionary turn.

The OP issue began with a science-based appreciation of OP substances. These OP substances had been carefully selected on the basis of their chemical structures to be effective against target pests. This regulatory approach to the problem of OP sheep dip bear most of the characteristics of the sound science approach, a typically linear process of defining hazard by directly measuring impacts of substances on individuals with little success in establishing a causal connection. This allows policy-makers to take little action to remedy the situation on the justification that more research is needed. However, in the OP story, the Government marginally adjusted its sound science stance, by introducing education for dip users, and by promising more research that hinted at a possible future change of stance, though there was little sign of any substantial precautionary thinking.

The BSE saga was an example of how the Government of the day began by claiming to be guided by science, but doing very little to solve the problem of an unknown disease in cattle, or its potential for harm to humans. The lack of scientific certainty in the *Southwood Report*, for example, did not stop the Government from justifying itself for its limited or lack of action. There was very little attempt in the early stages, for the Government to take any preventive action. Moreover, early advisory bodies established to look into the disease did not include in their membership the appropriate type of scientific expertise, while much of the advice given to government by its expert committees was not adopted or was adopted very late, in case it undermined the government's reassuring message to the public. So the eventual shift in policy was not properly a shift towards a precautionary approach – weak or otherwise, rather, the government was forced by political pressures to adopt what was, in effect, a precautionary approach. (as we shall see in the next section).

In the MMR case, the Government's reaction to Wakefield's hypothesis was to claim there was no evidence that a problem existed with the MMR vaccine programme, its vaccination policy was based on sound science - the vaccine had been thoroughly tested before coming into general use in the UK, and saw little evidence to change a settled vaccination policy. With pressure from the media and parents to suspend the use of the MMR vaccine in favour of a return to separate inoculations against the three diseases, it launched a review of its vaccine policy, but acted in a precautionary way because it was important to maintain 'herd' immunity in the child population.

In summary, the GM crops case alone, among the four cases, explicitly changed from a risk assessment procedure that focused on a narrow range of effects to a precautionary stance in which a broader range of expertise and some public consultation took place as regulation evolved. In the OP case, there was only a marginal softening of its sound science stance,

towards more care in its implementation which is, at most, a very weak form of precaution. The history of the BSE story shows that the Government of the day placed its own policy preferences over any other strategy for remedying the situation, and its later research efforts and policy decisions were slow to evolve, all of the time hiding behind scientific experts pronouncements, though in the end, its policy stance could be described as including precautionary elements. The MMR case study is an example of how the Government's stance changed little over time – its scientific stance was defended as simultaneously in accordance with the precautionary idea.

b). *Political pressures of one kind or another largely precipitated the above shifts.*

From the case studies presented in this Thesis, it can be seen that GM crops, BSE and MMR quickly assumed high political salience, and remained so throughout, while the OPs problem was never a high profile political issue, as it involved only a small section of society and never gained as much media attention as the other three issues.

The regulation of GM crops developed in the mid 1990s from a neo-liberal view of agriculture: nature as an asset in which to invest capital; and, GM products as environmental friendly and promoting a more efficient use of resources. But as the debate on biotechnology got into full swing, with public mistrust of the idea of interfering with plants and food, the issue became a political hot potato and led to a different approach to the regulation of these novel technologies. There was tension between, on the one hand, the Government's (and, in particular, the Prime Minister's personal commitment) to the development of Britain's biotechnology industry, and on the other hand, pressure from pressure groups such as RSPB, FOE and organic farming groups who, in the late 1990s, lobbied for a moratorium on the growing of GM crops. The Government therefore came under public pressure to delay commercialisation pending more research into the possible effects of GM plants and crops on the environment.

The BSE case also became a high profile issue for farmers, allied industries and consumers alike, and highlights the tension between the Government's duty to protect public health and its duty to promote the interests of the beef and meat processing industries. The Government of the day 'was ideologically committed to deregulation and removed many of the state's previously established regulation procedures' (Bartlett 1999: 237). In the case of the beef and meat processing industries, this meant that firms should determine how best to make or process their products. This tension showed in official government efforts to reassure the public that all was well. Moreover, British risk political culture, suggests that civil servants advised ministers 'to "take a low key" stance on BSE issues in public in order not to

jeopardize the British economy' (Dressell 2000: 6). This argument supports what Dressell calls 'scientific non-knowledge' of the disease: the only available evidence was that BSE was similar to scrapie in sheep, but no acknowledgement of this similarity could be made by MAFF in case it jeopardized the export trade in cattle. BSE therefore became a 'taboo disease' for veterinarians (Dressell 2000: 6). This low-key approach suited the agricultural industry: the beef industry, according to one analyst, was 'dominated by a profit oriented agribusiness style' (Grant 1997: 343), which had close links with the Conservative Party: out of the 391 Conservative MPs in the House of Commons in 1987, 202 had connections with the food industry (Cannon 1987: 395). Food processing companies were known to be donors to the Conservative Party funds; farmers were often represented in Cabinet; and several Conservative MPs were also senior managers in retail firms. Thus, as Grant concluded: 'The whole "food chain"...has a close network of links with a Conservative Government' (Grant 1997: 343). This context influenced the policy-making throughout the period covered by this case study.

The MMR episode began with the Government taking a sound science stance in the face of the media campaign and some parents of small children campaigning to have the MMR vaccination policy changed. This pressure caused a rush of research effort, both by UK Government expert bodies and by child health institutes around the world. However, throughout, the Government defended its sound science stance, which can be interpreted as embodying the notion of precaution.

In summary, there were pressures on policy-makers to resolve the regulatory problems in three of our four cases. Only in one case, GM crops, did this pressure result in a major change in the direction of the regulatory process. The BSE affair developed into an international crisis involving EU scientists and political actors, and only the EU ban on the export of beef and beef products changed the British Government's stance in that Britain was forced to develop a slaughter policy for affected cattle herds. In the MMR case, the government faced down the media pressure for a change of policy, confident in the knowledge that the vast majority of the elite and public opinion supported its firm stand.

c). *These shifts were significantly different in character in the four cases.*

In the OPs case the policy was sound science driven: there had been enough scientific research over the decades to indicate that the products were dangerous for users. Moreover, some of the research into the effects of the OP dips used by Government was produced by the chemical industry - science commissioned by government, which is a feature of sound science defined in Chapter 3. The fact that a regulatory policy was put into place that made PPE a

mandatory condition of using sheep dip solutions is not necessarily evidence of the application of either the precautionary principle, or the precautionary approach. A policy based on the precautionary principle would have taken regulatory measures even though no causal relationship between farmers' ill health and the use of the sheep dip had been established. Similarly, if the precautionary approach had been applied, the considerable research evidence of toxicity that was available to the Government should have directed policy-makers to look for alternative substances, or different farming practices, in a more determined way. Such regulation as there was, was preventive in nature, produced in the absence of any causal evidence. Thus in the OP case there was no significant shift in stance from sound science to precaution. The COT report, although thorough in its review, followed the official Government stance on OPs, that it was not possible for there to be any long-term effects following acute exposure to OPs – despite considerable evidence to the contrary obtained from numerous studies.

In the case of GM crops, the early experimentation was precautionary in the sense that a novel technology needs careful risk assessment, and this was established with the Genetically Modified Organisms (Deliberate Releases) Regulations 1992, but the risk assessment procedure was eventually considered to be too narrow in focus, and did not acknowledge the provisional nature of scientific knowledge, or enough attention to potential hazards or effects of experiments on the environment. By the late 1990s, with a new government in power, institutional changes, such as the creation of the AEBC, the public consultation exercise, field evaluations and a science panel deliberation, have broadened expert advice and ideas of what constitutes harmful effects. Such changes were prompted by public and media suspicion of biotechnology products. This can be seen as a precautionary approach.

The BSE case study does not reveal any significant shift from its initial sound science stance, although it is true that there was little scientific knowledge available to the Government in the early years of the problem. Regulation was, however, introduced in a reactionary way rather than in a proactive way (by attempting to anticipate problems), which could be seen as a covertly precautionary move. Rather, the events of the affair demonstrate that government decisions were framed by its own policy considerations: concern for public expenditure and containing public fears. This attitude persisted throughout the years of the crisis. Although, using a precautionary approach at the beginning of this problem would have been difficult due to the fact that a great number of diseased cattle had been already consumed, yet, it is possible that a more proactive approach to the problem could have lessened the risks to consumers if MAFF had recognised the lack of knowledge about the disease at an earlier stage.

The MMR case stands out as different from the other three cases. The Government showed a sound science approach to justify its existing MMR vaccination policy by reminding the public that the products had been thoroughly tested before being introduced. Yet it seems to have acted in a (weak) precautionary way in that a review of the policy was conducted, and more importantly for public health, it avoided a weakening of 'herd' immunity.

In summary, the case studies show no consistent pattern in the shifts in stance over the four case studies. OPs and BSE show a clear sound science approach which did not explicitly change; the GM crops issue began with the scientists on expert bodies establishing of risk assessment procedures, which, over time, evolved to include a wider expertise and some public participation – a more precautionary stance; while in the MMR case, the Government appears to have weighed up the risks and benefits of continuing with the multiple vaccine, and maintained this sound science stance throughout, which - in view of its responsibility towards the general population, could be said to be precautionary thinking.

d). *The usual government response was to play down the danger until pressured either by public opinion or new scientific research.*

The Government's response to information that OP dips may be dangerous to the users was to emphasis the use of PPE and education about safe use for farmers. Government experts on pesticides appeared to have a very narrow view of safety in acknowledging that OPs are dangerous yet suggesting to the Government that they can continue to be used. When under pressure from studies that suggested there were problems with sheep dip, the then Minister of State for the Environment, Jeff Rooker, stated that 'If we are to ban or suspend use of OP sheep dip, I have to have a really good reason – one that is judge-proof, so some slick lawyer doesn't run around the corner and unstitch what we have done' (quoted in Miekle 1999). The message was that until there is proof that OP solutions are unsafe, then it can be assumed to be safe.

In the GM crops issue, regulation proceeded with limited research on effects, by considering single well-defined events without any wider social or agricultural aspects being deliberated. The Government officially took a disinterested approach, claiming to be guided by science and at the same time proceeding in a precautionary manner. Yet the Prime Minister and many eminent scientists publicly committed themselves to the advancement of the biotechnology industry. The change of direction came after public and media concerns about the safety aspects of GM technology. Yet all of the efforts to widen the research base (FSEs, public consultation, science review) did not produce much good news: the FSE report

gave mixed conclusions; the public proved to be averse to GM products; and the science panel admitted it did not yet have sufficient scientific knowledge to make adequate predictions about the effects of GMOs on the environment.

Despite some early evidence that indicated BSE exhibited distinct transmission characteristics from scrapie, the Government played down the potential dangers of BSE and human health. Decisions were based upon concern for public expenditure and the protection of certain industries, rather than on what risks there were. Only when the evidence became irrefutable, and the pressure from Europe became irresistible, did the government take action.

In the MMR case, health ministers and officials responded to Wakefield's hypothesis by immediately reassuring the public that the MMR vaccine was absolutely safe, before any review of the vaccine's safety had been done. This did not change throughout the period of the controversy. Of course this refusal to shift away from a settled vaccination policy had its logic, as 'herd' immunity depended on the continuation of the current policy and this was the prime responsibility for the Government at the time - which makes it difficult to fault the official policy line.

To summarize, in all of our case studies, the potential dangers resulting from the perceived problems, were at first minimised by Government ministers or senior public officials. For sheep dips, health problems in users were blamed on the users, and said to be remedied by education and more protection. In the BSE problem, the Government initially introduced minimal regulation, and at the same time denied that there was a major problem. Similarly, during the MMR scare, the Government took every opportunity to reassure the public about the safety of the vaccine. As for GM crops, the risk assessment procedure that had been developed for research into newly genetically modified plants was thought to be adequate until public and media pressure led to a wider view being taken on risk assessment procedure, and subsequent new scientific evidence led to more informed decisions.

8.3.2. *That the government's shifts, partial shifts, and non-shifts in the precautionary direction, reflect deep-rooted differences of opinion over evidence and scientific method.*

Turning to my second main conclusion, in all of our case studies there are signs of the marginalization of scientific opinion that did not suit the policy community. Although this is to a lesser extent in the OP case than for GM crops or BSE, nevertheless there was disagreement between, on the one hand, the Government expert committees emphasis on a quantitative, reductive method in attempting to establish a causal link between OP substances and the health problems claimed by farmers and their families; and, on the other hand,

farmers representatives and some academic scientists who urged a broader investigation of how farmers/dippers actually work. The Woods report rejected this wider approach (Woods 1999: 2).). In terms of evidence of harm, once again, the official expert committees aimed to establish quantifiable amounts of OPs in individuals, despite the fact that many researchers argue that no safe threshold can be determined for neurotoxic chemicals such as OPs (PAN UK n.d.; Fairclough 2003: 139). Yet, as Watterson stated, the history of OP regulation presents a compelling case to say that there is already enough evidence with which to form a viable policy on the subject of OPs in sheep dip. There were also uncertainties about whether there was evidence that dip solutions can cause chronic health problems in users, and whether PPE is an effective remedy. Over the decades there have been numerous studies produced by occupational health and other university departments, but government expert bodies have dismissed the findings of these research efforts, finding faults in their methodologies. The advisory body considering the effect of OP could not, with any certainty, determine whether there were any long-term effects from a single small exposure to the substance; they came to no firm conclusions as whether prolonged exposure could cause psychiatric illnesses; and they were uncertain as to the effects of low-level doses an a small sub-group of people who may be susceptible to OPs, or people who had other disabling illnesses.

There are clear parallels in the GM crops and BSE case studies on the way scientific evidence was viewed. Both of these issues contain examples of networks of 'in' and 'out' scientists, where in the policy making process, the research efforts of the 'outs' were denigrated or marginalized, and in some cases the individuals were ridiculed in the media and severely criticised by their scientific peers. This can be seen in the way Lacey, Dealler and Narang were treated in the BSE case, and Pusztai, Chapala, and Ho in the GM crops research. 'Out' scientists also appear to have been excluded from the GM Science Panel, according to one ex-member of the panel:

> ...I think most of the science-based representatives [on the panel] were very much pro-exploitation [of GM crops], and then obviously industry representatives were from the seed companies [who] wanted to commercialise the stuff. I think it's very difficult to see how they could have been anything else (Leifert 2003: personal interview).

In terms of uncertainties about the evidence, in the GM crops case, the debate polarised around two broad groups. The first group comprised those who were fundamentally opposed to GM technology for ideological reasons, some because they have very deep anxieties about its implications for the future of sustainable agriculture, together with scientists who are

concerned that the safety questions have not been answered. The second group comprised those who were pro-GM, such as the Prime Minister, who is personally committed to the wealth-creating potential of the British biotechnology industry; large biotechnology corporations, many of them not British, who would profit from this technology; the scientific professions in general that see the opportunity for progress for mankind; and individual scientists who are interested in genetic modification (and of course, their careers) and see advantages in using plant genetics in pharmaceuticals as a way of improving the health of the population. While the second group have accepted the regulatory regime first formulated in the late 1980s and early 1990s, some scientists attempted to show the uncertainties and dangers in the research. They claim that many GM genes are untested for toxicity and once they are expressed, could reactivate dormant viruses that could then jump species (Ho 2004).

The BSE episode revealed problems, not so much with disputes about evidence, as to lack of urgency in researching the problem. The possibility that the disease might transmit to humans was accepted by MAFF veterinary officials when the disease was first diagnosed in 1985. However, the probability that BSE might be pathogenic to humans was thought to be slight. Thus, no urgent research took place, a decision that as noted in Chapter 6, caused the UK Government to be criticised by the European Parliament (EP).

The MMR case also shows very strong indications of dissenting science, although the scenario was somewhat different from the GM crops and BSE examples above. During the MMR scare, there was what the media, and some medical authorities called a 'maverick scientist' – Dr Wakefield – whose speculations on the MMR vaccine and autism are no nearer to being proven correct eight years on. At the time, Dr Wakefield used the media (who were very supportive) to propagate his theories and to attempt to persuade the Government to discontinue the use of the MMR vaccine. More recently, however, some journalists have turned against Wakefield, portraying his work as 'junk science'. On the other hand, a further feature of the MMR case in respect of dissenting science is that certain journalists and contributors to Internet medical journals have subjected to personal abuse, those researchers who spoke against Wakefield's work (Fitzpatrick 2004: 3). The MMR issue also showed a division between those (Wakefield and co), who used clinical experiments, and government scientists, academic scientists and child health professionals who relied on statistical and epidemiological studies to provide evidence to support their cases.

In summary, the case studies show there were disputes over scientific method and evidence and this was a cause of government moves, not always explicitly in the direction of precaution. In all of the cases studied, government experts used conventional scientific

method in order to establish causal links between a perceived health or environmental problem and the products under investigation, and, inevitably, there were some experts who disagreed with the conclusions of the research. In the case of OPs, research over many years highlighted the dangers of working with OPs, yet MAFF continued to insist that OP products could be safely used. GM crops and BSE on the other hand, demonstrate how some experts were marginalized for holding views that did not suit the policy community involved in these areas. In the GM case opinion was polarized into two opposing groups with different perspectives on biotechnology, while in the BSE case, there were a number of scientists outside of the MAFF policy community suggesting lines of enquiry different from those being pursued by official experts. The MMR case is different from the other three cases in that there was no shift in stance by the Government because the scientific communities in the UK and abroad, by and large, did not accept Wakefield's hypothesis.

8.4. The research questions revisited

In Chapter One, I listed four research questions that were to drive my research effort. It is time to return to those questions and provide answers.

8.4.1. *Who are the scientific advisers to policy-makers and what does knowledge about them tell us about their place in the policy process?*

The type of people who serve on government advisory bodies, as we have seen from Chapter Two and the case study chapters, are scientists of high formal qualifications in often quite narrow specialisms. Many have knighthoods and are members of the Royal Society. As Gummett observed, the kind of people who are sought after for service on these expert bodies are likely to know other scientists and science institutes that enable them to be consulted about future candidates for such posts (Gummett 1980, *op cit*). Their recruitment, as we have heard from a former minister, is from a highly exclusive list maintained by senior government officials, of those considered to be suitable for membership of advisory committees: a tendency 'to select top scientists who are likely to agree with their policy aims' (Meacher 2004, *op cit*) - in other words, a network of 'the great and the good'. Under these arrangements, there is a potential for conflicts of interest. Fairclough, in her study of organophosphates, was concerned to find that scientific experts providing advice on pesticides in agriculture had extensive interests in chemical companies (Fairclough 2003). This does not mean that this closeness to industry will inevitably lead to biased decisions but it does increase the risk of bias in decisions.

The scientific advisory system as presently organised appears to be one in which scientists are used essentially to support the authority of Ministers in decision-making. This is

noticeable in the handling of the OP problem by Government advisers where their recommendations always reflected the official line on OPs.

8.4.2. *Is science commissioned by government just a protective shield used to justify decisions made by ministers?*

There is clear evidence that politicians and senior departmental officials use scientific reports, risk assessments and the recommendations of committees to justify their actions. In the OP case, MAFF ministers were able to hide behind the uncertainties that continued to occur when attempting to establish causality; in the BSE, case the communication of risk was manipulated in order not to upset consumers and industry alike. To an extent this was also the case in the early years of regulating GMOs, until media and public pressure forced ministers to be more open about potential risks.

8.4.3. *To what extent do ministers put a political spin or gloss on the scientific advice they are given, especially when they explain that advice to the public?*

There is clear evidence in the case studies that Ministers regularly do use the advice given by their own scientific experts in a disingenuous way. The actions of ministers during the BSE crisis is a prime example of this tendency, by claiming that scientific evidence indicated British beef was safe when the scientific experts dealing with the issues had said no such thing – it is an example of ministers hiding behind science and pretending to follow the advice of experts, while doing something entirely different.

8.4.4. *Do Governments pay only lip service to the idea of precaution?*

As long ago as 1990, in the White Paper, *This Common Inheritance*, the British Government, listed the precautionary principle as one of five principles with which to guide future environmental policy-making (DoE 1990, *op cit*). And since then, a great many official documents and political pronouncements have referred to the precautionary principle, or the precautionary approach. But in the past there were many instances where the precautionary idea was needed, that is, where advisory science has come up against uncertainties, yet governments often appeared to fall back on a sound science position, claiming that there is no evidence to support remedial action. Since the Phillips Report into BSE, which made specific recommendations on scientific advisory committees, resulting in OST's Guidelines for Scientific Advice, and the fact that the Government has signed up to the EU Commission's position on the precautionary principle, risk, assessment procedure has slowly changed to include a wider range of expertise and public consultation. However, the Government's actions during the late 1990s over the development of regulation for GM crops shows an ingrained habit of citing sound scientific evidence for the basis of decision-making

on newly developed products, even when other authorities have doubts, only to become more precautionary after political pressure.

8.5. Conclusions: lessons from the case studies

The issues examined in this Thesis suggest that there are problems with the system of scientific advice to government. The importance given to insisting on a positivist scientific basis for policies lies at the root of this problem because it entails an idealized model of risk. Under this model, risk associated with new technology is perceived to be the *probability* of harm to people and the environment. Such a definition gives the Government's own scientific experts a privileged position 'to define agendas and impose bounding premises *a priori* on risk discourse (Beck 1992: 4). This 'expert's model entails utilizing statutory expert knowledge in an attempt to establish causal links, in the hope that, should a link be found, remedial action will follow. Where no causal link is found, more research is recommended before any decision on remedial action can be contemplated. In this process, independent scientists and those with specialized lay knowledge outside the policy community are ignored. Furthermore, favouring positivist scientific approach means that there is a bias in favour of technical rather than ethical issues: finding no evidence, or only partial evidence, is a reason to do nothing.

In the OP case, the Government may have been preoccupied with the prospect of being sued for compensation if it admitted that there was a long-term effect from acute doses of OP dip; in the GM crops case, the biotechnology industry needed to be supported; in the BSE case, the consumer must not be scared off beef products, because the beef and meat processing industry needed to be protected. In these instances, expert advice was subverted and used to suit the needs of Ministers. There is also evidence that scientific experts themselves accepted the official Government line. This can be seen clearly in the OP study where official scientific expert committees such as COT and ACP, continued to deny any causal links between the OP products and ill health in users despite what Watterson described as 'an accumulating wealth of available data' (quoted in Fairclough 2003: 436) on the dangers of OP sheep dips. The Southwood Working Party on BSE also gave the impression of being the kind of body that would promote a consensual view that was consistent with Government policy. Similarly with the MMR case: there was a privileging of medical expertise that underlined the government's sound science stance.

There is a clear lesson from the GM crops case. Listening to the concerns of environmental scientists and the public has allowed a widening of official expertise, with more and different questions being put to risk researchers, where GM products being assessed for the market are

subject to more experimentation, with their DNA structure being subject to closer scrutiny. In short a weak version of the precautionary idea. If this approach had been adopted in the OP and BSE cases, a better outcome would have occurred. In the case of MMR, it seems that sound science and precaution are integrally related.

A key lesson from the case studies is that scientific studies of environmental and public health issues all have elements of uncertainty, because it is extremely difficult to extrapolate the results of laboratory experiments to the natural environment and thus, proving causality in this way is fraught with difficulties. The precautionary approach is a rational response to uncertainties in scientific evidence, and these uncertainties, observed at the risk assessment stage, need to be made clear to all parties involved in decision-making, including the general public. As one environmentalist and member of several government advisory bodies asserted, 'the precautionary approach is about having a very wide perspective, broadening expertise and not having it [advice] only down to particular scientific disciplines ...consulting with people [so that] they know how you have done the risk assessment...' (Hill 2004: personal interview). Moreover, this approach requires a much more competent political handling of risk, and a more honest explanation of uncertainty arising from environmental and health issues than normally accompanies a sound science approach.

The difficulties and the mistakes of handling risk and uncertainty can be seen in all four case studies where the issue was, in essence, to find evidence of harm or potential harm. Research was carried out under a system of scientific advice that is closed and consensual, has little parliamentary oversight or public access and where decisions are made by ministers and officials that often do not accord with the scientific advice they have been given. However, as we have seen from Government strategies over the commercialization of GM crops, the precautionary approach can result in a more inclusive advisory process, even if, as in this example, precaution is the result of political pressure.

To return to my hypothesis, the case studies show that on the whole, environmental and public health issues are often approached on the basis of reductive, quantitative scientific evidence, and that precaution is seen by government as a threat to technological innovation and industrial activities.

APPENDIX 1: LIST OF THOSE EITHER INTERVIEWED OR LISTENED TO FOR THIS RESEARCH

Professor Janet Bainbridge, Formerly Chair of Advisory Committee on Novel Foods – *11 February 2003 – Gene Futures debate, Royal society of Arts, London.*

Professor David Baulcombe, Director of Sainsbury Laboratory – *11 February 2003- Gene Futures debate, Royal Society of Arts, London.*

Lim Li Ching, Researcher, Sustainable Agriculture, Third World Network – *29 April 2004 – Special Parliamentary Briefing, Grand Committee Room, House of Commons.*

Dr Barry Commoner, Biologist and Environmental Scientist, New York University – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Alison Craig, Project Coordinator, Pesticide Action Network, UK (PANUK) – *interviewed 13 February 2004.*

Professor Joe Cummins, Genetics Researcher, University of Western Ontario, Canada – *19 January 2004 – GM Crops Debate, City Hall, London*

Dr Stanley Ewen, Consultant Histopathologist, Grampian University Hospital Trust – *19 January 2004 – Special Parliamentary Briefing, Grand Committee Room, House of Commons.*

Dr Ian Gibson, MP, Chairman, Science Select Committee, House of Commons – *interviewed 1 March 2004.*

Professor Robin Grove-White, Member, Agricultural & Environmental Biotechnology Commission – *12 November 2002 – ESRC/Prospect Debate, Royal Society, London.*

Sir Ben Gill, President, National Farmers Union – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Professor David Harvey, Agricultural Economist, School of Agriculture, Food & Rural Development, University of Newcastle upon Tyne – *interviewed 2 November 2004.*

Professor Alistair Hay, Member of HSE Advisory Committee on Toxic Substances and Molecular Epidemiologist, School of Medicine, Leeds University – *interviewed 17 February 2004.*

Julie Hill, Green Alliance & Deputy Chair, of Agricultural & Environmental Biotechnology Commission – *interviewed 16 June 2004.*

Dr David Howarth, Director of the Masters Programme in Ideology and Discourse Analysis, University of Essex, *12 – 16 August 2002.*

Tony Juniper, Director of Friends of the Earth – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Dr Mae-Wan Ho, Bio-physicist, Director, Institute for Science in Society – *19 January & 29 April 2004 – Briefings: City Hall, London and Grand Committee Room, House of Commons.*

Dr Mike Joffe, Member of COT Working Group on Organophosphates – *interviewed 5 April 2004.*

Brian John, Environmental Scientist & member of GM-Free Cymru Group – *29 April 2004 – Special Parliamentary Briefing, Grand Committee Room, House of Commons.*

Dr Brian Johnson, Head of Agricultural Technologies Group, English Nature – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Professor Sir David King, Chief Scientific Officer to the UK Government – *12 November 2002 – ESRC/Prospect Debate, Royal Society, London.*

Professor Carlo Leifert, Professor of Ecological Agriculture, Newcastle University – *interviewed 8 December 2003.*

Dr John Lingard, Senior Lecturer in Agricultural Economics, School of Agriculture, Food & Rural Development, University of Newcastle upon Tyne - *interviewed 20 October 2004*

Bill MacFarlane-Smith, Researcher, Scottish Crop Research Institute – *16 February 2004.*

Bernard Marantelli, Monsanto Europe – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Michael Meacher, MP, *Minister of State for the Environment, May 1997 – June 200. 3 – interviewed 2 March 2004.*

Professor Vivian Moses, Member of CROPGEN – *11 February 2003 – Gene Futures Conference, Royal Society of Arts, London.*

Dr Elaine Mutch, Senior Research Officer, Toxicology Unit, Medical School, University of Newcastle upon Tyne – *interviewed 14 April 2004.*

Dr Eve Novotny, Member, Scientists for Global Responsibility – *19 January 2004 – GM Briefing, City Hall, London.*

Dr Arpad Pusztai, Biochemist – *19 January 2004 – Briefing, City Hall, London*

Professor Peter Saunders, Mathematician, King's College, London – *19 January & 29 April 2004 – Briefings: City Hall, London and Grand Committee Room, House of Commons.*

Mrs Elizabeth Sigmund, *Coordinator*, Organo-phosphates Information Network (OPIN) – *interviewed 21 October 2003.*

Dr Andrew Stirling, Social Scientist, Senior Lecturer and Part time Fellow at SPRU, University of Sussex – *interviewed 18 November 2003.*

Colin Tudge, Research Fellow, LSE and Science Writer – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

Professor Andrew Watterson, Occupational & Environmental Health Researcher, University of Stirling – *interviewed 15 December 2003.*

Laurence Woodward, Director, Elm Farm Research Centre – *11 February 2003 – Gene Futures debate, Royal Society of Arts, London.*

APPENDIX 2: LIST OF CONFERENCES & BRIEFINGS ATTENDED

Summer School Course: Applying Discourse Theory, *Department of Government, University of Essex, 12 – 16 August 2002.*

Debate: "The Dilemma of Science and Government" *Royal Society, London, 12th November 2002*

Sponsor: ESRC and Prospect Magazine

Conference: "Gene Futures: Debating the use of GM Crops and Foods" *Royal Society of Arts, London,* **11th** *February 2003*

Sponsor: Guardian, GeneWatch, Unilever, Elm Farm

Briefing: "Winning the GM Debate" *London City Hall, 19th January 2004*

Sponsor: London Assembly Green Party, ISIS

Special Parliamentary Briefing: Independent Science Panel - Winning the GM Science Debate, *House of Commons, 28th April 2004*

Sponsor: Alan Simpson, MP and Institute for Science in Society

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